EVOTION

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1. Introduction

1.1. About EVOTION

Hearing Loss (HL) is one of the most prevalent chronic diseases and the 5th cause of disability. HL increases the risk of cognitive decline, mental illness, and depression, and leads to social isolation, unemployment/early retirement, loss of income and work discrimination. The pre-eminent management strategy for HL is the provision of Hearing Aids (HAs), although their use is often problematic, costly and with poor overall benefits. The holistic management of HL requires appropriate public health policies for HL prevention, early diagnosis, long-term treatment and rehabilitation; detection and prevention of cognitive decline; protection from noise; and socioeconomic inclusion of HL patients. However, currently the evidential basis for forming such policies is limited. Holistic HL management policies require the analysis of heterogeneous data, including HA usage, noise (TTS) episodes, audiological, physiological, cognitive, clinical and medication, personal, behavioral, life style, occupational and environmental data.

EVOTION has access to big datasets of such data from five different organizations and will support their continuous update by real time data produced by sensors and HAs used by HL patients. To utilize these data in forming holistic HL management policies, EVOTION aims to develop an integrated platform supporting: (a) the analysis of the above datasets to enable the identification of causal and other effects amongst them, (b) policy decision making focusing on the selection of effective interventions related to the holistic management of HL, based on the outcomes of (a) and the formulation of related public health policies, and (c) the specification and monitoring of such policies in a sustainable manner. To achieve this aim, EVOTION also brings together public health policy organizations, experts and authorities supporting the formation of the targeted policies and the validation of the EVOTION support for it.

1.2. About this deliverable

1.2.1. Introduction

One of the critical success factors in the development of a high quality on-line software application is the deep understanding of the user real requirements, as opposed to perceived ones. This is where many projects fail; they do not correctly identify what the system should do, with respect to what the targeted users require and what the respective innovations should provide.

The user requirements survey and analysis is the process by which user desires, needs, and expectations are gathered in order to establish what users will actually use the application for.

Essentially, user requirements analysis[1] is about setting the baseline for developing the application and refining it as the implementation is in progress, so that it meets customer needs.

A user requirements survey can therefore be difficult because:

- The developers are not the final users, and ICT specialists typically find it hard to understand the real needs of the non-ICT enabled people;

[1] Methodology of the User Requirement Analysis: http://www.vnet5.org/pub/approach/ura.html

- Inadequate requirements information may be collected from users;
- Each individual type of user may have their individual requirements, but cannot define the overall system requirements;
- Users do not know what the particular system can and cannot do;
- Too many “nice-to-have’s” that would not actually be used.

Once identified, user requirements effectively lay the foundation for developers, testers, and implementers to begin determining the functionality, responsiveness, and interoperability required for that system.

In this context, the strategy of gathering user requirements is crucial to a project’s success for developers and project managers to obtain accurate user requirements, as well as increase the level of end-user involvement in the project.

1.2.2. Executive Summary

This deliverable presents the methods used for the process of gathering and analysing user requirements for the EVOTION platform & components, and the results of this process. The ultimate goal is to translate user demands into the system (technical) requirements needed to develop the EVOTION system.

The identification of appropriate user requirements is a prerequisite for efficient system design. In the context of EVOTION, three representative user groups and a series of focus groups and interviews have been conducted. The results of this targeted dialogue and research is codified in a set of functional and non-functional requirements that will serve as a direct input to the EVOTION software analysts and architects.

2. State of the art

In order to set-up the scene, a complete state of the art is elaborated. In this section we give an overview of the main topics covered. Each topic is discussed from the project point of view and scope which lead to the identification of specific system requirements to be addressed by the EVOTION project. Those are presented in Sections 0 & 0.

2.1. Hearing Aid Technologies

This section describes developments in the hearing aid technology since the writing of the EVOTION Grant Application in early 2016 included in the EVOTION Grant Agreement [1], p. 28, Part B].

The summary of the following subsections is that a number of the EVOTION components are now entering the hearing aid market, however, the components are far from being connected into a platform like the EVOTION platform, and moreover the implementation of the components target the solely the hearing aid user and audiologists.

2.1.1. Hearing aid processing

In this section, the focus is on new developments in signal processing strategies that relate to or have potential impact on the EVOTION project.

2.1.1.1. Oticon OpenSound Navigator™

In May 2016 Oticon launched the Oticon OPN Hearing Aid featuring the OpenSound Navigator™ [31] which lowers the cognitive load for people with hearing impairment [32]. In the present form, the personalization of OpenSound Navigator™ takes place during the fitting of the hearing aid and remains fixed thereafter. However, an extended personalization of OpenSound Navigator™ settings fits within the EVOTION objectives of providing the users with the ability to either rate different processing options or chose directly between various degrees of the OpenSound Navigator™ processing. Combining OpenSound Navigator™ with the EVOTION platform, the consortium enables personalization and self-adjustment of an important hearing aid processing feature.

2.1.2. eHealth & Internet of Things

This section focus reports on new developments that utilize that hearing aids via smartphones connect to various service providers – being the manufacturers directly, large-scale hearing care providers, or Internet of Things services like *If This Then That* (IFTTT).

2.1.2.1. Unitron

Unitron is part of the Swiss hearing care company SONOVA (www.sonova.com) more known for their Phonak brand of hearing aids and Cochlear Implants company Advanced Bionics.

Unitron now offers an app for the Unitron FLEX hearing aids that enables the hearing aid user to rate the current sound scene while the app combines the rating with the current sound environment situation and hearing aid program settings [33]. This enables the Audiologist to get a clearer picture of how the hearing solution works and offer consultation and modified settings in response to this. The exchange of data between hearing aid user and audiologist fits well in the scope of the EVOTION project and demonstrates how an EVOTION platform in the future can involve other hearing aid manufacturers than Oticon.

2.1.2.2. Sivantos

Sivantos (www.sivantos.com) formerly Siemens Audiology Solutions, is another well-known hearing aid company. Their premium brand is Signia. Through Signia Telecare [34], Sivantos offers a solution similar to Unitron where the hearing aid user can inform the audiologist about situations that work and situations that

do not work. In relation to the auditory training intervention in EVOTION, Signia Telecare also contains with some hearing training sessions, where audiologist can choose lessons about noise perception, communication, and environmental sounds for the hearing aid user.

Moreover, the audiologist is capable of adjusting the hearing aid settings remotely. In their trials, Sivantos showed that returns dropped 30%, number of visits dropped 40%, and that the length of the trial period dropped 18% [35] with their Telecare solution including remote fitting administered by the audiologist.

An EVOTION platform could in the future also encompass this interaction and further collect evidence for grater satisfaction from ratings or behavior in everyday life arising from the Telecare solution.

2.1.2.3. Veterans Affairs

Figure 1: Overview of future eSolutions identified by US Veterans Health Administration [36].

US Veterans Health Administration is preparing future services delivery in three ways, 1) at specialized centers, 2) in Community Based Outpatient Clinic (CBOC), and 3) via eHealth. Oticon and Phonak (part of SONOVA) collaborates with Veterans Health Administration under their innovation framework on Hearing Aid Distance Fitting App [37] – an eAdjust solution. The collaboration with Phonak and Oticon is how Veterans Health Administration develops the future of their own services. Comparing Figure 1 provided by Veterans Health Administration and EVOTION, it is evident that their roadmap shares components with EVOTION platform and generally fits within the EVOTION platform. If Veterans Health Administration adopted the EVOTION platform, they would be able to link the future implementation of the various eSolutions with data collected in everyday life and thus guide the implementation of each of them based on collected evidence.

2.1.2.4. Oticon ON – IFTTT Service

Oticon ON enables Oticon Opn hearing aids to interact with other Internet-connected devices and services [38].

Oticon ON is a smartphone app that connects Oticon OPN hearing aids to other internet-connected devices and services using the *If This Then That* IFTTT service. E.g. within IFFTT it is possible connect your internet-connected doorbell to your hearing aid such that the hearing aid will speak out “Someone is at the door”

right after the doorbell was pressed. Turning the hearing aids on in the morning, can also trigger the lightning in the house or the coffee-machine.

Moreover, and closer to EVOTION IFTTT and Oticon ON enables the user to collect their own usage pattern data, as they just need to connect the hearing aid actions (currently : volume adjustments and program shifts) with a service that stores the actions in a spreadsheet. An audiologist that wanted to make an independent survey could set up similar combination of hearing aid actions and spreadsheets to collect data from several hearing aid users. Finally, the current Oticon OPN hearing aids do not export data about the sound environment as the EVOTION hearing aids will do, and thus the EVOTION hearing aids are required to feed the EVOTION Big Data Analytics in order to fulfil the EVOTION objectives.

2.1.3. Hearables

Hearables is a new emerging consumer product category where wireless headphones shrink in size to match in-the-ear hearing aids. The most well-known examples are Apple's wireless EarPods closely followed by Kickstarter success Dash by Bragi in Germany. It is a market which is likely to grow in the coming years, and in a recent review from November 2016 Nick Hunn [39] states:

> *"Apple's unexpected entry into the hearables market heralds a period of major change. The result is likely to be a faster move to wireless headphones, an acceleration in the take-up of earbuds, and the prospect of an overall market revenue exceeding $40 billion in 2020"*

While the EVOTION project will recruit people with hearing loss and hearing aids to reach its goals, subsequent exploitation of the developed platform will not be limited to hearing aids, and therefore it would be interesting to look into the emerging consumer product Hearables. This could allow the EVOTION platform to be used to collect evidence in public health scenarios outside hearing loss i.e for normal-hearing person who do not use hearing aids.

2.2. Policy Modeling and Tools

2.2.1. Overview

The purpose of this section is to provide an overview of techniques, methods, processes, guidelines and tools supporting the formation of public policy with a special focus on public policy in the area of health. This is important in order to establish the baseline for developing the public health policy formation capabilities of the EVOTION platform.

The World Health Organization (WHO) defines "health policy" as the "decisions, plans, and actions that are undertaken to achieve specific health care goals within a society" [52]. In this context, the term "policy" itself is defined by WHO as "a law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions" [42]. A health policy is further qualified as public if it is made by public institutions and for large groups of populations at regional, national or even international level. Public health policy making consists of four key stages:

i) *Situation analysis* – This stage is concerned with the assessment of the needs and gaps, the resources available, and eventually the gaps and the strengths, weaknesses, opportunities and threats (SWOT) arising in connection with a situation that needs to be addressed by health policy.
ii) *Development of action plan* – This stage is concerned with setting the initial aim, objectives, activities and all priorities for implementing a health policy programme, and identifying the resources needed for this implementation.

iii) *Implementation and monitoring of programme* – This stage is concerned with the execution of the action plan for implementing a health programme and monitoring the adherence of implementation activities to the action plan.
iv) *Programme evaluation* – This stage is concerned with the assessment of the effects and other outcomes of implemented health policy programmes.

Our review of the state of the art on health policy making has identified strands of work, which could be classified into the following three general categories:

a) *Policy modelling* – This category includes strands of work focusing on the development of methods, techniques and/or tools for specifying policies and policy making processes.
b) *Policy formation processes and/or guidelines* – This category includes strands of work focusing on the development and proposal of processes for establishing policies. In certain instances, works in these strands propose guidelines for establishing policies that may fall short of what could be thought of as a comprehensive policy making process.
c) *Policy making tools* – This category includes strands of work focusing on the development of tools for policy making. Such tools may support the specification of policies and/or policy making processes, as well as the different stages of policy making, discussed above.

In the following sections, we provide a summary of the identified strands of work, organized by the main category (a)-(c) as above that they fall under. After providing an overview of each of the reviewed strands of work, we also examine the support that it offers (if any) for the four key stages in policy making.

2.2.2. Policy modelling techniques

2.2.2.1. Government (G2G) Collaboration

2.2.2.1.1. Overview

[46] has developed an ontology based approach for modelling public policies and managing these across their entire life cycle (i.e., a concept corresponding to the stages in policy making that we outlined above). This approach has been developed with the intention to support policy modelling and management in a collaborative manner involving interactions between different stakeholders involved in such activities, and in particular cases where policy modelling and life cycle management involves collaboration between different government stakeholders (i.e., G2G collaboration).

[46] has proposed a domain independent (aka "horizontal") ontology for modelling public health policy processes, which – according to the author – could be used for governmental policy formation processes in different domains subject to extensions of the core horizontal ontology with domain specific ontologies. The modelling of policies in this approach is based on five core ontological concepts. These are: the issue (i.e., the problem to be solved or goal to be achieved by the policy); the alternatives (i.e., the alternative directions of action/ways in which the issue(s) can be addressed); the positions that different stakeholders may express on different alternatives (positions can support or object to alternatives); the preferences that different stakeholders may express for different positions to indicate their relative importance; and the criteria that will be used to reach decisions.

2.2.2.1.2. Situational analysis

The approach of [46] provides support for situational analysis in policy modelling and formation. This is based on identifying and modelling the strengths, weaknesses, opportunities and threats (SWOT) that may give rise to issues that need to be tackled by a policy (this phase in policy formation is referred to as "strategic analysis" in [46]).

2.2.2.1.3. Development of action plan

The development of an action plan is also supported in the G2G ontology, using a collaborative and iterative process. This process involves the consultation of individual stakeholders with the aim to elicit their positions and preferences, and alternatives courses of action that could be used to pursue these positions. The initial consultation phase, which focuses on these issues, is followed by a second consultation in which the eligibility of alternative courses of actions is assessed from a resource availability and a regulation perspective. The second consultation phase results in the selected action plan, i.e., a (policy) programme addressing the issues and a project with tasks, deliverables and assignments for realising the programme.

2.2.2.1.4. Implementation of the programme

The implementation of policy is addressed through the formation of a project that realizes a policy programme.

2.2.2.1.5. Programme evaluation and monitoring

The main objective of the monitoring phase is to offer support for the collaborative monitoring of each a project. Monitoring covers both the physical implementation and the consumption of financial resources. The evaluation phase is not explicitly supported in the approach of [46].

2.2.2.1.6. Relation to EVOTION

The G2G approach provides a potential basis for specifying policies in EVOTION. If this approach is selected, it would need to be extended in order to support the specification of processes for automated data acquisition and analysis in order to generate the evidence required for making selections between alternative policy options. It could also be enhanced by default criteria for selecting and evaluating alternatives, which have been developed in frameworks focusing on health services (e.g., by WHO) and are reviewed below.

2.2.3. Policy Formation processes and/or guidelines

2.2.3.1. Canadian Foundation processes for healthcare improvement

2.2.3.1.1. Overview

The Canadian Foundation for Healthcare Improvement (CFHI) has developed a framework of 18 processes to support Evidence-Informed Health Policymaking [41]. These processes are aimed at ensuring that relevant research is identified, appraised and used to inform decisions about the formation of health policies and programs. The processes have been written for people responsible for health policy decision-making (e.g., health system managers and policy-makers) and those who support them. The CHFI framework addresses all four stages of policy formation, albeit to a different extent.

2.2.3.1.2. Situational analysis

The focus of situational analysis in the CFHI framework is on identifying and analyzing the health service needs of a population. In order to identify the population needs CHFI monitors its performance against its population goals and addresses the needs of its patient population by engaging healthcare providers and front-line managers. Their aim is to develop clinical leadership for improvement initiatives.

2.2.3.1.3. Development of action plan

In the CFHI initiative, the steps that need to be taken in order to develop an action plan are the following:

- Analyse existing improvement frameworks for healthcare organizations in order to identify the key attributes of such high-performing organizations.
- Consider the identified attributes in light of hands-on and practical experience (of CFHI) in driving healthcare improvement in a specific context (i.e., Canada in the case of CFHI).

- Select key targeted levers for healthcare improvement. The framework identifies six levers of improvement, and provides questionnaires for making assessments in reference to these six levels. The six levers and questionnaires are related to: (a) focusing on population needs, (2) engaging healthcare providers and front-line managers in creating the improvement initiatives/culture, (3) building organizational capacity, (4) creating supportive policy and incentives, (5) engaging patients and citizens, and (6) promoting evidence-informed decision-making.
- Develop assessment questions per each lever that further clarify the need for and pathway to change.
- Review and revise action plan based on consultation with health service, policy and quality improvement leaders.
- Pilot the action plan with healthcare delivery and policy organizations to test and improve its application

2.2.3.1.4. Implementation and monitoring

In the CFHI framework, the monitoring of the realization of an action program is performed by a team of healthcare leaders. Monitoring is based on a rating system using an "1-5" point scale where 1 means "Strongly disagree" and 5 is "Strongly Agree".

2.2.3.1.5. Programme evaluation

Policy evaluation in the CFHI framework is the responsibility of healthcare leaders. The framework expects the collection of evidence that can help an organization (or a health system) to

- assess how it performs
- identify the available improvement expertise, assets and strengths (after the completion of assessment a group should spend time to understand the strengths and weaknesses according to their own responses to each of the six layers as they described in implementation and monitoring part).
- develop its improvement capacity, and
- undertake the next step for healthcare improvement

2.2.3.1.6. Relation to EVOTION

The CHFI framework can be useful in the context of EVOTION in providing inputs to the articulation of a scheme for specifying potential healthcare services improvement targets, selecting them in the context of specific public health policy making models, and assessing progress related to these, once they have been adopted.

2.2.3.2. World Health Organization guide for Health Impact Assessment

2.2.3.2.1. Overview

WHO offers a number of short guides for health impact assessment (HIA). These support the identification and improvement of consequences of policies or activities on health. HIA was developed for National Health System (NHS) Executive London [44]. To understand whether or not to carry out a health impact assessment in a project/policy in Sweden, for example, the authors created a checklist of the items to be considered. These items were [48]:

- The description of the policy
- Questioning whether the policy affects selected determinants of health. These determinants are: participation in influence on the society; economic and social security; safe and favorable growing up conditions; healthy working life; sound and safe environments and products; health promoting

medical care; physical activity; eating habits and safe food; tobacco, alcohol, illicit drugs, doping and gambling; and prevention of infectious diseases.

- Questioning whether the policy affects the whole population or 13 selected vulnerable groups by gender. The 13 vulnerable groups are: children; Adults; Elderly; Chronically ill; People with a handicap/impairment or allergies; People with an addiction, alcohol, drugs etc.; Unemployed; Immigrants; Refugees; Single-parents; People with low income; Homeless people; and Homosexuals.

The strength of HIA is that its recommendations is connected to a group of stakeholders as participants where they provide a fully considered view of issues that affect the health of local communities.

2.2.3.2.2. Situational analysis

The situational analysis in HIA is based on understanding whether HIA as a tool could be used overall. Assuming that HIA is worth pursuing, situational analysis is based on [44]:

- Screening - HIA may not be possible to use on every project, policy or programme. To determine when to use it, HIA has an initial screening step. Screening involves a quick assessment of the potential of a programme/policy to affect the health of the population. Although screening is the typical first step in deciding whether HIA should be used, there have been cases where it has been skipped, following a decision by key stakeholders (e.g., public health authorities, health planners, managers) and funding is available for it [54].
- Scoping - Scoping is used in cases where screening has identified a positive potential for a programme/policy and involves four key tasks. These are: (1) to establish the boundaries for the appraisal of health impact of the programme, (2) to come to an agreement regarding the way in which the appraisal of the programme/policy will be managed, (3) to decide who will be responsible for decision making, and (4) to agree how to monitor and evaluate the HIA process.

2.2.3.2.3. Development of action plan

The steps that may be taken to create the action plan in HIA are:

- The appraisal of the potential health effects/impacts. Appraisal is based on analyzing the policy, programme or project, profiling the affected population, identifying and characterizing the potential health impacts, and reporting on the impacts and making recommendations for the management of those impacts [44].
- Decision-making. Decision making is about deciding on an action plan based on the outcomes of appraisal. The stakeholders, who participate in this stage, are those who have agreed to do so during scoping.

2.2.3.2.4. Implementation and monitoring

The implementation of a HIA programme involves the following steps [44]: (1) identifying expertise that already exists within the organization/ partnership and could be deployed in support of HIA; (2) raising awareness about HIA within the organizations involved; and (3) performing a rapid appraisal of possible starting points. HIA does not make special provision for monitoring.

2.2.3.2.5. Programme evaluation

Whilst HIA recognizes the need for programme evaluation and views this process as a process that should be driven by the impact on health and health services, it does not offer a special process for programme evaluation.

2.2.3.2.6. Relation to EVOTION

HIA can be useful for the EVOTION project in making it clearer to understand the key features of health impact assessment.

2.2.3.3. Applicability and Transferability of Evidence Tool

2.2.3.3.1. Overview

The applicability and transferability of evidence tool (A&T Tool) was first introduced by [40] in 2007. Subsequently, it was updated by the National Collaborating Centre for Methods and Tools [47] to help public health managers and planners make decisions about local health planning priorities. However, although it is referred to as a "tool" by its creators, for the purposes of our survey we will refer to it as a method since it does not constitute a computer based public health policy making tool. The A&T tool can be used by public health decision-makers who want to incorporate high quality evidence in their planning as an aid to determine whether a policy or program is relevant or feasible. Created for public health, A&T Tool includes questions relevant to public health context such as collaboration with stakeholders, needs for local implementation, assessment of the political and organizational climates, and evaluation of the costs related to outcome. This tool can be used by decision-makers in any public health program area.

2.2.3.3.2. Situational analysis

In A&T Tool, situational analysis is carried out by setting first the users' aims for the method (e.g., to explore whether and how to apply evidence into public health decision making and also policy making). The questions A&T Tool provides are aimed at evaluating political acceptability or leverage, social acceptability, available resources and organizational expertise and capacity. The stakeholders, who should be involved in situational analysis involve inter-sectorial, multidisciplinary and consumer groups. According to [47], the preliminary steps that someone should follow are: (i) to generate a question to drive literature search and review process; (ii) to search and retrieve relevant literature, and (iii) to critically appraise the literature. It is also worth mentioning that users of A&T Tool can assign their own scoring system for the tool.

2.2.3.3.3. Development of action plan

As suggested by [47], the development of an action plan for the study of the literature involves 6 steps. These are:

- Establishing a facilitator for the overall process who can act as group leader and maintain timelines.
- Selecting key stakeholders to form a group that will make use of the A&T Tool and the method that it imposes.
- Selecting questions for assessing the applicability and transferability of alternative options that are most important for the intervention of interest and local context.
- Identifying a scoring system for the assessment questions (e.g. an 1-to-5 point scale where 1 is low level impact and 5 is high level impact). Priority goes to the highest scoring intervention or program.
- Rating the importance of different criteria.
- Documenting the scoring process used by the group

Although the above is relevant to the study of the literature it does not constitute public health policy action plan making as such.

2.2.3.3.4. Implementation and monitoring

The A&T tool does not support public health policy implementation and monitoring.

2.2.3.3.5. Programme evaluation

The A&T tool does not support public health policy implementation and monitoring.

2.2.3.3.6. Relation to EVOTION

The A&Tool can be useful to EVOTION as a method for conducting investigations of the literature as part of public health policy decision making. Although this process in EVOTION is based mainly on analysis of real data, the analysis of relevant literature can also be important to evaluate, interpret and confirm the outcomes of data analysis.

2.2.3.4. The Delphi Method

2.2.3.4.1. Overview

Delphi (Delbecq et al., 1975) is a method that is aimed at producing information suitable for decision making. This method is based on a structured process that collects knowledge through an iterative process whereby the knowledge is refined until a consensus is reached amongst a group of experts using questionnaires. The overall aim of this method is to support judgmental or heuristic decision making in the fields of both social policy and public health. The method was created in order to improve the exchange of information, to support social policy and public health-related agencies, as well as other decision-making bodies. Delphi is also a method for improving the generation of critical ideas and processing the information collected from experts.

2.2.3.4.2. Situational analysis

The method comprises a series of questionnaires sent to a group of experts. The questionnaires are designed to develop individual responses to the problems posed and to enable the experts to identify whether the work's progress is going according to the plan or not. There are two phases in the Delphi method. The first one is characterized as the 'exploration phase' and the second one 'evaluation phase'. In the first phase the subject under discussion is explored and then additional information is provided. The second phase involves the process of assessing and gathering the expert's views. If there is a disagreement, then this can be explored further in order to find a solution. The Delphi method has four outcomes as described by (Delbecq et al., 1975). These are the areas of agreement, the areas of disagreement, the areas needing clarification and understanding areas. The overall expectation of the Delphi method is that the judgements achieved within a group through the Delphi method are more reliable than individual judgments.

2.2.3.4.3. Development of action plan

The development of an action plan for public health policy could be based on the use of Delphi questionnaires.

2.2.3.4.4. Implementation and monitoring

The Delphi method does not support implementation and monitoring of public health policy explicitly. Delphi questionnaires may, nevertheless, be used for monitoring.

2.2.3.4.5. Programme evaluation

The Delphi method do not cover health programme evaluation. Delphi questionnaires may, nevertheless, be used for programme evaluation.

2.2.3.4.6. Relation to EVOTION

Thee Delphi method could be useful in devising questionnaires that can aid setting up the objectives and action plans for public health policies, and for monitoring and evaluation of public health policy realization programmes.

2.2.3.5. Planning and monitoring of national strategies manual

2.2.3.5.1. Overview

The World Health Organization has developed a manual for planning and monitoring of national health strategies. The national strategies are professional programmes aiming at the development of a holistic and integrated strategic plan for the provision of effective and sustainable health services. The reason behind the creation of this manual was the need to provide effective and sustainable ear and hearing care services. The manual provides guidance on how to develop and implement such a strategy. The goal of the guidance is to: raise awareness about ear and hearing problems among individuals and communities tailored for and targeted at the general public, policy-makers, programme managers and funding providers separately [53]. By doing this it will help secure the political commitment and also facilitate the collection of resources needed in order to develop a plan and a strategy.

2.2.3.5.2. Situational analysis

To analyze a situation related to the development of a strategy for ear and hearing services, the WHO manual suggests the evaluation of the needs of the population and the resources available for addressing them. To accomplish this evaluation, the manual suggests [51]:

- assessing the magnitude and profile (type, causes, age pattern, geographical distribution) of hearing loss and ear diseases;
- obtaining general country information, including population profile, socioeconomic profile and health indicators;
- determining the health system infrastructure and organization;
- assessing the availability of human resources;
- determining what ear and hearing care services are available;
- Performing stakeholder analysis.

The manual also suggests the use of strengths, weakness opportunities and threats (SWOT) analysis. In this context, strengths may be related to availability of trained health workers working in the community, who can be engaged to deliver ear and hearing care services; weaknesses may be related to lack of trained audiologists to provide specialized services; opportunities may be related to increasing engagement in the country of an nongovernmental organization (NGO) working in the field of hearing care, and threats may be related to political unrest. These are just examples provided by the developers of the manual and do not constitute the only SWOT's that should be considered.

2.2.3.5.3. Development of action plan

The development of an action plan in this approach is based on the overall aim that needs to be achieved. This aim must be specified after taking into account the different views of the stakeholders. It must also be agreed on by all the parties involved and not just the majority of them. The manual provides examples of possible aims such as: "To reduce the overall prevalence of hearing loss in the country by 25%" or "To provide equitable access and coverage of cost-effective, quality health services for ear and hearing care, as close to the people of the country as possible" [51]. The manual introduces also the concept of a "road map" for achieving the aim. The "road map" states the things that need to be done and sets the activities needed to achieve an objective. In the development of an action plan, practical difficulties and the available resources need also to be considered. Lastly, any objectives set towards achieving the overall aim should be [51]:

- Specific, i.e., clearly focused on a particular result
- Measurable, i.e., each objective should have a precise measurable target

- Achievable, i.e., the objective is feasible and can be achieved in the time set
- Realistic, i.e., each objective should be considered with regard to constraints such as resources, personnel, cost, and time frame required for it
- Time-bound, i.e., a timeline should be specified for their achievement.

2.2.3.5.4. Implementation of programme

The implementation of a programme goes through three key phases:

- *Pilot phase*: In this phase the feasibility and the proposed interventions of the strategy or plan first tested in one or more parts of the country and then in a national level. This happens in order to refine the plan on the basis of feedback. This phase is closely monitored and evaluated.
- *Expansion phase*: In the pilot phase, due to negative feedbacks, some interventions may have to be dropped. Others may be added if there is supportive feedback from the community.
- *Evaluation phase*: Evaluation follows the implementation phase and focuses on assessing the overall implementation and impact of the strategy.

2.2.3.5.5. Support for programme evaluation and monitoring

Monitoring in WHO's manual is aimed at correcting deviations from objectives and improving performance [51]. Every programme must have a national committee. This committee forms a task force in order to draft sections of the national strategy document. The members of the task force need to have knowledge about the "country's health system and public health approach to ear and hearing care, as well as its medical, surgical, rehabilitative and social aspects" [51]. The task force needs to work with all stakeholders and members of national committees and take in consideration the views and interests of all stakeholders participating in strategy development. The monitoring of the development of strategy should be done by the task force that has been set for the program to check that it is on point. The problems that may occur should be solved before the strategy is finalized. The monitoring of the national strategy is based on:

- an appropriate set of indicators that measures the day-to-day achievements of the strategy or process being monitored
- monitoring tools that allow the systematic collection of relevant information.

The evaluation of a program can be carried out at several stages in the life cycle of a program [51] According to the stage that it is conducted an evaluation is:

- ongoing evaluation: carried out at the end of a pre-agreed period or midway through a strategy or programme
- terminal evaluation: within 6–12 months after completion of a programme
- ex-post evaluation: after several years, when the full impact could be expected to have been realized.

2.2.3.5.6. Relation to EVOTION

The EVOTION project can use the approach described above as guidance for developing public health policies related to hearing loss.

2.2.3.6. Deloitte's framework for assessing hearing services

2.2.3.6.1. Overview

Action on Hearing loss (AHL) is a non-profit organization that aims to help patients suffering from hearing loss (HL) in the UK by providing advice, communication services, and day-to-day care. AHL commissioned Deloitte to create a framework on hearing services that could be used to evaluate and compare hearing service providers. Their aim was to help adult HL patients to make informed choices regarding services and

service providers, by making it easier to collect report information. The framework that Deloitte created is innovative as it enables the identification of new areas of hearing services and evaluating qualified service providers (referred to as "Any Qualified Provider" or AQP in the framework). The framework also creates a collection of information on important features that will be useful for service users and other stakeholders to consider. Although this framework does not constitute a policy making tool, process or modelling framework, it is relevant to policy making through the provision of a means for evaluating hearing services. To this end, we have included it in our review.

2.2.3.6.2. Support for situation analysis

This framework focuses on the analysis and evaluation of hearing services. Hence, situational analysis in the context of this framework is supported in only as far as service situational analysis is concerned. To carry out such analysis, the framework identifies key service performance domains and performance indicators. The performance domains are [43]:

- Accessibility and responsiveness - This performance domain considers whether a service is located near service users, it has flexible appointment times and acceptable waiting/response times.
- Integration with other services - This performance domain considers whether there is a smooth service user transition between services and if the related process is efficient and effective.
- Public health outcomes - This performance domain considers if the service improves service user hearing and quality of life.
- Cost - This performance domain considers if the cost of the service to the service user is affordable.
- Service user focus - This performance domain considers whether service users are satisfied, if there was an individual management plan and if the information provided to service users is helpful and sufficient.
- Quality - This performance domain considers if service providers follow guidelines and professional standards and if their staff are qualified and follows the established processes.
- Safety - This performance domain considers if the service has any related adverse events that have been reported by the provider.
- Innovation - This performance domain considers whether there is a systematic approach to introduce service improvements based on user feedback.

The hearing services targeted by this framework include hearing assessment, hearing aid fitting, follow up visits and aftercare services. Each of these services is examined and assessed in terms of inputs (i.e., the resources invested in undertaking service activities), activities (i.e., the steps taken during the consultation between the service user and hearing service), outputs (i.e., the immediate deliverables of the service) and outcome (i.e., the impact of the service within 6 months (short term) and beyond 6 months (long term)) in order to form assessments with regards to the key performance area.

Evaluation in the context of Deloitte's framework has three different categories: evaluation of the impact of AQP, evaluation of the service users' access to hearing services and lastly, evaluation of the service value. The evaluation of the impact of AQP could be done by both registered and non-registered service providers because the performance indicator outcomes would be compared between registered and non-registered services in the same geographic area. The second category was created in order to determine whether there is equality in access of hearing services for different groups. There is also a way to measure access to hearing services as the total numbers of service users.

2.2.3.6.3. Implementation and monitoring of programme

This framework does not cover the implementation and monitoring of health policies.

2.2.3.6.4. Support for programme evaluation

This framework does not cover the evaluation of health policies. However, the performance indicators that it proposes for the evaluation of hearing services could also be useful as criteria for evaluating certain types of hearing service related health policy programmes.

2.2.3.6.5. Relation to EVOTION

The performance indicators that are proposed by this framework for the evaluation of hearing services could also be useful as criteria for evaluating certain types of hearing service related health policy programmes.

2.2.3.7. WHO's situational analysis tool for hearing care

2.2.3.7.1. Overview

[50] developed a tool to support situational analysis for hearing care. Despite having been termed as "tool" by WHO, for the purposes of our survey this tool constitutes a method rather than a computer based tool. Hence we will refer to it as "WHO method" in the following. The WHO method includes a questionnaire and an annex providing guidance on how to complete it. The aim of the questionnaire is to collect evidence that is necessary for situational analysis in order to develop a strategy for national ear and hearing care. This questionnaire can help preventing, identifying and treating ear diseases and hearing loss as well as rehabilitating and supporting people with hearing loss. The questionnaire focuses on the country profile, burden of disease, epidemiology of hearing loss etc. Beyond the questionnaire, the WHO method also suggests collecting information from stakeholders through interviews. After the information is collected and analyzed as documentary evidence and in cases where this is not possible, the source or person that provided the information must be included.

2.2.3.7.2. Support for Situation Analysis

The WHO method aids the understanding of the epidemiology of hearing loss and the status of they existed systems that support related hearing care. The method has also created an opportunity to reduce the gap between ideal situations and existing ones.

2.2.3.7.3. Support for Development of Action Plan

[50] has also created an action plan formation manual as a complement to its questionnaire. The aim of this manual has been to provide guidance on action plan formation following a situational analysis. The given manual is an annex that provides guidance on how to complete the questionnaire and on resources that may provide needed information. More specifically, for each stage there is a guidance on how one can find the detailed information needed in order to complete this step and also the resources that are available.

2.2.3.7.4. Implementation and monitoring of programme

The WHO method does not cover this stage of policy making explicitly.

2.2.3.7.5. Support for programme evaluation

The WHO method does not cover this stage of policy making explicitly.

2.2.3.7.6. Relation to EVOTION

The use of the questionnaire developed by WHO can be useful for the EVOTION project in collecting evidence.

2.2.4. Policy Making Tools

None of the existing papers and articles that we have examined would qualify as computer based tools for public health policy making.

2.2.5. Conclusions and Advancements of EVOTION

EVOTION aims to create an evidence based policy making approach enabled by big data analysis, decision making and simulation techniques. Its objective to produce executable PHPDM models linked to clear decision making rules and BDA processes goes well beyond the current state of the art.

This is evident from the reviewed information presented in the previous section. This review has indicated that most of the available frameworks present guidelines on how to formulate public health priorities and policies, how to assess health population needs and health services, how to use evidence and how to monitor health policies in the short and long term. However, none of the existing approaches comes anywhere close to the vision of EVOTION, which is the development of a platform supporting the specification of public health policy decision making (PHPDM) models based on analysis of evidence that can be generated in explicitly specified ways, and the monitoring of the policies instilled by such models based also on the automated and continuous analysis of evidence using big data techniques.

To achieve its overall aim, EVOTION will also develop a language for specifying interpretable PHPDM models and a social media campaigning capabilities to disseminate outcomes of public health policy formed by these models, and collect and analyses feedback and public perceptions on policies.

2.3. Big Data Technologies

In the following section, we catalogue Big Data technologies focusing on the native type of analysis provided, namely batch or stream analysis. Currently, many of the available BDA technologies offer hybrid solutions providing support for both batch and stream for instance using the concepts of micro-batches to approximate streams with batch-oriented technologies or saving streams to distributed file system or databases to execute batch analysis later. Such approaches are in general materialized in BDA architectures providing batch and real time BDA. After presenting the prominent Big Data technologies, we describe two popular BDA architectures implementing them.

2.3.1. Batch processing

Batch processing is mainly motivated by the need of storing and then processing a big amount of information. This processing requires high computational power achievable via parallelization of tasks. Parallelization can be achieved distributing tasks, without the need to keep strict real-time constraints.

Google was one of the first big ICT companies facing this problem for storing and recalculating the index of the crawled webpages in a timely fashion. Its approach is presented in two seminal papers describing the Google file system, a distributed file system with fault tolerance capabilities [1] and the distributed processing framework called Map Reduce [2]. These two papers have a recognized impact in the area of Big Data processing and principally in batch processing. In the following, we present some of the prominent technologies for batch processing starting from the mostly famous Hadoop and including Spark, Flink and H2O. For each of them, when relevant, we also presents tools and collection of libraries for analytics evaluation using machine learning/data mining algorithms.

2.3.1.1. Hadoop (Map/Reduce)

Hadoop was initially introduced at Yahoo as an extension of Apache Nutch aimed at implementing the MapReduce processing engine linked with a distributed file system taking inspiration from the google approach in [1][2]. It then has evolved into a vast ecosystem covering every step of a big data workflow, including data collection, storage, processing, and analysis. The work in [4] presents a complete survey on the Hadoop ecosystem.

Initially Hadoop project includes both the distributed file system and the processing framework but later in 2009 the two areas were separated in two subprojects, Hadoop Distributed File System (HDFS) [3] and Hadoop MapReduce, respectively.

Hadoop HDFS is a scalable and fault-tolerant distributed file system developed in Java able to provide a reliable file system on commodity hardware. Most of the current big data projects relies on HDFS file system architecture, which is able to provide monitoring features (e.g. Health Utilities) and high availability as well as rollback mechanisms. The main issue with HDFS is that it does not perform well with small files since it has been designed for storing big sequential indexes.

Hadoop processing framework implements the Map Reduce described in the Google paper [3] which is composed by two phases: Map (organize row data) and Reduce (process in parallel) plus an intermediate phase called shuffling (feed parallel process with map data). The Map phase takes as input a set of objects and generates a set of key values pairs. The criteria by which these key values pairs are created depend on the implementation and on the problem to solve. After the Map phase, there is the Shuffling phase, which is an intermediate re-organizing phase where all the outputs of the Map phases are forwarded to the Reduce phase. Shuffling forwards the Key Value elements by creating new lists composed by all the elements with the same Key. These new lists are then forwarded each one to a different node for the Reduce phase. The Reduce phase takes as input the list of Key Value pairs and creates a new list of Key Values pairs using a cumulative metric e.g. using the sum.

With Hadoop MapReduce, the output of the Map phase is stored physically in the HDFS resulting in a bottleneck where frequent disk intensive operations become very expensive in terms of latency, computational resources, and network bandwidth.

YARN (Yet Another Resource Negotiator) was introduced in Hadoop to take care of the resource management duties, allowing a separation between infrastructure and the programming model, solving many of the issues present in the old Hadoop MapReduce like bottlenecks (i.e. YARN is able to run on larger clusters). YARN makes Hadoop more general and MapReduce is just one type of YARN application.

A set of frameworks for Machine Learning has been developed on top of Hadoop Map Reduce aiming at efficient distribution of machine learning tasks. Apache Mahout is one of the prominent representative tools for Machine Learning with Hadoop.

2.3.1.2. Mahout

Apache Mahout[2] is both a single machine and a distributed machine learning library that can be integrated with different processing frameworks including Hadoop, Spark, H2O and Flink. Mahout provided a set of machine learning algorithms that are translated (where possible) into distributed processes for the underlying processing framework, however the set of ready-to-use algorithms depends of the processing engine. The set of ready-to-use algorithms released with Mahout can address only specific tasks out of the box like address classification, collaborative filtering, clustering, dimensionality reduction, topic modelling.

Mahout is currently moving its focus from native Map Reduced environments only, to generic math environment called Samsara for avoiding inefficiency of the Hadoop Map Reduce framework. This results in a limited support of machine learning tools for Map Reduce mainly limited to naive Bayes classification, collaborative filtering and dimension reduction. On the other hand it offers a more flexible solution to specific machine learning problems, allowing the composition of distributed algorithms from a set of simple

[2] http://mahout.apache.org/

operations showing interesting machine learning potential as well as flexibility in the creation of customized ML algorithms. The principal criticisms to Mahout were raised due to the difficulty with configuration, integration and development of new algorithms.

A number of additional tools are developed in the Hadoop ecosystem for providing parallelizable algorithms suitable for BDA. For instance, RapidMiner Radoop[3] is a visual environment for designing advanced analytic processes triggering computations down to Hadoop cluster. It works in synergy with Apache Hive is a data warehouse infrastructure

Hadoop processing framework, still one of the mostly used and diffused, but is now competing with much more novel systems such as Spark, Flink and H2O, aimed at introducing additional features and overcoming the inefficiencies.

2.3.1.3. Spark

Spark[4] was developed initially at the Berkeley and now is one of the Apache project based on Map Reduce but aimed at addressing the disk intensive inefficiencies of Hadoop. It supports iterative computation and improves speed and resource utilization by adopting an in-memory computation model. The main data abstraction used in Spark is called Resilient Distributed Datasets (RDD), which consists of a read-only distributed in-memory storage providing naturally a fault tolerance mechanism without the need for physical replication of data on disk. RDDs can be the result of an input process, for example importing data from HDFS file system or the result of a transformation process from others RDDs to new RDDs.

The architecture of Spark is composed by a driver node and a set of worker nodes. The driver node is where the program logic is executed, while the worker nodes store and perform operations on the RDDs. Whenever is possible, there will be no data exchange between workers nodes. Using this approach, the intermediate results of the Map Reduce computations, constituting the reason for the main performance issues of Hadoop systems, are stored in the distributed memory, significantly reducing on the number of read and write operations on the file system and data exchange between nodes.

Spark, additionally to Hadoop, adapts to different programming languages (e.g. Python, Scala and R), making it easier to develop and adapt to different environments. Spark solves many of the deficiencies of the Map Reduce paradigm using the iterative batch approach to data processing, but also introduces additional concerns in terms of distribution of data across nodes [5]. More specifically, when data transfers take place throughout the network, due to the job isolation mechanism, only one driver can serve requests to all of its RDDs. This may lead to bottleneck issues within the network in case of multiple requests to multiple nodes.

Spark, does not offer real-time processing but micro-batching processing, which is a technique that simulate real-time processing (i.e. Spark Streaming). In this approach, an incoming stream is packaged into sequences of small chunks of data (micro-batch), which can then be processed by a batch system. While this can be considered adequate for many projects, it is not realistic real-time system.
In addition to the Mahout library, Spark also have its own Machine Learning library called MLlib .

2.3.1.4. MLlib

MLlib is a library, similarly to the early versions of Mahout, provides the same set of Machine Learning algorithms plus topic modelling and frequent patterns mining. MLlib takes advantage of Spark architecture for iterative batch processing, stream (micro-batch) processing and in-memory caching of intermediate

[3] https://rapidminer.com/products/radoop/
[4] http://spark.apache.org/

results and it is able to deliver much better performances compared to Mahout. MLlib provides standardized APIs for machine learning algorithms, which makes easier to combine MLlib algorithms into a processing pipeline. Such pipeline is offered by Spark via ML pipeline, built on top of Spark-SQL library, allowing users to set up, build and execute Machine Learning processing pipelines.

Mlib shows some performance issues due to slow convergence of some algorithms and some limitations in terms of assumptions made on the data dimensions.

2.3.1.5. Flink

Apache Flink[5] is a relatively new approach supporting stream and batch processing (see Lambda architecture) developed by the University of Berlin [6], now part of the Apache ecosystem. It combines database technology, stream processing technology and Map Reduce technology, to keep on one side the processing of user defined functions, complex data types, and the scalability of map reduce systems. It can be integrated with HDFS or run completely independent from the Hadoop ecosystem.

Similarly to Spark architecture, Flink is composed by a JobManager and many TaskManager nodes. The JobManager executes the program logic, while the TaskManager executes the atomic operations on data. Flink's processing framework is based on transformations that are applied to the data collections in the nodes. These transformations can be generic traditional Map Reduce functions, but also some more specialized functions such as group, join and iterate. Flink execution model includes a cost-based optimizer that automatically selects the best execution strategy for each process. Even if Flink is relatively young with respect of Hadoop and Spark, some machine learning tools are available for the framework. As already mentioned a portion of the algorithms available in Mahout has been implemented to support Flink even if Flink project has its own machine learning library, called FlinkML .

With respect to Mahout and MLlib, the list of algorithms in FlinkML is currently limited to Support Vector Machines (SVM) and multiple linear regression in terms of supervised algorithms available, while K-nearest neighbours is the only unsupervised algorithm implemented. An Alternating Least Squares (ALS) recommendation algorithm is also available as well as some data pre-processing methods and support utilities such as cross validation.

In terms of practical perspective, Flink is more resources intensive, but seems faster than Spark (see the benchmark in [9]) for some specific tasks.

2.3.1.6. H2O

H2O[6] is an open source project providing a distributed processing engine, but also data pre-processing, analytics, math, machine learning libraries and evaluation tools. As well as Spark, it offers support for Java, Python, and Scala languages and it is able to execute Spark processes via Sparking Water library. H2O is able to execute its own processing models on top of Spark and Storm. It also offers for users with no programming expertise a Web interface for defining processing pipelines.

H2O, similar to Flink, processes data in-memory using multiple execution methods. The H2O approach for job deployment is a divide and conquers technique called Distributed Fork/Join applied to massively parallel tasks. This approach divides a processing job into smaller jobs, which are executed in parallel, resulting in dynamic fine-grain load balancing for Map Reduce jobs as well as graphs and streams.

[5] https://flink.apache.org/
[6] http://www.h2o.ai/

Again, Mahout Library offers implementation of most of its machine library algorithms for H2O. However, H2O platform is shipped with a ready-made machine-learning module that in addition to traditional machine learning algorithms offer a set of tools for deep neural networks.

The machine learning tools offered with H2O are able to address a relatively wide set of machine learning tasks including classification, clustering, generalized linear models, statistical analysis, ensembles, optimization tools, data pre-processing options and deep neural networks.

2.3.2. Stream processing

Nevertheless, Hadoop is designed for batch processing, it shows a multi-purpose features but not the ones required for a real-time and high performance engine, due to the high throughout latency in its implementations. For certain stream data applications, such as log file processing, industrial sensing applications, stream processing for real-time analytics is necessary. There are a number of different challenges to Map/Reduce framework, when such streams is concerns

Some of the above batch frameworks show certain capacity to deal with streams (e.g. Flink) but not often in real-time manner. Some native real-time Big Data platforms, such as Storm and Splunk, are specifically designed for real-time stream data analytics. It means that the ongoing data processing requires a very low latency of response therefore there are very rarely storing phases in the streaming pipeline.

2.3.2.1. Storm

Storm is specifically designed for distributed fault-tolerant real-time processing initially conceived to overcome deficiencies of other processors in collecting and analyzing social media streams and currently released as open source.

To implement real-time computation on Storm, users need to create different topologies. A topology is a graph of computation representing the transformations of the stream, each node in the topology executes in parallel and the topology can be created and submitted using programming language. The Storm architecture consists of spouts and bolts. A spout represents one of the starting point of the graph denoting source of streams, while bolt processes input streams and outputs new streams. Each node in a topology contains processing logic and links between nodes indicate how data should be processed between nodes. A Storm cluster consists of two kinds of working nodes, i) one master node and ii) several worker nodes. The master node (Nimbus) and worker nodes (supervisor) implement two kinds of daemons showing responsible for distributing code across the Storm cluster, scheduling works assigning tasks to worker nodes, monitoring the whole system. The supervisor complies with tasks assigned by Nimbus, and starts or stops worker processes when necessary. The entire computational topology is partitioned and distributed to a number of worker processes implementing a part of the topology.

Storm was built as a stand-alone system independent from Hadoop. Recently some effort have been devoted to integrate the two projects in the framework of the so-called Nathan Marz's "Lambda architecture".

Storm does not ship with a machine learning library, but for instance: i) SAMOA platform for mining

big data streams has implementations for classification and clustering algorithms running on Storm, ii) H2O has also offered a way to link the two projects, iii) Trident-ML offers a library of learning algorithms built on

Storm, to name but a few.

2.3.2.2. Apache Flume

Flume[7] is a distributed, reliable, service based on streaming data flows for efficiently collecting, aggregating, and moving large amounts of log data. It is robust and fault tolerant with tunable reliability mechanisms and many failover and recovery mechanisms. It is often used inside hadoop ecosystem as data transfer system where Flume streams are moved into the Hadoop Distributed File System (HDFS). Inside the hadoop ecosystem it works in cooperation with YARD coordinating data ingestion.

2.3.2.3. S4

S4[8] is a general-purpose, distributed, scalable, fault-tolerant, pluggable computing platform for continuous processing of unbounded streams of data.

It was initially released by Yahoo! in 2010 and has become an Apache Incubator project since 2011. S4 allows programmers to easily develop applications, and possesses several competitive properties, including robustness, decentralization, scalability, cluster management and extensibility.

The core platform of S4 is written in Java. The implementation of a S4 job is designed to be modular and pluggable for easily and dynamically processing large-scale stream data. S4 also employs Apache ZooKeeper to manage its cluster, like Storm does. S4 has been used in the in production systems at Yahoo for processing thousands of search queries, and also good performances showed up in other applications. Last release dates back to 2013.

2.3.2.4. Splunk

Splunk[9] is a real-time Big Data platform specifically designed for machine-generated Big Data. Splunk combines cloud technologies and Big Data to help users to search, monitor and analyze their machine-generated data using web interface. It is designed to provide metrics for different domains as well as intelligence for business operations.

Splunk is different from the other stream processing tools. Its peculiarities include indexing structured or unstructured machine-generated data, real-time searching, reporting analytical results and dashboards. It is now commercial product available as generic Operational intelligence tool.

2.3.2.5. Apache Kafka

Kafka[10] is a high-throughput distributed publish-subscribe messaging system that was initially developed at LinkedIn. It works as a tool to manage streaming and operational data via in-memory analytical techniques for obtaining real-time decision-making. Kafka has persistent messaging, high-throughput, support for distributed processing, and support for parallel data load into Hadoop. Kafka combines off-line and on-line processing to provide real-time computation and produce ad hoc solution for these two kinds of data. Its streams API allows an application to act as a stream processor, consuming and producing input/output streams. It is mainly used in combination with other framework e.g. for building Lambda architecture.

2.3.2.6. Apache Samza

Apache Samza[11] is a distributed stream processing framework. It uses Apache Kafka for messaging, and Apache Hadoop YARN to provide fault tolerance (i.e. task migration), processor isolation, security, and

[7] https://flume.apache.org/
[8] http://incubator.apache.org/s4/
[9] https://www.splunk.com/
[10] https://kafka.apache.org/
[11] http://samza.apache.org/

resource management. Samza manages snapshotting and restoration of a stream processor's state via consistent snapshot and provides processor and resource isolation through Linux CGroups. It is part of the Hadoop ecosystem but also works with other messaging and executing environment thanks to the API.

2.3.2.7. Spark Streaming

As anticipated in batch related Section, Spark Streaming is an extension of Spark enabling scalable, high-throughput, fault-tolerant stream processing. Data ingestion can be originated from many sources like Kafka, Flume, TCP sockets, and can be processed using complex algorithms like map/reduce, as well as Spark's machine learning and graph processing algorithms. Processed data can be stored to filesystems, databases, and made useful in live dashboards. Spark Streaming provides a high-level abstraction called DStream (discretized stream) which represents a continuous stream of data as a sequence of RDDs. It divides the data into batches, which are then processed by the Spark engine to generate the final stream of results in batches.

2.3.3. Runtime Architectures

Any of the above solutions, both streaming -based and batch-based relies on storing capabilities. There are a number of different storing solutions like Hadoop distributed file system HDFS , the Hadoop YARN, Apache HBase , Apache Cassandra , Amazon EC2 and S3, to name but a few. They are in general applicable to any of the above technologies and exchangeable depending on the processing needs. Processing type, storing strategies, analytics capabilities, performance and security requirements, are some of the key factors underling any BDA architecture. The above BDA technologies including storing technologies show natural integration capabilities especially the ones developed within the same ecosystem (e.g. Apache). They can be arranged in a number of architectural solutions showing different peculiarities, targeting batch only, batch and streams or streams only processing. Below we discuss the two popular big data logical architectures called Lambda and Kappa architecture.

2.3.4. Lambda Architecture

The Lambda Architecture, consists of three layers: speed, batch and serving layer. The batch layer merges incoming data to historical data, and reiterates the procedural workflows on all the combined data input, in order to achieve results. The accuracy of batch views, comes at the cost of high latency, therefore Lambda Architecture must also be able to compute incremental updates via speed layer, in order to guarantee a good level of responsiveness.

The speed layer takes as input the new data in the form of either micro-batches (ingested on a regular basis) or single records. It also takes as input the last update of batch data output, which implies that a mandatory condition for algorithms to run in the speed layer is being capable of processing data incrementally, providing in a short time model updates influenced by fresh data delivered. One of the most prominent hurdles to overcome to deal with batch and speed views is synchronizing them to prevent data redundancy or data loss.

In order to address this problem Vanhove et al. [22] proposes the solution of tagging data as soon as it enters the system, to keep track of its delivery time and thus keeping track of what corresponding information can be removed from speed data views, when batch processes produce results.

The serving layer arranges some ad-hoc queries in order to provide an aggregate view of both batch and speed layer data, resulting as a suitable interface layer for reporting and visualization tasks.

The Apache Oryx 2[12] is a realization of the lambda architecture built on Apache Spark and Apache Kafka, but with specialization for real-time large scale machine learning. The results of batch and speed analytics, intended as models and model updates, converge to the serving layer, where they are used to evaluate incoming data with ad-hoc queries. The output of these queries merges the input flow.

One criticism against lambda architecture is that maintaining code that needs to produce the same result in two complex distributed systems requires twice as the effort to maintain the streaming codebase only.

The major downside of lambda is its complexity. To overcome this some simpler alternatives providing similar benefits handling the full problem set but with lower complexity were proposed. One approach is to adopt a pure streaming approach, and use a flexible framework such as Apache Samza to provide some type of batch processing (i.e. consume a bunch of messages from the same stream partition in sequence) see Kappa architecture. On the opposite, a flexible batch framework can be used, allowing processing of micro-batches, small enough to be close to real-time, for instance using Apache Spark/Spark Streaming or Storm's Trident. Spark streaming is sequence of small batch processes while Trident is an extension of Storm providing a high-level abstraction that can process streams as small batches as well as do batch aggregation.

As additional alternative, it can be feasible to use a technology stack already combining batch and real-time, such as Spring "XD", Summingbird or Lambdoop. Summingbird ("Streaming MapReduce") is a hybrid system where both batch/real-time workflows can be run at the same time and the results merged automatically. The Speed layer runs on Storm and the Batch layer on Hadoop, Lambdoop (Lambda-Hadoop, with HBase, Storm and Redis) also combines batch/real-time by offering a single API for both processing paradigms

2.3.5. Kappa Architecture

The main idea behind Kappa architecture is that some stream processing algorithms can be used to perform both incremental or batch computations with a single streaming engine running over a distributed append-only topic where incoming data is stored with a long retain period.

The reason for having to retain a large data set is to allow the reprocessing of a considerable amount of historical data, to maintain the capabilities of a batch framework together with the stream processing.

Despite most of use cases where high-throughput tasks must be fired off could be accomplished by incremental algorithm implementations, thus avoiding reiterations over historical data, reprocessing is still an issue in Kappa architecture only when code changes, as data views should be updated anyway, involving all retained data inputs. One solution proposed for code change reprocessing in [29] is to i) set up a retain period long enough to cover the amount of data to reprocess, ii) when the code changes, start another job instance to reprocess all of the retained data up that moment, writing output to another table, iii) when the second job is done, make the client applications point to the new table, and iv) stop the old version of the job, and delete the old output table.

2.4. Sensors

Sensors are of great significance because of their capability to resolve a potentially large number of analytical problems and challenges in very diverse areas such as environmental monitoring and medicine. The expanding role of sensing in society and a real-world environment has led to an exponential growth of the R&D efforts around the world. Such expedient growth is driven by several factors including medical and

[12] http://oryx.io/

health problems such as a growing population and the rising incidence of chronic diseases, significant problems with environmental monitoring and serious challenges in security applications [10]. Sensors can provide cost-effective, easy-to-use, sensitive and highly accurate detection devices in a variety of research and commercial applications.

As shown in the Table of Data, EVOTION's solution will mainly use sensors for recording physiological, severe episode related and environmental data. Latest models of sensors underpinned by the EVOTION solution include IHealth's® Wireless Blood Pressure Wrist Monitor, which measures systolic, diastolic and pulse rate and Wireless Pulse Oximeter, which measures SpO2 and pulse rate, empatica 's E4 wristband measuring heart rate, electrodermal activity, skin conductance, temperature and heat flux activity, movement activity, Microsoft's Band which monitors heart rate and location.

Wearable sensors are externally used devices fastened to an individual, in order to measure physiological parameters of interest [11]. The range of these sensors varies from minuscule to large scaled devices physically fitted to the user, operating on wired or, in most cases, wireless terms. Sensors are mainly used to monitor three types of signals: activity-related, physiological and environmental ones. More specifically, wearable sensors are used to measure activity levels and physiological signals. Different types of sensors are being developed and used for monitoring physiological parameters indoors and outdoors. Examples of these sensors include piezoresistive-, sweat rate-, blood pressure-, pulse oximetry- and light-sensors, as well as accelerometers [12]. The most common physiological parameters that are measured by the wearable sensors are body temperature, heart and respiration rate, blood pressure, blood oxygen saturation, ECG, gait analysis, sweat rate and skin conductance [13].

Wearable sensors show great promise, especially for healthcare monitoring [14]. Sensors connected externally to different parts of the body as well as to garments can specifically detect the parameter they are used for. Some of these sensors are designed in a way to assist the diagnosis of more than one physiological parameters. A large amount of work has been accomplished toward the integration of wearable technologies and communication, and data analysis technologies, for the remote monitoring indoors. Smartwatches can also provide a significant amount of physiological information, as well as monitoring of physical activities [15].

The smartwatch wearable has become a promising technology trend, since IBM launched the first one in 2000. Many considerable manufacturers have shown interest in releasing related products, platforms or applications. The IDC (Internet Data Center) predicts that this market will grow to 200 million by 2019 [16]. A smartwatch is "a wrist-worn device with computational power, which can connect to other devices via short range wireless connectivity; provides alert notifications; collects personal data through a range of sensors and stores them; and has an integrated clock". Smartwatches are wrist mounted, so they possess strong advantages over other devices: their mount location, and the continuous connection to the skin. These characteristics give smartwatches new possibilities in remote health care and other applications. Smartwatches are thus an emerging area of academic research and since the smartwatch is an individual, consumer oriented hardware, it is essential to investigate an individual's intrinsic perceptions such as social motivation [17].

Overall, the basic architecture for a human activity monitoring system consists of three basic elements: a sensor, a processor and a display. Depending on the task of monitoring, different types of sensors can be used, from which raw data are collected and then processed and displayed. The data may or may not be completely processed at the sensors end but most of them are stored and processed in a computer. Extensive display is possible either in a graphical format and/or as a numerical value [18]. This type of systems consists

of many sensors used to measure physiological parameters such as body temperature and heart-rate. All the measured physiological data are collected by a microcontroller to be processed and analyzed. Founded on the processed data, the central controller can either generate a warning message to the caregiver based on the current physiological state of the person being monitored and/or can help to detect early disease and possible health threats [11].

The architecture and the platform of the sensor networks of a human activity monitoring system play a significant role for the continuous monitoring of physiological parameters especially for the elderly or chronic patients. The network should be selected based on its cost, performance, ease of configuration, addition of extra sensor nodes, range and power consumption. Different IEEE protocols which are currently available for the human activity monitoring system include the ZigBee, Bluetooth, WiFi and WiMax protocols. There may be also different ad-hoc networks on which research are currently undergoing [11].

The last-generation monitoring system is a nascent research area that aims to combine continuous health monitoring with other sources of medical knowledge. In addition to the pervasive sensing modalities of the older generations, the objective of present generation applications is to integrate intelligent agents that implement technologies, such as stream processing, data mining and genetic data. These agents are, thus, responsible for extracting information from a variety of sources including clinical trials, patient records and laboratory generated reports. This system can advocate the decision-making process controlled by the latest evidence in biomedical and health informatics. Integrating knowledge from multiple sources has great potential to improve and personalize clinical care in the future [19].

Though there are many wearable sensors available in the market, most of them are still not universally accepted by the general public. In order to make wearable devices a common item of our everyday life, there is a need to overcome several major technological and social challenges, the most important being the drastic reduction of the fabrication cost for the wearable sensors [20]. Some others very significant reasons are weight reduction, power efficiency, quality of service and privacy [21].

Even though there are significant challenges about design issues, usage and acceptability, the sensors market and its development is at full swing. Continuous research continuously address the issues faced by the wearable electronic sensors. Though there may be some issues in terms of long-term monitoring, sensors and wireless technology has advanced to a point where they could bring amazing experiences to fitness and health of a patient, even for a short duration. Wearable electronics could also lead to new applications such as memory aids and navigational tools [17].

As far as EVOTION is concerned, we hereby present a list of the existing sensory systems (Figure 2) allowing the monitoring of physiological data, as described in the project:

Wearable	Cost ($)	Heart Rate	Respiratory Rate	Blood pressure	Temperature	Electodermal Activity Sensor	Pulse Oximeter	Compatibility	Connectivity
Acc URate Pro Series CMS 500DL	18,95						x	-	-
Jawbone UP4	52	x	x		x	x		Android, iOS	WiFi
iHealth Air	69,95	x					x	iOS	Bluetooth
iHealth Sense	79,95	x		x				iOS	Bluetooth
iHealth Feel	99,95			x				Android, iOS	Bluetooth
Withings Pulse O2	99,95	x					x	Android	Bluetooth
Huawei Fit	99,99	x	x				x	Android, iOS	Bluetooth
Spire	119		x					Android, iOS	Bluetooth
Fitbit Charge 2	149,95	x	x					Android, iOS, Win	Bluetooth
Innovo CMS 50F Plus	169,99	x					x	-	Bluetooth
Microsoft Band 2	198,56	x			x	x		Android, iOS, Win	Bluetooth
Empatica Embrace Watch	199				x	x		Android, iOS	Bluetooth
VinCense	240	x			x		x	Android	Bluetooth
Helo	320	x	x	x				Android, iOS	Bluetooth
Garmin fēnix 3 HR	599,99	x					x	Android, iOS, Win	Bluetooth
Empatica E4 Wristband	1690	x			x	x		Android, iOS	Bluetooth
Amiigo	N/A	x	x	x	x		x	Android, iOS	Bluetooth
Scanadu	N/A	x	x	x	x		x	Android, iOS	Bluetooth
Health Care Originals ADAMM	N/A	x	x						
Zensorium's Tinke	N/A	x	x				x	Android, iOS	Bluetooth

Figure 2: List of Commercially Available Sensory Systems for Physiological Data Monitoring

2.5. Decision support system technologies

A decision-support system (DSS) can be seen as a tool to support the decision-making process. If it uses readily available clinical and demographic features, it could permit a more rapid, evidence-based decision making in public health. Up until now, there has been limited use of such systems in public health policy making (PHPM). The present section serves as an initial attempt to concentrate the most updated use of decision support models/tools/systems in public health policy making over the last 5 years.

One of the most recent examples is the probabilistic decision support algorithm for tuberculosis control, presented in [22]. Mamiya et al. used a logistic regression model using clinical and demographic information of tuberculosis cases (there were reported to Montreal Public Health between 1997 and 2007). They measured the predictive performance, in terms of sensitivity, specificity, negative predictive value, positive predictive value, the Receiver Operating Characteristic (ROC) curve and the Area Under the ROC (AUC).

The prediction model they used was that of the logistic regression and their methodology was based on the Bayesian Information Criterion (BIC) of a model containing all the predictors (i.e. main model) and compared to the BIC derived from the same model plus the interaction term. BIC-based model selection is "substantially more conservative than other statistical criteria such as Akaike's Information Criterion and the likelihood ratio test due to its stronger penalization mechanism", so it was "less likely to select interaction terms resulting from noise of the development data". They also performed screening of the interaction process and assessed the linearity of the age variable with the use of fractional polynomials [22].

The optimal model for their case was the Bayesian Model Averaging (BMA), which "estimates the posterior probabilities of all possible models given the training data, chooses a set of candidate models according to their posterior probability distributions, and averages the coefficients of the selected models using the posterior probabilities as weights" [22]. A graphical representation of their model is shown in Figure 3.

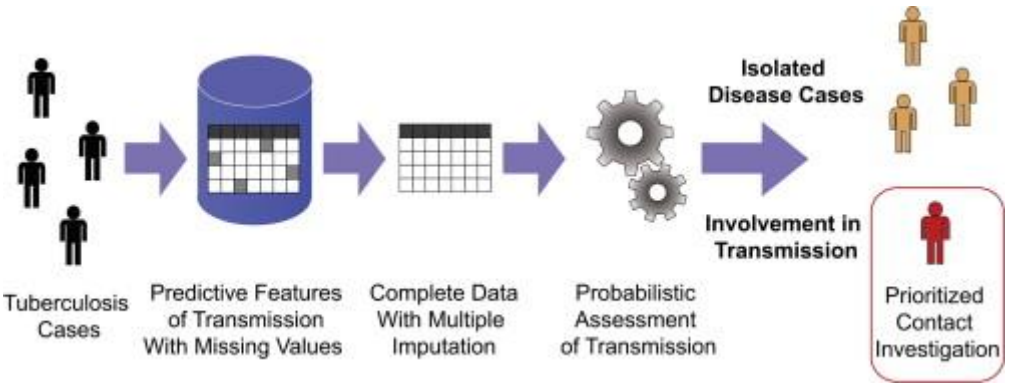

Figure 3: Graphical Representation of the Decision Support System developed in [22]

As they conclude, "patient attributes available at the time of disease reporting can be used to predict whether a tuberculosis case reported to public health is involved in recent transmission". Similar models have the potential to be included in a DSS and guide evidence-based public health practice.

The GEMSS (Geospatial Emergency Management Support System) is a "browser-based application designed to assemble geospatial information from multiple local or remote sources in a common operating environment, allowing for multi-data visualization" [23]. The system was used as a multi-data platform to visually analyse spatial patterns of selected indicators at a local level. These indicators (climate change environmental public health ones) relied on socio-environmental and demographic vulnerability, health, policy, and weather data. The health policy indicators result from geo-referenced indicators for the surveillance of public health impacts of climate change, as population vulnerability to climate change depends on numerous factors [24].

A DSS for brain tumor information aimed at health policy decision makers, based on the three major technologies of data mining, data warehousing and ontology was presented in [25]. The aim of the aforementioned DSS was to "present an automated data mining system that allows public health decision makers to access analytical information regarding brain tumors". Santos et al. used ontologies in an automated data mining process. The system architecture is shown in Figure 4, whereas detailed information for each component of the system can be found in [25].

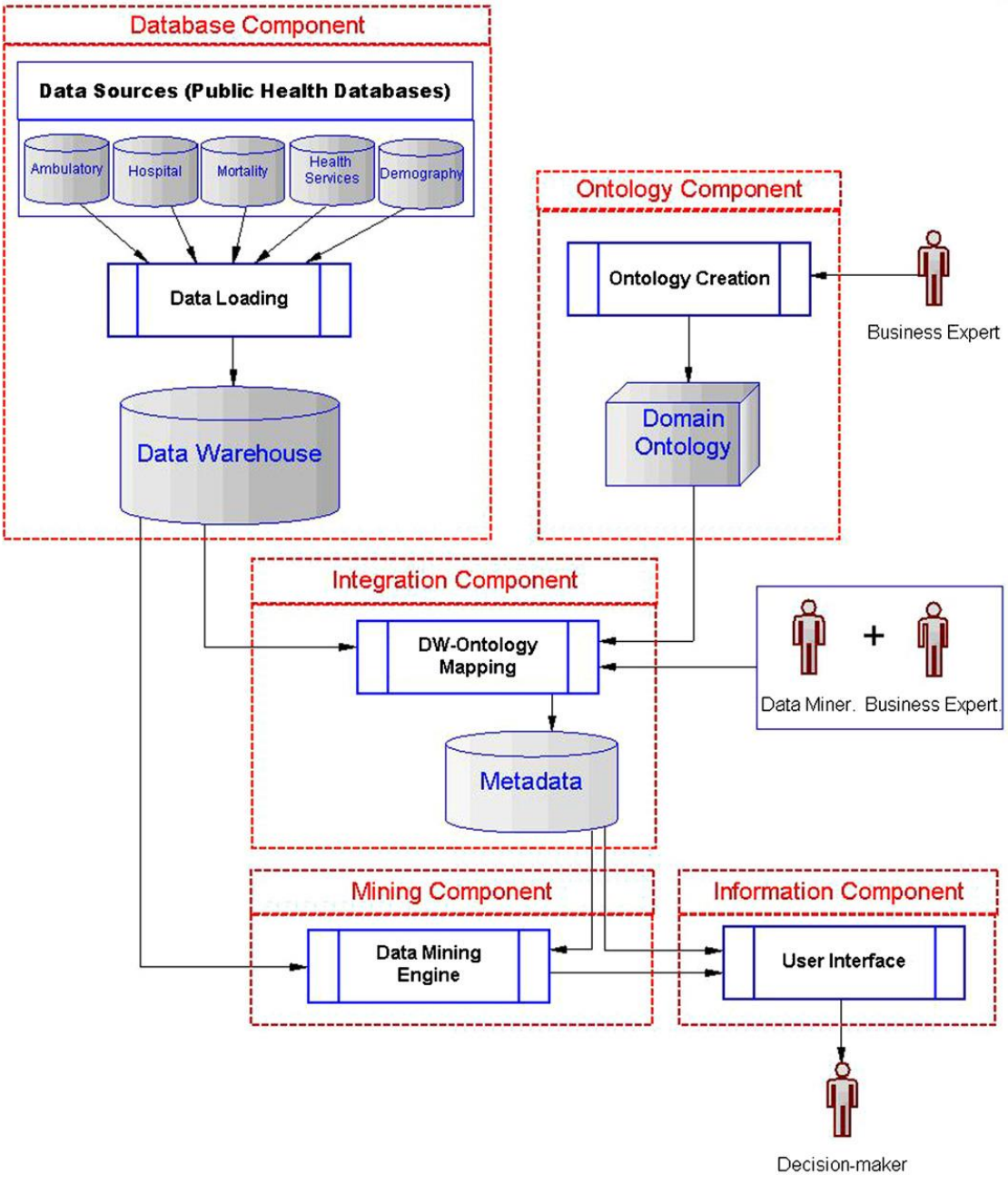

Figure 4: DSS System Architecture as presented in [25]

Public health decision makers evaluated the relevance of the information to the context, whereas data miners examined the consistency of the information produced by the system, to determine if its output was

correct. Information obtained by non-experts who tried that system, were relevant to the management of public programs for the treatment of brain tumors [25].

The development of a public health surveillance framework in Jordan was the main topic covered in [26] by Sheikhali et al. The system proposed in shown in Figure 5.

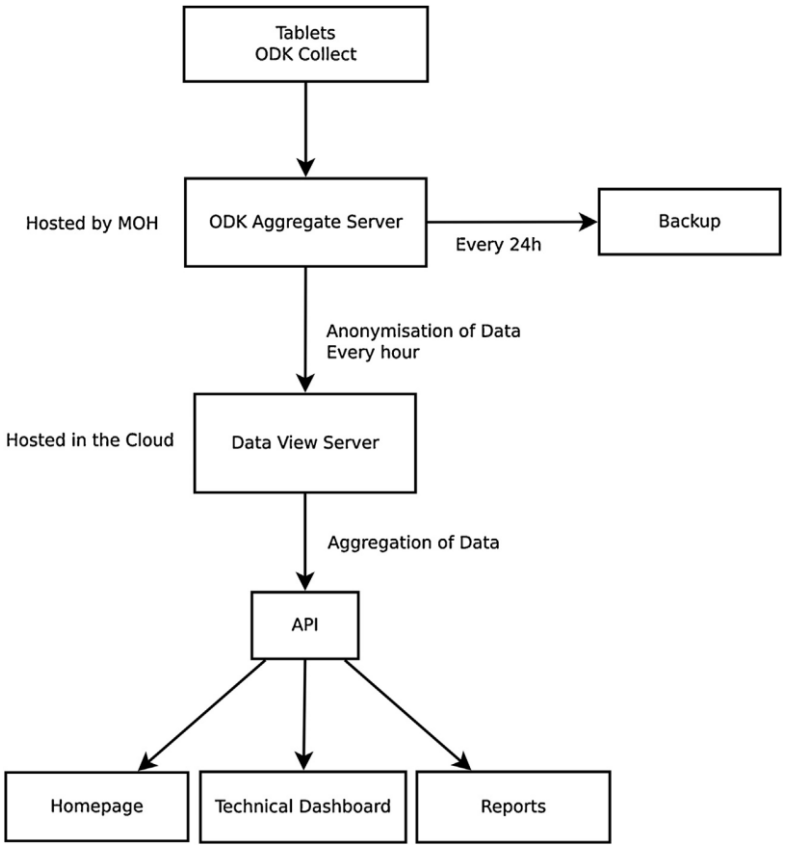

Figure 5: Diagram of public health surveillance system components and data flow. [5]

The system was built using free, open source software and is implemented as a cloud-based model, where the server and data are hosted centrally by the Ministry of Health in Jordan and not by individual clinics. The data architecture of the system includes a data model, data dictionary and classification of standards and systems used. Reported information is made available within 1 hour via an online framework, with support for analysis, mapping and reporting that is accessed at all levels of Ministry of Health, while essential health system indicators are also collected through the system [26].

An agent-based DSS for an "Environment-Public Health" system was presented in [6] by Sokolova and Fernández-Caballero. The system is logically and functionally divided into 3 layers: the first one dedicated to meta-data creation (information fusion), the second to knowledge discovery (data mining) and the third to provide real-time generation of alternative scenarios for decision making. As they state in their research, decision makers cannot afford to explore a large area of the decision variable space or conduct a time-consuming search for the best set of decision variables, therefore use of a model-driven DSS has become increasingly important to decision makers.

Hierarchical agents with teams of subordinate agents were used, allowing the control over the whole system. Moreover, in case there is a need to add some additional functionality to any role, often it can be solved by adding a plan capability to the subordinate or principal agent. The implementation of the system was

performed within the JACK Development Environment, and some plug-ins were used to code data fusion procedures when the ontologies used were read from the OWL-files, generating neural network models and visualized results [27].

Figure 6: Goal Correlation [27]

2.6. Security and privacy technologies

2.6.1. Overview

Whilst the exact architectural design of the overall EVOTION platform is an ongoing activity at the time of authoring this report, the platform that will be used in order to store, process and provide access to the data collected from the EVOTION hearing aids, biosensors and mobile applications resembles the characteristics of platforms used for big data analytics.

A recent report by ENISA [68], whose purpose was to provide a comprehensive overview of the security threats that arise for such platforms, has specified a high level conceptual architecture of the computational capabilities and assets involved in big data analytics platforms (BDA platform). This architecture is shown in Figure 7. According to it, the main computational capabilities of a BDA platform are organized in layers, concerned with:

- the sources that provide the data (data sources);
- the integration of data from external sources;
- the storage of data;
- the analytic processes and computing models,
- the presentation of data to external users.

The reference architecture includes also the computational infrastructure – i.e., the set of hardware devices, network, operating systems and other middleware (e.g., virtualization or cloud service middleware) for accessing them – which is used to deploy the software components that realize the capabilities identified above.

For the purposes of this survey, we consider the data sources layer to include: (a) the hearing aids, the mobile phones and the biosensors that provide data to the rest of the EVOTION platform; and (b) the local Bluetooth network that connects the hearing aids and biosensors to the mobile phones. Also, we consider the "infrastructure" in the BDA reference architecture to include the wide area network that connects mobile phones to the rest of the EVOTION platform, and the local or wide area networks which are used to connect the computer clusters upon which the EVOTION platform is deployed and the individual nodes (computers) within these clusters.

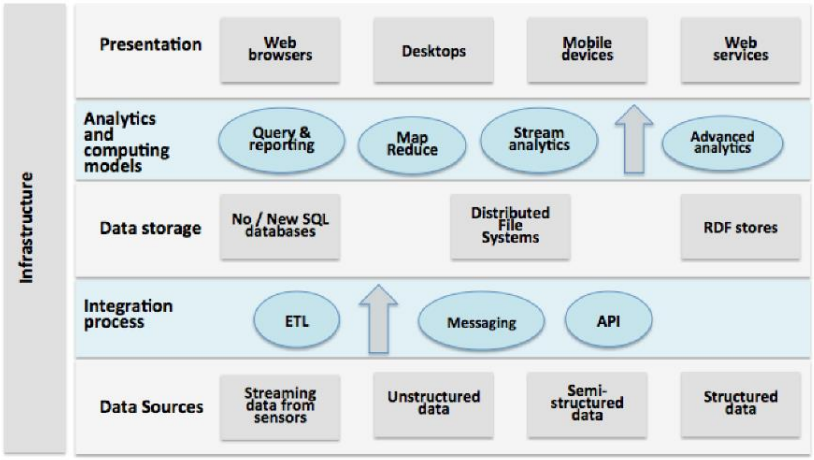

Figure 7: Conceptual Big Data Analytics Platform Architecture (as suggested by [68])

In the following, we review the security issues and solutions that are relevant to BDA platforms in reference to this architecture. More specifically, security issues and solutions are distinguished into those related to infrastructure, data storage and management security, big data analytic processes security and presentation layer. Furthermore, the security issues and solutions for each of these architectural areas are grouped by the fundamental security property that they aim to ensure.

The fundamental security properties that we assume are:

- Confidentiality: This property requires that no data held within a system should be accessible to anyone who is not authorized to have access to the data.
- Integrity: This property requires that no one without appropriate authorization rights should be able to modify data held within the system and/or execute any system operation.

- Availability: This property requires that the operations provided by a system should always be accessible in a manner that satisfies given correctness conditions. Availability is typically assessed in an approximate manner in which system operation accessibility is considered satisfactory if it exceeds a given threshold (e.g., in 99% of the invocations of a given system operation, the operation produced a correct response within 10 milliseconds).
- Privacy: This property requires that personal data related to a physical person is under the control of that person, in terms of who can access the data and the purpose of accessing them, and that the particular person should not be identifiable from the available data within a certain group.
    - The data stored on the hearing aid can either be read via a cable or a secure Bluetooth Low Energy connection and interpreted using proprietary software and specifications.

It should be noted that confidentiality, integrity and privacy can only be realized if a system has the following two key capabilities:

- Authentication: This is the capability of a system to verify the identity of an actor (i.e., an external system or a human user) interacting with it or an asset held or used by it (e.g., the genuineness of a data element passed onto to it).
- Authorization: This is the capability of a system to check if an actor (i.e., an external system or a human user) has appropriate access rights over a system asset (e.g., a system operation or a data element held by the system).

Although in the literature authentication and authorization are often treated as separate security properties in this survey we regard them as system capabilities and discuss possible mechanisms that could be used to realize them as part of the confidentiality property.

2.6.2. Security of the data source layer

2.6.2.1. Mobile phones security

Mobile phones are an essential element of the EVOTION platform as they will be the component of the platform that will be collecting data from biosensors and hearing aids and transmit them to the components of the “back end” of the platform. Hence, their security is of paramount importance for the end-to-end security of the entire EVOTION platform.

Breaches of security on mobile phones have been continuously increasing in the last few years due to the wide spread use of such devices and their use for applications that generate or require sensitive personal or financial data. Thus, mobile phones have become one of the primary targets of attackers [64]. Security breaches on mobile phones are caused mainly by different types of malware (i.e., viruses, worms, Trojans, rootkits, botnets) that are installed on mobile phones without the phone user being aware of them. Malware of these types can launch different types of attacks, including stealing sensitive personal data of the phone users, sending SMS message to high premium services at the expense of the user etc. In the following, we review the risks to security properties of confidentiality, integrity, availability and privacy and the security solutions that are available for mitigating them. As reported by [74], security breaches on mobile phones may also be caused by connections to non-secure free Wi-Fi networks, connections to trap Wi-Fi networks (aka spoofing), and improper session handling by mobile applications (apps), which to provide easy access for mobile transactions, use of “tokens,” allow users to perform multiple actions without being forced to re-authenticate their identity.

In the following, we review the main issues security issues for mobile phones and the security mechanisms available for mitigating them, grouped by the main security property that they relate to.

2.6.2.1.1. Confidentiality

Breaches of confidentiality on mobile phones may be caused by the absence of strong encryption, authentication an authorization mechanisms.

Authentication on mobile phones is typically based on a self-selected or allocated user name and password. Passwords can be one-time or regularly updated. They may also be required to meet certain security strengthening conditions (e.g., to be of a minimal length, to include – or not – specific types characters or combinations of such types). Passwords may be substituted for by security tokens, i.e., physical or virtual object that store authentication information, such as smartcards or ID badges [84]. User authentication on mobile phones may also be based on biometric characteristics of the user, including fingerprints, retina scans, hand geometry scans, voice samples or facial picture [61]. Although biometric authentication enjoys increasing adoption, it creates difficulties in low signal-to-noise ratio scenarios (e.g., when fingers are wet, when voice authentication is attempted in noise environments and when face recognition is attempted in low lighting environments [61]. Also, despite common perceptions which view biometric authentication as more secure than password based authentication, biometric authentication can also be fooled (e.g., with fingerprint molds or user photographs [61]). Mobile phones, which use biometric authentication as their primary form of authentication, can revert to password or card based secondary authentication when their primary mechanism fails. They may also use multi-factor authentication requiring the use of at least two different authentication factors, to strengthen the authentication process. Finally, multi-level authentication may be required, i.e., authentication to access the device, followed by authentication to access specific applications upon it.

Encryption is available as, an operating system service, on most popular mobile phone platforms, including Android and iOS and in newer versions of both these OSs it is set up as a default.

From Android 5.0 onwards, full-disk encryption is supported using a single key, protected with the user's device password. The encryption algorithm used for full encryption is the Advanced Encryption Standard (AES) 128 with cipher-block chaining (CBC) and ESSIV:SHA256. The master key is encrypted with 128-bit AES via calls to the OpenSSL library [56]. Android 7.0 and above supports file-based encryption in which different files are encrypted with different keys that can be unlocked independently. The encryption algorithm used is the Advanced Encryption Standard (AES) 256 in XTS mode (thus, it needs two 256-bit keys). The encryption policy applied is at the directory level but specific directories can be excluded (Android, 2016).

iOS also supports file based encryption based on a built in Advanced Encryption Standard (AES) 256 crypto engine [58]. From A7 onwards, the cryptographic key management in iOS is supported by dedicated coprocessor, called SecureEnclave. This processor provides all the cryptographic operations required for the key management of encryption capability (known as Data Protection) and maintains its integrity even if the kernel of the device has been compromised.

1.2.1.2 Integrity

A significant measure for enhancing the integrity of mobile phones is to allow the execution of only applications (apps) which are coming from a trustworthy source and have not been tampered with.

A general mechanism for ensuring this is the use of a Mobile Platform Module (MPM) with Platform Configuration Registers (PCRs). In mobiles enabled by a TPM, the OS can measure the loaded applications and stores their integrity values in PCRs before executing them. Subsequently, when an attestation challenge from a third party arises, the TPM signs a set of PCR values with an Attestation Identity Key (AIK) and sends them to the challenger, who can then make decisions on the trust status of the platform by verifying the

integrity of the sent values with expected values. Standard specifications for MPM based attestation have been proposed by the TCG Mobile Phone Working Group [87].

iOS realises achieves app integrity by requiring that all executable code that can run on the device must have been signed using an Apple-issued certificate. This is based on the pre-authentication of the identity of the application developer by Apple and the consequent provision of the Apple certificate to him/her that can be used to sign off the app that he/she has developed. For apps using dynamic libraries, iOS performs a code signature validation of all the dynamic libraries that a process links against at launch time. In iOS, all third-party apps are also "sandboxed" [58]. This restricts them from accessing files stored by other apps and making changes to the device. Given sandboxing, if a third-party app needs to access information other than its own, it does so only by using services explicitly provided by iOS [58]. Access by third-party apps to user information in iOS is also controlled by the so called "entitlements". Entitlements are digitally signed key value pairs that cannot be changed. iOS also provides random address space allocation (through a feature called "ASLR") to prevent manipulation of the memory address space of individual apps by other apps [58].

Android supports requires apps which run within the "sandbox" that it provides to have been signed. Applications can be signed by a third-party (OEM, operator, alternative market) or self-signed [56]. Android accepts self-signed code certificates that developers can generate, without requiring apps to be signed by a central authority. Also, it does not perform CA verification for app certificates.

2.6.2.1.2. Availability

The availability of mobile phones may be compromised by malware installed upon it. Such malware can deplete the limited resources of mobile phones (e.g., exhaust the available memory, deplete battery, and overload the CPU). To protect devise availability, it might be useful to install malware detection software.

iOS offers some built-in support for availability. The relatively strict signing scheme and the runtime checks over execution permissions that it operates makes it less likely to have malware that is hidden in other apps to be installed and executed on devices. Also, third apps can only perform background processing through system-provided APIs. This enables controls over the execution of apps that can prevent degrading performance or dramatically impacting battery life.

Android phones are more vulnerable to malware [64]. To address this vulnerability, several security solutions have been developed to detect malware. These solutions include signature and anomaly based intrusion detection systems, which try to detect malware by analyzing the communication requests sent and received by a mobile device and the system calls (OS events) made by the apps installed on them. Other solutions try to detect potential vulnerabilities by monitoring power consumption. A comprehensive review of such solutions is provided in [64].

2.6.2.1.3. Privacy

The encryption and authorization mechanisms supporting confidentiality also reduce the likelihood of privacy breaches. Nevertheless, for privacy preservation in a BDA platform, the de-identification of private data at their source is recommended [67]. This can be achieved by the replacement of identifies by pseudo-identifiers in the data sent from the mobile phone to the back-end components of the EVOTION platform and the use of k-anonymity techniques that reduce the likelihood of re-identification.

It should be noted that iOS provides some support for setting user privacy preferences. More specifically, users can decide to grant or prevent access to personal (home) data like Contacts, Photos, and other iOS data sources, to specific apps when the latter request it, similar to [58].

2.6.2.2. Sensors security

As most of the sensors that will be used in the EVOTION, have as their main wireless connectivity standard the Bluetooth technology, we will be looking into several aspects regarding Bluetooth security.

Based on our preliminary report, an initial list of wearable sensors for EVOTION are presented in the below table.

Wearable	Bluetooth Core version
Acc U Rate Pro Series CMS 500DL	-
Jawbone UP4	-
iHealth Air	4.0 BLE
iHealth Sense	3.0 + EDR Class 2 SPP
iHealth Feel	3.0 + EDR
Withings Pulse O2	2.0 or higher
Huawei Fit	4.2 BLE
Spire	Low Energy
Fitbit Charge 2	Low Energy
Innovo CMS 50F Plus	
Microsoft Band 2	4.0 (Low Energy)
Empatica Embrace Watch	Low Energy Smart
VinCense	Low Energy
Helo	Low Energy
Garmin fēnix 3 HR	4.0 Low Energy
Empatica E4 Wristband	Low Energy Smart
Amiigo	4.0
Scanadu	Low Energy
Health Care Originals ADAMM	-
Zensorium's Tinke	yes, but no data

Table 1: Bluetooth Core version supported in Commercially Available Sensory Systems for Physiological Data Monitoring

The Bluetooth Core version along with the i/o capabilities of each BT device suggest the security levels that could apply for each one (see Sect. 2.6.2.4.3). All EVOTION components establishing BT communications, will bear the maximum possible security features as recommended by the NIST [83] (see Sect. 2.6.2.4.4).

2.6.2.3. Hearing aids security

The security of the hearing aids in EVOTION contain a few more items than the Confidentiality, Integrity, Availability, and Privacy considered for the other components of the EVOTION platform.

- Confidentiality: This property requires that no data held within a system should be accessible to anyone who is not authorized to have access to the data.
    - The hearing aids will only share data with the paired smartphone and rely on Bluetooth Low Energy Security measures to ensure this.
- Integrity: This property requires that no one without appropriate authorization rights should be able to modify data held within the system and/or execute any system operation.

    - The hearing aids will only respond to modifications of processing from the buttons on the hearing aid or from the smartphone over the paired Bluetooth connection.
- Availability: This property requires that the operations provided by a system should always be accessible in a manner that satisfies given correctness conditions. Availability is typically assessed in an approximate manner in which system operation accessibility is considered satisfactory if it exceeds a given threshold (e.g., in 99% of the invocations of a given system operation, the operation produced a correct response within 10 milliseconds).
- Privacy: This property requires that personal data related to a physical person is under the control of that person, in terms of who can access the data and the purpose of accessing them, and that the particular person should not be identifiable from the available data within a certain group
    - The data stored on the hearing aid can only be read via a cable and interpreted using proprietary software and specifications.

Hearing aids are that are CE marked medical devices and registered with US Food and Drug Agency (FDA) and similar authorities around the world. Manufacturers of hearing aids.

The basis for the EVOTION Has is the Oticon OPN hearing aids. The Oticon OPN range of hearing aids became available in Spring 2016 and the range has been extended in the autumn of 2016. The products are CE marked and registered as medical devices with US Food and Drug Agency (FDA). This means that the mechanical design and the handling of the hearing aids is reliable and safe. From the EVOTION perspective there is special focus on if the EVOTION components interfere with the hearing aid security.

Looking at the hearing aids from the EVOTION platform point of view, the following sections describe the security relating to the EVOTION HAs.

The physical design of the EVOTION HAs is identical to the commercially available and CE marked Oticon OPN hearing aids. The initial fitting of the EVOTION HAs follow the standard procedure and use the audiogram to specify the amount of amplification. The self-adjustment in EVOTION is restricted within programs defined during the initial fitting to ensure that EVOTION patients cannot self-adjust into hazardous settings. The change of programs and change of volume is already standard features of hearing aids.

The embedded software of the EVOTION HAs extend commercially available Oticon OPN hearing aids released to market autumn 2016, in two ways

The embedded software of the EVOTION HAs extend commercially available Oticon OPN hearing aids released to market autumn 2016, in two ways:

1. A minor update of the embedded software enables the hearing aid to time stamped logging of HA use, volume changes, intentional and automatic program shifts, sound environment measures, and sound environment classifications over a paired Bluetooth connection. This modification will enable the EVOTION platform to identify patterns in the operation of the HAs. The frequency is one logging per minute or slower, and thus this logging will not enable restoration of the conversation around the hearing aids. The EVOTION hearing aids will not store additional internal data compared to the histograms in the commercial OTICON hearing aids. These histograms contain aggregated information about hours used, sound environments etc., and further each entry into the histograms is not logged with time.
2. Via the paired Bluetooth connection, the EVOTION mobile app will be able to adjust the default programs and default volume. This means that it can change which program the hearing aid starts

with, however, it cannot change the contents of that program. It can also change the start-up volume however not beyond the limits set at the fitting by the audiologist.

The Hearing Aids include a Bluetooth Low Energy interface to communicate with mobile apps and the Oticon the manufacture declares that the hearing aids are in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. The communication via Bluetooth Low Energy between the mobile app and hearing aids require prior pairing of the devices.

The Oticon ON the remote control app which is available for download already does enable the user to change programs and adjust volume from the remote control app.

The self-adjustment available to the participants is restricted within a range of standard programs. Thus, EVOTION patients will not be able to self-adjust into hazardous settings.

The Hearing Aid uses the following Low Energy core profiles and services.

1. *Generic Access Profile (GAP)*: GAP handles the procedures between two devices related to discovery and connecting (link and connection establishment) for the case where none of the two devices has any link established as well as the case where (at least) one device has a link established (possibly to a third device) before starting the described procedure.
2. *Generic Attribute Profile (GATT)*: The Generic Attribute Profile (GATT) defines a service framework using the Attribute Protocol. This framework defines procedures and formats of services and their characteristics. The procedures defined include discovering, reading, writing, notifying and indicating characteristics, as well as configuring the broadcast of characteristics.
3. *Battery Service 1.0 (BAS)*: BAS exposes the state of a battery within the device.
4. Device Information Service 1.1 (DIS): DIS exposes manufacturer and/or vendor information about a device.
5. *Proprietary Remote Control service*: This proprietary service exposes proprietary information to remotely control the volume and program shift via an App or a remote control.
6. Proprietary Fitting service: This proprietary service exposes proprietary information for fitting the Hearing Aid via the secure Bluetooth Low Energy connection.

The Hearing Aid GAP and GATT and Security Manager comply with the Bluetooth 4.0 specification

2.6.2.4. Data sources local network security

The communication between hearing aids and biosensors to the mobile phones and applications that will be used in EVOTION will be based on the Bluetooth standard [63][62]. Thus, the security of this communication will have as baseline the security mechanisms provided by Bluetooth. In the following, we provide an overview of these mechanisms, the threats which arise and the security levels that can be expected from it given the current state of the art.

2.6.2.4.1. Overview of Bluetooth

Hearing aids and sensor security refers to the security of the data communicated by these devices to the mobile application in the EVOTION architecture. These communications are based on the Bluetooth standard, i.e., an open standard for short-range radio frequency (RF) communication. Bluetooth enables the creation of ad hoc networks between different types of devices in close physical proximity (i.e., from 1 to 100 meters), which operate on the same channel and use the same frequency hopping sequence. Bluetooth networks are small wireless networks, known as “piconets”, which can be used to transfer voice and data.

Characteristic	Bluetooth BR/EDR		Bluetooth Low Energy	
	Prior to 4.1	4.1 onwards	Prior to 4.2	4.2 onwards
RF Physical Channels	79 channels with 1 MHz channel spacing		40 channels with 2 MHz channel spacing	
Discovery/Connect	Inquiry/Paging		Advertising	
Number of Piconet Slaves	7 (active)/255 (total)		Unlimited	
Device Address Privacy	None		Private device addressing available	
Max Data Rate	1–3 Mbps		1 Mbps via GFSK modulation	
Pairing Algorithm	Prior to 2.1: E21/E22/SAFER+ 2.1-4.0: P-192 Elliptic Curve, HMAC-SHA-256	P-256 Elliptic Curve, HMAC-SHA-256	AES-128	P-256 Elliptic Curve, AES-CMAC
Device Authentication Algorithm	E1/SAFER	HMAC-SHA-256	AES-CCM[9]	
Encryption Algorithm	E0/SAFER+	AES-CCM	AES-CCM	
Typical Range	30 meters		50 meters	
Max Output Power	100 mW (20 dBm)		10 mW (10 dBm)[10]	

Table 2: Bluetooth BR/EDR and LE features (taken from [83])

Bluetooth may operate in different modes. These have been introduced in order to strike a balance between the speed of data transmission (data rate) and energy consumption. The two prominent modes are: basic and enhanced data rate (BR/EDR) mode and low energy (LE) mode. Piconets operating in BR/EDR can have up to 7 active and 255 inactive slave Bluetooth devices, whilst piconets operating in LE mode can have an unlimited number of slave devices.

BR/EDR mode operating devices uses 79 different radio channels (1 MHz each) and change frequencies about 1600 times per second for data/voice links [83]. In BR/EDR channels are used for short periods (e.g., 625 microseconds for data/voice links). Channel changes (aka frequency hopping spread spectrum, or shortly FHSS) are determined pseudo-randomly. The purpose of using FHSS is to reduce communication interference in the frequency band used by Bluetooth. This band is overcrowded as several other communication technologies operate in it (e.g., the IEEE 802.11b/g standard. In LE mode devices operate in the same frequency rate as BR/EDR but use only 40 channels. Table 2, which has been taken from [83], summarizes the main features and differences between the BR/EDR and the LE modes.

2.6.2.4.2. Bluetooth security services

As described in [83], Bluetooth specifies the following five security services:

- *Authentication*, i.e., the service responsible for verifying the identity of communicating devices using the standard using their Bluetooth address.
- *Confidentiality*, i.e., the service responsible for ensuring confidentiality by guaranteeing that only authenticated and authorized devices can access and view the data transmitted in a Bluetooth communication.
- *Authorization*, i.e., the service responsible for authorizing a device before permitting it to control any other resource interacting with it by using Bluetooth.
- *Message Integrity*, i.e., the service responsible for verifying that a message transmitted between two Bluetooth devices cannot be modified, whilst it is in transit.
- *Pairing/Bonding*, i.e., the service responsible for creating shared secret keys and storing them for use in device communications.

A summary of the security mechanisms deployed for realizing these services is provided below. Our summary is based on [83] and the interested reader may refer to our source for a full account of the services.

2.6.2.4.3. Bluetooth security levels and mechanisms

Device authentication in Bluetooth can be link- or service-level. In link-level, authentication and encryption are initiated before the physical connection between the devices is completely established. In service-level, authentication and encryption are initiated after the Bluetooth physical link has already been fully established and logical channels partially established.

BR/EDR/HS devices may operate in four security modes, known as Security Mode 1, 2, 3 and 4. Security mode 1 is not secure as authentication and encryption required for confidentiality are never initiated. Security Mode 2 uses a service level authentication. This takes place after the establishment of physical connectivity and before the creation of logical communication channels. In this mode, devices rely on a centralized security manager, which maintains access control policies granting access only to selected device services/interfaces. Security mode 3 realizes link level authentication and requires that all connections to and from a device are authenticated and encrypted. Typically, however, after a device is authenticated, there is no further service-level authorization in Security Mode 3. Security mode 4 realizes service-level authentication that takes place after a physical and a logical communication link is established. Security Mode 4 uses Secure Simple Pairing (SSP), in which ECDH key agreement is utilized for link key generation. Security Mode 4 requires encryption for all services and is mandatory between Bluetooth 2.1 and later BR/EDR devices [83]. Within security mode 4, there is a distinction of 4 levels of security. These support backward compatibility and vary with regards to whether they require encryption in connections, the level of the authentication/encryption algorithms they use and the use of user interactions during device pairing. Level 4 is the strongest stipulating device authentication using the FIPS-approved Hash Message Authentication Code Secure Hash Algorithm 256-bit (HMAC-SHA-256) and encryption using the FIPS-approved AES-Counter with CBC-MAC (AES-CCM) algorithm, which also provides message integrity. Level 4 requires also user participation in device pairing and provides protection against man-in-the-middle (MITM) attacks. Next to it, in terms of security is level 3 which requires authenticated link keys and is the lowest security level recommended by NIST [83].

Essential to the authentication and encryption mechanisms provided by Bluetooth is the generation of a secret symmetric key. In Bluetooth BR/EDR this key is called the Link Key and in Bluetooth low energy this key is called the Long Term Key. In older LE pairing, a Short Term Key is generated, which is used to distribute the Slave and/or Master Long Term Key, while in low energy Secure Connections, the Long Term Key is generated by each device and not distributed.

In Bluetooth 4.1 and 4.2, LE mode devices operate as BR/EDR/HS devices with a few differences. One of those relates to keys. In LE devices, pairing requires the generation of a Long-Term Key (LTK) rather than a Link Key (LK). LTK and LK function similarly but are established in different ways. More specifically, in LE pairing, one device determines the LTK and securely sends it over to the other device, instead of both devices generating the same key individually. LE security modes are also similar to BR/EDR service-level security modes (i.e., Security Modes 2 and 4) in that each service can have its own security requirements. However, in LE each service request can have its own security requirements as well. LE may operate in two security modes. The first mode (LE Security Mode 1) has multiple levels depending on encryption. Level 1 requires no authentication and encryption. Level 2 uses unauthenticated pairing with encryption. Level 3 uses authenticated pairing with encryption. Level 4 which requires authenticated low energy Secure Connections pairing with encryption. LE Security Mode 2 has two levels depending on data signing. These are: Level 1 which uses unauthenticated pairing with data signing, and Level 2 which uses authenticated pairing with data

signing. Finally, it should be noted that In LE, if a particular service request and the associated service have different security modes and/or levels, the stronger security conditions prevail [83].

LE uses AES-CCM to provide confidentiality and packet authentication and integrity. However, it does make deploy any separate authentication challenge/response step to verify that both communicating devices have the same key as BR/EDR/HS devices.

2.6.2.4.4. Overall recommendation and risks

As suggested in [83], for BR/EDR, and High Speed (HS), Security Mode 4, Level 4 is the strongest because it requires secure connections, using authenticated pairing and encryption based on 128-bit strength keys generated using FIPS-approved Advanced Encryption Standard (AES). For Bluetooth 2.1 through 4.0 devices, Security Mode 4, Level 3 is the most secure. For Bluetooth 2.0 and older devices Security Mode 3 is recommended [83]. Security Modes 2 and 4 can also use authentication and encryption, but do not initiate them until after the Bluetooth physical link has already been fully established and logical channels partially established. Security Mode 1 devices never initiate security and therefore should never be used. In summary, devices supporting Bluetooth version 2.1 and above must operate in security mode 4 when connecting with other devices supporting the same range of protocol versions, and in security mode 3 when connecting to devices supporting Bluetooth version 2.0 or lower. Within security mode 4, connections between devices supporting Bluetooth version 4.1 and above should operate in Level 4 [83]. All other connections (i.e., connections involving one device supporting Bluetooth version 2.1 to version 4.0 should operate in at least level 3 [83]. Lower security modes should be avoided for BR/EDR/HS devices.

In the case of LE devices, Security Mode 1 Level 4 is the strongest mode because it requires authenticated low energy secure connections pairing with Elliptic Curve Diffie-Hellman (ECDH) based encryption. Security Mode 1 Level 3 requires authenticated pairing and encryption. However, it does not use ECDH, and thus it does not offer eavesdropping protection. Other security modes/levels allow unauthenticated pairing (meaning no man-in-the-middle protection is provided during cryptographic key establishment), and some do not require any security at all. Hence, NIST recommends Security Mode 1 Level 4 as the most secure modes/level and recommends its use for all LE connections between devices supporting Bluetooth 4.2 [83]. For 4.0 and 4.1 LE connections, NIST strongly recommends using Security Mode 1 Level 3 as it requires authenticated pairing and encryption [83].

Despite the use of specific security mechanisms, the use of Bluetooth entails certain remaining security threats. Even in the case of 4.1. and 4.2 devices, which operate at the highest recommended security modes and levels, there can be security vulnerabilities, which have identified as follows:

- The Just Works association model does not provide MITM protection during pairing.
- SSP ECDH key pairs may be static or may have been generated by weak methods.
- Static SSP passkeys facilitate man-in-the-middle attacks.
- Security Mode 4 devices (i.e., 2.1 or later) may operate in reduce security mode when interacting with devices supporting lower security modes (i.e., devices 2.0 and earlier).
- Repeatable attempts for authentication must be limited in number and be allowed only with some time intervals between them.
- LE privacy may be compromised if the Bluetooth address is captured and associated with a particular user.
- LE legacy pairing provides no passive eavesdropping protection.
- Le Security Mode 1 Level 1 does not require any security mechanisms (i.e., no authentication or encryption).

- Link keys might be stored improperly.
- If weak, Random Number Generation may produce static or periodic numbers that may reduce the effectiveness of the security mechanisms.

EVOTION will need to address these vulnerabilities in designing and implementing its platform. Furthermore, it will take additional non-operational security measures. These have been identified using the Bluetooth security checklist recommended by NIST [83].

2.6.3. Big Data Analytics Platform Security

2.6.3.1. Infrastructure security

Potential breaches of BDA platform security at the level of infrastructure stem from two main sources: (a) the use of multi-tenancy at the infrastructure level, i.e., the use of a single infrastructure for hosting distinct applications, and (b) the network that is used to connect data sources to infrastructure, the computer clusters that constitute the infrastructure, and the individual nodes (computers) within these clusters. In the following, we provide an overview of the security issues and solutions related to these two sources, grouped by the security property that they are primarily related to.

2.6.3.1.1. Confidentiality

Breaches of confidentiality at the infrastructure layer arise primarily in cases where the infrastructure supports multitenancy. In multi-tenancy, an infrastructure typically hosts distinct applications running as different virtual machines (VMs) upon it. A VM embedding malicious code may attack other VMs. These are known as cross-VM attacks or VM-hoping and can result in data steals from the target VM that breach confidentiality. Such attacks may be launched in different ways including, for example, passive VM communication observation, observing VMs CPU usage, exploiting VM relocation within and across clusters and exploiting hardware interrupts and/or VM resetting. [71] have provided a comprehensive survey of VM attacks and pointed out possible remedies. The latter are based on mechanisms offering strong VM isolation and runtime VM monitoring We expect that such attacks won't be relevant to the EVOTION platform as there will be no multi-tenancy on the infrastructure that will be used to deploy it.

Breaches of confidentiality may also occur at the network level. Using strong encryption and authentication like Kerberos [80] for mutual authentication between networked processes is the recommended practice against this risk.

2.6.3.1.2. Integrity

Integrity needs to be ensured across all nodes of an infrastructure cluster and in communications between the infrastructure and external data sources. For this, besides strong authentication, it is also recommended to deploy trusted platform modules (TPM) in which the integrity of the relevant processes can be verified through hardware produced measures [67]. Also, deploying data retention and backup policies at the infrastructure level and

2.6.3.1.3. Availability

Availability is one of the main threat areas for BDA platforms at the infrastructure level. Slowing or ceasing BDA services at the infrastructure level may be the result of denial-of-service attacks on the infrastructure itself, on co-tenant applications (in case that multitenancy is allowed) or the network that connects the nodes of the infrastructure and/or the infrastructure with external data sources. Availability attacks may be caused through memory corruption (by malware or cross VM attacks); memory exhaustion; blocking, delaying or replicating communications over the infrastructure connectivity networks; overloading any of the tenant applications of the infrastructure with an extreme load of service requests aka "flooding attacks" [71].

Distributed denial-of-service attacks are also common and may be caused by botnets sending millions of TCP messages to the target server.

The main defense mechanism against availability attacks is communication traffic monitoring and control. This can be both at the level of the network (i.e., monitoring network traffic) and at the level of the infrastructure clusters. Traditionally, network firewalls have been used to filter out incoming and outgoing traffic by protocol, service port, and/or IP address. Additional security mechanisms deployed at the network level can include Intrusion Detection and Prevention Systems [66] [79]. Additional security mechanisms that may be used at the network or the infrastructure cluster level include honeypots [59], placed with the purpose of attracting attacks and learn their behavior; antivirus malware and botnet detectors [85]; [78], and infrastructure resource and application execution monitors [75].

2.6.3.1.4. Privacy

Breaches of privacy at the infrastructure level can occur due to the same reasons that can cause confidentiality breaches. If privacy, however, is addressed adequately at the layers of data storage (see Sect. 2.6.3.2.4) and big data analytic processes (see Sect. 2.6.3.3.3), then privacy breaches will not be a concern at this level.

2.6.3.2. Data storage and management security

2.6.3.2.1. Confidentiality

Data confidentiality can be supported by the encryption of data-at-rest and in-transit within the BDA infrastructure. Effective support for confidentiality requires also strong authentication and authorisation mechanisms, ensuring the security of user credentials, and the application of effective access control policies. Authentication and authorisation at the data storage and management layer is typically based on digital certificates that convey authentication information about a user and/or a process. These are typically the same certificates as those used at the presentation layer and have been generated as discussed in Sect. 2.6.3.3.4. The use of encryption in big data analytic platforms is faced with specific challenges related to maintaining performance and scalability, and protecting not only files and disks, but also of logical and physical data fragments. Some ad hoc industrial solutions to data encryption and key management tools are available for such purposes (e.g., Gazzang's key management solution). It should be noted, however, encrypted data are not generally amenable to big data analytic processes. Hence, the application of such processes can either be restricted to (non-encrypted) meta data summarizing or describing the data or will require that data are decrypted before any processing takes place.

2.6.3.2.2. Integrity

Encryption, authorization and authentication and access control mechanisms, along with mechanisms supporting the atomicity, consistency, isolation and durability (ACID) of data insertion, querying and updating transactions can provide effective support for data integrity [71], in settings where the underlying computational infrastructure does not support multi tenancy (as we expect in the case of EVOTION). Such mechanisms provide the basis for performing operation level same access control checks for each operation that is accessed at this layer, even if similar checks have been performed at the presentation layer [82]; see also Sect. 2.6.3.4.2. A good rule of thumb for ensuring this is to check the call tree of all operations that are accessible at the presentation layer have adequate authorization checks implemented at this layer as well.

Data integrity at this layer requires also mechanisms preventing injection attacks. Injection attacks occur when an application sends data querying and/or modification instructions hidden within data values passed

for operation parameters of the normal API that is available from a data server (e.g., injection SQL, NoSQL and Xpath queries). Whilst injection instructions are relatively easy to discover when inspecting the code hidden in data parameters, they are hard to discover via testing. The most effective way to mitigate injection attacks is to use safe APIs which formulate the instructions that they send data server interpreters internally rather than passing input parameter values to them directly.

2.6.3.2.3. Availability

Availability at the data storage and management layer may be affected by slow performance due to infrastructure overloading, data server failures, lack of data backups or insufficient data recovery services. The availability problems originating from this layer are less likely than those originating from other layers, especially when state of the art data management platforms are used, and heuristic rules regarding data back-ups are applied (e.g., daily back-ups, complementary off-site storage, 3-2-1 back-up rule [71]).

2.6.3.2.4. Privacy

In stored data, personally identifiable information (PII) for the subject of the data can be masked or removed from it. Since privacy may also be compromised due to quasi-identifiers, i.e., data items that may depending on the exact data set uniquely identify a data subject, such as the zip code of a subject or almost unique physiological information about it), techniques like k-anonymity [86] may be applied to reduce the risk of implicit identification.

2.6.3.3. Big data analytic processes security

BDA processes are typically implemented in distributed programming frameworks (BDA frameworks) such as Apache Hadoop and Spark. These frameworks are based on cycles of massively parallel data computations and transformations. The computational processes of such frameworks can be distinguished into “master” and “worker” processes and into “compute” and “aggregation” processes. In the former distinction, delegate computational tasks on partial data sets to processes of the latter types and use the outcomes of the latter processes to produce their final outcomes or ensure data and service resilience and reliability. In the latter distinction, compute processes perform computations upon data sets and aggregation processes combine the outcomes of compute processes.

2.6.3.3.1. Confidentiality

Maintaining data confidentiality in BDA processes is an open challenge [68]. This is because although there is significant ongoing research on techniques supporting searching and reporting on encrypted data in a manner that guarantee that any information about the data that is not deducible from the search criteria can remain hidden, like functional encryption [83] and homomorphic encryption [73], such techniques cannot support practical – in terms of generality, efficiency and scalability – searches on big data.

2.6.3.3.2. Integrity

Integrity needs to be ensured across all processes involved in BDA computations. For this, the networked processes need to be mutually authenticated. And, as n the case of cluster nodes, trusted platform modules (TPM) can be used to verify process integrity [67]. Data integrity may be further enhanced through security-tagging in which mark every tuple arriving on a specified data source is tagged with a tamper proof security tag identifying its producer and the time of production.

2.6.3.3.3. Availability

Availability breaches are unlikely to have their origin at the BDA process level, as much of the research on BDA programming frameworks focuses and addresses effectively performance and scalability issues (through the optimized initial allocation and dynamic re-allocation of BDA processes and data across infrastructure

cluster nodes and clusters). Hence, availability protection mechanisms need to be deployed at the network and infrastructure layer (see Sect. 2.6.3.1.3).

2.6.3.3.4. Privacy

In addition to preserving anonymity of data at rest (see Sect.2.6.3.2.4), differential privacy [69] may be used to minimize the chances of identifying individuals through the outcomes of BDA processing whilst maximizing the accuracy of such outcomes.

2.6.3.4. Presentation layer security

Whether accessible through an end user interface or an application programming interface (APIs), ensuring security at the presentation level of a big data analytic platform is often the hardest objective to achieve due to the range of security threats that may affect this layer. As discussed in [68], threats like information leakage due to human error, insecure APIs; eavesdropping, Interception and hijacking; identity fraud; denial of service attacks; injections and other malicious code attacks; misuse of audit processes; abuse of authorizations; and skill shortages can affect the security of data. The mechanisms that are available to mitigate risks at this layer are discussed in the following.

2.6.3.4.1. Confidentiality

As in the case of the data management layer, confidentiality at the presentation layer can be realized using encryption of data in-transit from mobile applications to this layer and from this layer to the bid data analytic and data store layers, and strong authentication and authorisation mechanisms.

Authentication at the presentation layer may be performed using user, process, and/or device credentials or combinations of all of them. At this level, authentication is more likely to need to be based on passwords and electronic certificates carrying authentication information rather than biometric information or smart cards. Certificates are issued by a public certification authority that is trusted (e.g., a public key infrastructure (PKI)) can be used for enforcing access control at this layer [88]. An example such certificates are X.509 certificates which are generated by a PKI and include the public key of an entity, a distinct domain name bound to it and additional information regarding, for example, the cryptographic operations that may be performed using the public key, constraints for validating the certificate etc. More generally, attribute certificates like X.509 ones, are signed by certification authorities (CAs) and contain attribute–value pairs about the subject to whom they apply. Such certificates can be applied for attribute based access control schemes, in which access decisions are based on the attributes of requesters, resources, and the environment [88]. Such schemes provide the flexibility and scalability that are necessary in distributed systems such as the EVOTION platform.

Despite the wide adoption of certificate based access control, such schemes are not immune to attacks. As [68] point out, the generation of rogue certificates is a threat cutting across all layers of a big data analytics platform and needs to be mitigated by: the use of strong hashing functions (e.g., SHA-256 or SHA-512) for signing certificates, and “whitelisting” certification authorities and accepting certificates of only reputable ones. Additional weaknesses in presentation layer authentication are also introduced by custom made authentication and session management schemes [82] having vulnerabilities related to session IDs (e.g., session ID exposure to URL, absence of session ID timeouts, improper invalidation of session tokens etc.).

Confidentiality at the presentation layer may also be compromised by cross site scripting (XSS) attacks [82]. XSS attacks occur when malicious script, i.e., a code script that the browser through which a web accessible platform is accessed can execute, is included in dynamic content that is sent to a web user without being sanitized. Such scripts can compromise confidentiality by transmitting user data (e.g., cookies, session IDs or other session information), to the attacker, redirecting the user to a web site controlled by the attacker, or

performing other malicious operations on the attacked user's machine. XSS can be mitigated using sanitization [71] and content security policies at the browser level.

2.6.3.4.2. Integrity

To ensure integrity, operation level access rights need to be verified before making that functionality visible in the UI. Furthermore, direct references to restricted resources need to be avoided or checks of user authorization rights for the directly referenced resource need to be performed [82].

Also, as pointed out in [82], data integrity at this layer requires mechanisms preventing injection, cross site scripting attacks, and cross site request forgery (CSRF) attacks. Injection attacks and mitigation mechanisms are similar to those discussed in Sect. 2.6.3.2.2. In addition to injection attacks targeted to data servers, it should be noted that executable injection commands may also target other platform components such as the operating system; XML parsers, other middleware etc. Designing and implementing an injection safe API is the best defence against such attacks. CSRF attacks are illegitimate data and/or operation requests that cannot be distinguished from legitimate ones. Such requests may be generated by including in them security tokens (e.g., session cookies) that are sent automatically by browsers. CSRF attacks can be prevented by code penetration testing and requiring users to prove their intention to submit the request, through re-authentication, or some other CAPTCHA test [82].

2.6.3.4.3. Availability

Availability compromises at the presentation layer are typically due to network, infrastructure (aka server), data access or data analytic failures (see Sect. 2.6.3.1and 2.6.3.2, respectively), rather than issues arising at this layer. Hence, the existence of appropriate availability mechanisms of those layers that have been discussed earlier can mitigate such risks.

2.7. Predictive Models of TTS

So far there exists no suitable method to predict individual vulnerability to TTS, as PTS following noise exposure. Previous attempts to predict noise susceptibility of the inner ear have largely failed. In the 1970s, a dip between 4 and 5 kHz in the audiogram after acute noise exposure was observed that was independent of exposure frequency but occurred particularly if exposure was at low frequencies. It was recently speculated that the magnitude of this TTS dip may predict PTS [128]. Recently, a novel non-invasive model for assessing risk of NIHL has been developed which uses data from a psychoacoustic noise dosimeter (PND) intended for real-time use [125][126][127][129]. The method takes into account the excitation of the basilar membrane occurring in the inner ear, has provisions for impulse noise using time constants for the acoustic reflex, and includes the metabolic and structural components of asymptotic threshold shift (ATS) to predict TTS due to presence of a specific noise. Based on the measurements of the instantaneous sound pressure levels, the psychoacoustic noise dosimeter enables determining, in real time, the TTS values in the critical bands, the time elapsing till the specified hearing threshold occurs, and the time necessary to restore the initial value of hearing threshold. [129] have further developed the initial model by Czyzewski et al to account for spectral and temporal characteristics of the noise exposure and allow integration with personal media players. The aforesaid models of TTS was developed and validated in young subjects with normal hearing.
For populations such as hearing aids users with preexisting sensorineural hearing loss, a specific model has been proposed [124]. This model assumes that TTS produced by a given noise exposure decreases as a function of the degree of pre-existing hearing loss. Thus, the amount of TTS in HA users, could be predicted from the in-ear noise levels and the subject's hearing levels (HLs) by means of a mathematical model

consisting of the Modified Power Law (MPL) of [122] combined with equations for predicting TTS in listeners with normal hearing published by [123]."

2.7.1. Progress beyond the State of the Art and EVOTION innovation:

EVOTION will apply the above models to determine the expected TTS due to episodes of exposure to specific noise, but use the HA rather than a media player for audio acquisition. Furthermore, actual TTS will be verified by HA's user through self-assessment of audiometric tests results (audiometric threshold shift at 4 kHz, and impairment of intelligibility of speech in noise). This will allow for the personalized short-term threshold shift risk management, and eventually HA adjustment. The improved model to be used in EVOTION is presented in detail in Figure 3 in section 1.3 (Concept and Approach). For long-term risk management, EVOTION will also track the development of HL compared to the baseline audiogram. In particular, the personalized rate of the PTS changes over years (e.g. prevalence of significant threshold shift) (Rabinowitz et al.) will be analysed in comparison with the expected rates for the reference populations (equivalent according to age, gender and other factors, e.g. noise exposure). The comparison of individual rates of HL with expected values will allow to assess whether the patient's hearing deteriorate faster or slower than could be predicted based on the existing computational prediction models.

2.8. Auditory Training

Auditory training (AT) involves listening exercises that are designed to improve the function of auditory system. Repeatedly doing the listening exercises enables a reorganisation (remapping) of the brain's neurons that capitalising on the brain's plasticity [102]. This cortical reorganisation of the auditory brain is driven by the auditory stimulation, which is thought to activate of inactive neuronal connections and/or trigger formation of new and more efficient synaptic connections [102] [91]. This reorganization of the auditory neural substrates is reflected on changes in neuroimaging and neurophysiologic indices and transfers in auditory/language test results [98] and improved listening behaviors [97].

The rationale behind auditory training is the expectation that a successfully learned auditory behaviour/skill within the training will be repeated and applied in a real life context and in situations different to that of the training paradigm. This is termed as transfer of training, or generalization. Generalization of learning can only occur if the neural circuits modified during training also influence the untrained task performance [100]. In general, auditory training tasks aims to train several abilities simultaneously such as linguistic, cognitive, and perceptual skills. The characteristics of the trained tasks influence the transfer and specificity of learning [115], and most AT regimes include more than one training tasks. The training dosage also affects AT outcome., delivered auditory training for and discussed if this length was sufficient to observe learning transfer, given that previous research reported successful generalisation of learning is reported after training of more than 10 hr [96] [116]) but not after 9hr ([101] - non-linguistic auditory training) or 6 hr [94]. It has also been proposed that combined auditory-cognitive training which targets enhancement of cognitive resources within the auditory task such as auditory scene monitoring, attention switching, and working memory, would be more effective as well as relevant to the needs of hearing impaired listeners in order to improve their listening skills in real life situations that are challenging to listening [93]. Additional key attributes of computer based programs in line with well accepted requirements for efficient and effective auditory training [90] are that these allow for precise control of the training stimulus, they facilitate adaptive training and thus provision of training at an appropriate training level for the individual, while they also establish standardisation of training. *Table 3* summarises key aspects and requirements for successful AT.

Auditory training principles	Description
Training material	The training material should be appropriate for the subject's language and cognitive resources.
Motivation	The subject should be motivated and willing to perform the AT tasks. To this end, understanding of the rationale and need for AT is essential.
Number, content and variety of AT tasks	Several different training tasks and stimuli should be used to ensure learning transfer, prevent boredom and enhance motivation; combined auditory/cognitive tasks should be incorporated; ideally topics of interest to the subject should be included in the AT programme.
Progression of AT tasks	The tasks should be presented systematically, progressively and adapted to the subject's performace so that the subject works "on the edge of competence". The task needs to be sufficiently challenging to elicit optimal change in the auditory system, but not excessively difficult. A success/failure criterion ratio of 7:3 before changing the level of task difficulty has been recommended [91] suggested.
AT time and dosage time	Sufficient therapy time with realistic goals should be allocated. A minimum of 10 hours in total over 6 - 8 weeks will successfully induce change or improvement in functional abilities.
Monitoring and feedback	Monitoring of the subject's progress, provision of feedback and reinforcement will allow the subject to monitor their progress nd promote their engagement. The clinician will also gain insight into the appropriateness of the AT programme with close monitoring and periodic evaluation of the subject's progress.

Table 3: Key auditory training principles and requirements (based on [102])

The training material in existing CBAT programmes includes predominantly speech material (such as phonemes, syllables, words as well as sentences) as well as non-speech sounds. CBAT targets both bottom-up sensory processing, ie "analytic training" and top-down linguistic and other higher order functions, i.e. "synthetic training" [108]. Table 4 provides information on the major CBAT evidenced based existing programmes in addition to apps and internet/computer based AT programmes available for HI listeners for which there us at least empirical evidence or some evidence based studies (reviewed in Olson 2015).

CBAT for children	Description
FastForWord (Scientific Learning Corporation, USA)	An adaptive intervention programme that employs acoustically modified non-speech and speech sounds (e.g. elongated tones, slower rate speech sounds) and is designed to train temporal processing, speech perception, and language comprehension skills.
Earobics (Houghton Mifflin Harcourt)	The activities aim to improve sound awareness, discrimination of sound in noise and quiet, sequencing sound, associating sound with letters, understanding of complex directions with and without background noise, and memory for sounds and words, and include

	items to strengthen reading, spelling, and comprehension.
LisN & Learn (NAL, Australia)	Aims to improve listening in noise for children diagnosed with spatial processing disorder (SPD). It involves word identification from a target sentence that appears to emanate from 0° azimuth while background noise (looped children's stories) comes from either + or - 90° simultaneously. The background noise can be in the same or different voice to the target sentence voice.
Adult AT	

''Listening and Communication Enhancement'' – LACE (Neuroton)	This is marketed as top down intervention for speech in noise difficulties and includes
	• Degraded Speech Tasks
	  ○ Speech in Noise
	  ○ Rapid Speech
	  ○ Competing Speakers
	• Cognitive Tasks
	  ○ Missing Word
	  ○ Word Memory
	• Interactive Communication Strategies
	  ○ Screens that include Helpful Hints and strategies for coping with hearing loss and difficult listening situations

Brain Fitness Program for auditory processing (Posit Science)	This includes six adaptive exercises, which aim to enhance the fidelity in auditory sensory input and language representations. Specifically designed for older adults. • ''High or Low'': identification of sequence of (upward or downward) frequency modulated sweeps. • ''Tell Us Apart'': identify a syllable (e.g.,_ba_) from a pair (e.g.,_ba_vs._da_). • ''Match It'': match short spoken rhyming consonant–vowel–consonant words (e.g., bad, dad) from a spatial grid. • ''Sound Replay'': reconstruct a sequence of short spoken words (identical to the third exercise stimuli). ''Listen and Do'': reconstruct a spoken series of instructions by using the computer mouse to click and drag icons on the computer screen.

	• "Story Teller": answer questions regarding short narratives.
Apps for AT for HI users (from Olson 2015)	
HearCoach, Starkey Laboratories	Words in quiet/different types noise, cognitive and auditory training
i-Angel sound, University of California	Environmental sounds, music, phonemes, monosyllabic words (2000 stimuli)
AB Clix, advanced bionics	Words and words in sentences (2300 words)
British English Vowel Training, Paul Iverson UCL	Aims to improve vowel perception; words
Computer programme: Read my Quips, Harry Levitt/Sense Synergy	Sentences/quips from witting sayings in quiet or noise

Table 4: Main CBAT programmes for children with auditory processing disorders (APD) and for adults with APD and/or with hearing impairment (HI)

There is a number of studies assessing efficacy of auditory training for adult listeners. Healthy young adults as well as older adults with normal hearing improved in terms of speech in noise test performance and auditory memory test performance after computer based auditory training (CBAT) that aimed to provide both analytic and synthetic training and that incorporated several training exercises [106][99]. The speech in noise training improvements correlated with improved sensory encoding, indicating that a bottom up mechanism drove the brain's plasticity, partly at least [106]. There is also indication that improvements from CBAT may generalise to untrained everyday problem solving that is underpinned by increased white matter integrity in attention serving neural substrates [107] [117]. Cognitive benefits of AT are of particular interest for the hearing impaired listeners since HA users depend more on their cognitive resources than normal hearing listeners in order to understand speech [118], and thus experience mental fatigue that is not wholly alleviated by the use of sophisticated current HAs [119]. Therefore, it would make sense that AT aiming to improve both the sensory representation of speech and the cognitive resources allocated to speech perception would make listening less effortful and more accurate in hearing impaired listeners. Hearing impaired adults show improvements in a range of indices after AT. An initial meta-analysis of CBAT for hearing impaired adults indicated that speech recognition in noise was improved by synthetic training [108], while a more recent meta-analysis similarly reported CBAT related improvement in speech intelligibility tests with untrained speech material, in cognitive and in self-reported hearing measures [95]. Of interest, new hearing aid users appear to derive greater benefit by CBAT compared to experienced HA users, indicating that such training should be initiated as soon as a hearing aid is fitted [103].

2.8.1. Progress beyond the State of the Art and EVOTION innovation:

While CBAT facilitates standardization of auditory training, Key disadvantages of current AT programs are that they relatively rigid and not sufficiently personalized to specific deficits of individual HL patients. A key AT good principle is that training should be individualized, depending on the specific deficits of the individual [90]. Existing studies indicate that although training benefits on untrained skills generalise, improvements may not generalize to untrained stimuli or to untrained tasks ([120] [121]). Also there is evidence that the needs of listeners depend on the type of their hearing/listening and potentially related cognitive impairments [89], indicating that the needs of listeners will depend on the type of the hearing/listening and potentially related cognitive impairments. Outcomes of AT vary highly for hearing impaired listeners [95]. It is possible that in this group, the combined effects of peripheral hearing loss and impaired auditory processing need to be addressed by different types of auditory training for the listener to derive maximal benefit by such interventions.

EVOTION will go beyond state of the art in this respect, in that it will continually monitor specific listening situations in which the user experiences difficulties in order to define the difficulties experienced and thus the type of training that would be most appropriate for the listener. Such AT may include:

- phoneme discrimination training for individuals missing beginning or ending of words,
- auditory directives/story in noise or digit span training for those with difficulties with auditory memory, (note: consider Simon says)
- training with two separate concurrent speakers at different locations (spatial processing deficit)
- training in a background of speech in cafeteria or other type noise for those experiencing difficulties in these situations, for words/sentences
- sound in words/word in sentence training to find the odd one out for those with impaired selective attention (e.g. they don't respond to their name unless called several times) or with sustained auditory attention deficits(e.g., they lose concentration very quickly during a conversation)

The EVOTION platform will collect information that will enable deficit specific interventions, progress tracking and compliance (all identified as elements for effective for AT [92]), and their evaluation as determined by real life performance. As CBAT is going to be provided by a Hearing Aid device and a mobile application that will be available to the user round the clock and a log will be kept of training performance and progress tracking, compliance with such training, which is a key factor for CBAT benefits is expected to be improved [92]. Early start of the CBAT after fitting of the EVOTION device will be facilitated, thus securing maximum benefits from such training. It is also anticipated that continuous monitoring of user experienced hearing/listening difficulties and CBAT progress tracking will help further define user auditory needs as well as his/her cognitive profile, and thus enable early identification of cognitive decline.

3. Related Data Security and Privacy Regulations

The EVOTION project extensively relies on personal data and shall therefore carefully consider the related requirements for data protection. Although at the beginning of the project (November 2016) the main applicable legal instrument is the EU Data Protection Directive 95/46/EC [109], as implemented in all Member States, it should be considered that the General Data Protection Regulation (GDPR) [110] will replace the Directive starting from 25 May 2018 and will be immediately applied to all Member States. It is, therefore, convenient to anticipate the application of the GDPR, adopting the new requirements for the EVOTION project.

3.1. Regulation Vs. Directive

While the objectives and principles of Directive 95/46/EC remain sound, its application and implementation in Member States has introduced relevant differences in the level of protection of natural persons (only natural persons' data are subject to the GDPR[13]) and provoked fragmentation in the implementation of data protection across the Union. This also lead to legal uncertainty and general lack of confidence in the public opinion about the effectiveness of personal data protection in the Union.

The instrument of the Regulation seeks to ensure a consistent and high level of protection of natural persons and to remove the obstacles to flows of personal data within the Union. With the application of the GDPR, the level of protection of the rights and freedoms of natural persons with regard to the processing of such data will be equivalent in all Member States.

With regard to the EVOTION project, this means that with the application of the GDPR, the legal framework for personal data protection will be the same for all partners, no more dependencies from national specific implementations and adoption procedures like for a Directive. It possibly remains to clarify the status of UK members after Brexit, the specific legal framework for personal data in UK and the legal framework for data flow among UK and the EU.

3.2. Personal Data Protection and Technology

The GDPR recognizes that rapid technological developments and globalisation have brought new challenges for the protection of personal data. The scale of the collection and sharing of personal data has increased significantly and both private companies and public authorities make use of personal data on an unprecedented scale in order to pursue their activities. Natural persons increasingly make personal information available publicly and globally. Those developments require a strong and more coherent data protection framework in the Union, backed by strong enforcement, given the importance of creating the trust that will allow the digital economy to develop across the internal market.

One fundamental assumption that the GDPR seeks to enforce is that natural persons should have control of their own personal data. and that such control must be made effectively comprehensible and available to natural persons.

[13] Recital 14 of the GDPR reads as follow: «The protection afforded by this Regulation should apply to natural persons, whatever their nationality or place of residence, in relation to the processing of their personal data. This Regulation does not cover the processing of personal data which concerns legal persons and in particular undertakings established as legal persons, including the name and the form of the legal person and the contact details of the legal person.»

The GDPR does not explicitly mention Big Data and analytics, one of the key issue of EVOTION. To this purpose, however, the European Data Protection Supervisor (EDPS) has produced formal Opinions during year 2015 and 2016, whose main points we will summarize in the following.

3.3. Definitions

Article 4 of the GDPR lists the main definitions:

3.3.1. Personal data and Identifiable natural person

Personal data means any information relating to an identified or identifiable natural person ('data subject'); an *identifiable natural person* is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

With respect to EVOTION, all real-time data collected from earing devices, smartphones and fitness sensors should be considered as personal data subject to the GDPR. The legal status of retrospective data is to be establish, by considering the difficulty/impossibility of collecting persons' consent. Anonymity should be enforced.

3.3.2. Processing

Processing means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

3.3.3. Profiling

Profiling means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.

With respect to EVOTION, it is not among the project's goals to profile single individuals through collected data, for instance for predicting their future behaviours or medical conditions, as well as to assume decisions influencing them based on the results of certain analytics. It is, however, a duty of the project to guarantee that no natural person profiling will be performed or made available as a side-effect of its activity to inform public health policy makers.

3.3.4. Pseudonymisation

Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

In EVOTION, we should guarantee pseudonymization of patients' data with organizational and technical measures applied to additional information (e.g., appropriate design of storage architecture, cryptographic means, and so on).

3.3.5. Controller

Controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

The EVOTION consortium act as controller with respect to patients' data.

3.3.6. Processor

Processor means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

EVOTION members processing patients' personal data act as Processors with respect to those data.

3.3.7. Recipient

Recipient means a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing.

Specific EVOTION member or members to which personal data are disclosed act as Recipients with respect to those data. It must be carefully analysed whether or not medical personnel and policy makers interacting with the EVOTION Big Data platform are able to disclose personal data.

3.3.8. Consent

Consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

Patients involved in EVOTION data collection must express their consent, according to the rules defined by the GDPR and retain all the rights that the GDPR attributes to them with regard to the consent, consent validity, the integrity of personal data, and data processing.

3.4. Principles

Article 5 of the GDPR establishes the fundamental principles relating to the processing of personal data.

Lawfulness, fairness and transparency - Personal data should be processed lawfully, fairly and in a transparent manner in relation to the data subject.

Purpose limitation - Personal data should be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.

Data minimisation - Personal data should be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed.

Accuracy - Personal data should be accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay.

Storage limitation - Personal data should be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed

Integrity and confidentiality - Personal data should be processed in a manner that ensures appropriate security, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

3.5. Lawfulness of processing and Conditions for consent

Article 6 and 7 of the GDPR define the conditions for a lawful processing of personal data and, whether the lawfulness is based on consent, the conditions required for a valid consent.

Among the conditions for the lawfulness of processing, the first one applies to EVOTION and it reads as:

the data subject has given consent to the processing of his or her personal data for one or more specific purposes.

Other conditions, not applicable to EVOTION, rely on the presence of contractual or legal obligations, vital interests of data subject or public interests.

Gathering the data subjects' consent is a fundamental step for EVOTION and it must comply with Article 7 of the GDPR establishing that:

1) *the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data*.

2) *If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language*.

3) *The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.*

4) *When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract*.

Therefore, the EVOTION consortium should define a clear, and possibly uniform among members, procedure for collecting data subjects' consent and a procedure (centralized or distributed is to be defined) to record consent expressions. The consent should be formulated clearly and, most important for operational issues, it must be as easy to withdraw as to give for data subjects. *The same solution deployed for collecting consent should be deployed for withdrawing it at data subjects will*. Data subjects must be fully informed about their right to withdraw the consent.

3.6. Data concerning health

Article 9 of the GDPR is specifically dedicated to special categories of personal data. Data concerning health are among those categories and are key for EVOTION. For those special categories of personal data, the GDPR imposes stricter requirements and also let member states introduce specific regulations.

Processing special categories of personal data is, in general, **prohibited**, unless at least one condition is met. The first condition, fundamental for EVOTION, requires that *the data subject has given explicit consent to the processing of those personal data for one or more specified purposes*. It is therefore of vital importance, lest the legal prohibition to process health data, to acquire data subjects' consent according to Article 7.

A different condition allowing the processing of health data is somehow related with EVOTION. In this case is required that *processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services.* This is not yet the case for EVOTION, whose aim is to design and develop a prototype system based on big data to inform public health policy decision makers (therefore, we must stick on consent), but it might be fundamental for a prospective application of the EVOTION approach to a general population of patients or citizens.

3.7. Information and access to personal data

For personal data acquired from data subjects, the controller shall, at the time when personal data are obtained, provide the data subject with all of the following information:

1) the *identity* and the *contact* details of the controller and, where applicable, of the controller's representative;
2) the contact details of the *data protection officer*[14], where applicable;
3) the *purposes of the processing* for which the personal data are intended as well as *the legal basis* for the processing;
4) the *legitimate interests* pursued by the controller
5) the *recipients* or categories of recipients of the personal data, if any.

In addition to this set of fundamental information, the controller should inform data subjects about:

6) the *period* for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;
7) the existence of the right to request from the controller *access* to and *rectification* or *erasure* of personal data or restriction of processing concerning the data subject or to *object* to processing as well as the right to data *portability*;
8) the existence of the right to *withdraw* consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;
9) the right to *lodge a complaint* with a Supervisory Authority[15];

All these requirements appear relevant for the lawfulness of EVOTION data collection.

3.8. Responsibility of the controller

The controller must adopt some practices to demonstrate his willing to fully comply to the GDPR. In particular, relevant for EVOTION:

1) Taking into account the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons, the controller shall *implement appropriate* technical and organisational measures *to ensure and to be able to* demonstrate *that processing is performed in accordance with this Regulation. Those measures shall be reviewed and updated where necessary*.
2) Where proportionate in relation to processing activities, the measures referred to in point 1 shall include the implementation of appropriate data protection policies by the controller.

[14] The Data Protection Officer is defined in Articles 37, 38, and 39.
[15] The Supervisory Authority is defined in Articles 51, 52, 53, and 54.

3) Adherence to approved codes of conduct as referred to in Article 40 or approved certification mechanisms as referred to in Article 42 may be used as an element by which to demonstrate compliance with the obligations of the controller.

The main aspect here is the controller's duty to be able to *factually demonstrate* to have operated to satisfy the requirements of the GDPR, by deploying verifiable technical and operational measures, establishing policies or adopting codes of conducts or certifications.

Point 3 refers to the possible definition of codes of conduct by associations or organizations of controllers, for example if any code of conduct exists for European Projects developed by the EU or for big data projects involving health data produced by healthcare associations. Certification adoption is likely to be out of scope for EVOTION.

3.9. Data protection by design and by default

Data protection *by design* and *by default* are two of the most publicized innovations of the GDPR with respect to the Directive. Despite the many debates among professionals, they are not, strictly speaking, technical definitions with clear and unambiguous procedures for achieving them. They are instead more management requirements and, let's say, philosophical approaches to technology design and development. In both cases, the aim is to take steps to prevent common *fault categories* (such as the deployment of systems with insecure configurations) and mitigate some *risk categories* (such as the risk of running out of budget/time if data protection is implemented in the final stages of a project).

Data protection by design and by default are both relevant for EVOTION and the project development should comply with those criteria.

More specifically, here how the GDPR define these approaches.

Data protection by design - Taking into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of natural persons posed by the processing, *the controller shall, both* at the time of the determination of the means for processing and at the time of the processing itself*, implement appropriate technical and organisational measures, such as pseudonymisation, which are designed to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing* in order to meet the requirements of this Regulation and protect the rights of data subjects.

Data protection by default - *The controller shall implement appropriate technical and organisational measures for ensuring that, by default, only personal data which are necessary for each specific purpose of the processing are processed*. That obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility. In particular, such measures shall ensure that by default personal data are not made accessible without the individual's intervention to an indefinite number of natural persons.

It is important to highlight that the controller is required to be able to demonstrate to have conducted his activity (e.g. the design and development of the project) aiming to satisfy both conditions.

3.10. Records of processing activities

Article 30 requires that each controller shall maintain a record of processing activities under its responsibility. That record shall contain all of the following information, relevant for EVOTION:

1) the *name* and *contact details* of the controller, the controller's representative and the data protection officer;
2) the *purposes* of the processing;
3) a description of the categories of *data subjects* and of the categories of *personal data*;
4) the categories of *recipients* to whom the personal data have been or will be disclosed including recipients in third countries or international organisations;
5) where possible, the envisaged *time limits* for erasure of the different categories of data;
6) where possible, a general description of the technical and organisational *security measures*.

Same procedure and information for recording processing activities should be followed by each processor.

3.11. Security of personal data

The controller and the processor are required to implement *appropriate technical and organisational measures to ensure a level of security appropriate to the risk*. In particular, relevant for EVOTION:

1) the pseudonymisation and encryption of personal data;
2) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
3) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
4) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

Furthermore, Article 32 requires that particular attention should be given to *risks that from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed*.

Connected to these specifications regarding the security of personal data, another much hyped novelty of the GDPR is represented by the *controller's duty to* notify *the supervisory authority in the event of a personal data breach*. This obligation, together with time constraints and other requirements, is defined in Article 33 and 34. For sake of brevity and for the prototypical nature of the EVOTION development, we omit the details of these specifications. However, it is important not to minimize the relevance of this prescription, which comes together with pecuniary fines in case of malpractice.

3.12. The GDPR and Big Data

It is a recognized fact by most commentators that Big Data analytics, by their nature, may risk to clash with the prescriptions of the GDPR, in particular for data storage, consent and profiling. The same EU, on the one side actively promotes the importance of Big Data as a strategic driver for European competitiveness and innovation, on the other has become stricter with respect to data protection. That said, it is likely that in the time remaining before the application of the GDPR, some important clarifications with regard the apparently difficult coexistence between Big Data and the GDPR will be released (according to the opinion of some analysts).

Not much official documentation is already available with this respect; however, some informed considerations can be expressed based on official sources.

In the factsheet titled "The EU Data Protection Reform and Big Data"[111] released by the European Commission in March 2016, it is remarked how Big Data are an important opportunity for European companies, which, combined with the highest standard in terms of data protection guaranteed by the GDPR,

should boost trust in EU-based companies managing personal data. The combination of GDPR and Big Data, while problematic on the one side, it is promoted, on the other side, as an important competitive advantage factor on the worldwide market for personal data handling. It is perhaps an over-optimistic view, but it is not groundless.

The enabling factors for business derived from the combination of data protection and Big Data that the European Commission remarks are then: more *consumer trust* in new services and products, *enhanced transparency* with respect to data subjects processing, *uniform legal framework* in the whole EU, and *data protection by design*, which is specifically stressed.

Another important official document, more comprehensive and detailed than the previous one, was published in 2015 by the European Data Protection Supervisor (EDPS) [112].

With respect to the challenges posed by Big Data to data protection, the EDPS notes that responsible and sustainable development of big data must rely on four essential elements:

• organisations must be much more transparent about how they process personal data;

• afford users a higher degree of control over how their data is used;

• design user friendly data protection into their products and services;

• become more accountable for what they do.

These, as we have seen, directly translate in some of the key prescriptions of the GDPR. EVOTION should fully adopt the stance highlighted by these four points.

It is important for EVOTION that the EDPS explicitly mentions scientific and medical research as striking examples in which Big Data may bring new insights and increase self-knowledge for individuals, products, services and medical treatments. On the other side, it made a specific reference, as personal data to be protected, to the exact category of data interested by the EVOTION project. It mentions the advent of the 'Internet of Things', observing that "much of the data collected and communicated by the increasing number of personal and other devices and sensors will be personal data: the data collected by them can be easily related to the users of these devices whose behaviour they will monitor. These may include highly sensitive data including health information and information relating to our thinking patterns and psychological make-up." This description fits almost perfectly with the EVOTION data model.

With respect to Big Data analytics there is a call for more transparency about the logic implemented in them. That is, "disclosing the logic of decision-making can help individuals better to verify whether the conclusions drawn by the organisations processing the data and impacting the individuals are accurate and fair. " This observation is important for those Big Data applications aimed at implementing automated decision-making procedures that, by extracting some knowledge from the body of data, then trigger an action (a decision, a reconfiguration, a policy fix, etc.). This way, an individual could be mistakenly flagged as an outlier (i.e., a statistical anomaly) or as underperforming according to some measures or misaligned with respect a reference population and suffer adverse consequences even without the possibility to know why and how that would have been possible. Problems of social injustice produced by automatic decision-making frameworks have been documented in the recent literature.

This is not the case of EVOTION, though, but, at any rate, it is probably worth to act in a way to clearly disambiguate any possible resemblance with that scenario. It should be very clear that EVOTION Big Data

analytics and procedures are not and will not produce automatic decisions possibly affecting people's welfare. Transparency and accountability look again of outmost importance.

Another, but related, aspect that the EDPS' opinion highlights is to explicitly share the benefits of Big Data with the individuals. Often such benefits do not appear obvious or tangible to individuals; it is instead important to make them very clear. To this end, EVOTION should very clearly show the benefits for patients and public health policies that the Big Data approach is seeking.

More recently, the EDPS has released a new Opinion regarding Big Data [113]. The overall aim of this Opinion is to "recommends establishing a Digital Clearing House for enforcement in the EU digital sector, a voluntary network of regulatory bodies to share information, voluntarily and within the bounds of their respective competences, about possible abuses in the digital ecosystem and the most effective way of tackling them. This should be supplemented by guidance on how regulators could coherently apply rules protecting the individual." At the moment, this in not relevant for EVOTION and the compliance with EU regulation, but could become interesting whether such Digital Clearing House will provide guidelines, code of conducts or other indications in terms of better compatibility of Big Data projects with data protection principles.

4. Related projects

Recently, the EU funded many research initiatives on e-health and new health technologies in various programmes, such as the EC Public Health Programme and Horizon 2020 ICT calls. In the proposal some of these initiatives were already highlighted. Some more were funded in more recent Horizon 2020 calls.

The following table provides an overview of the most current (either on-going or recently finished) European funded projects in the field of ICT for health and wellbeing ('eHealth') and their relation to EVOTION given by a level of relevance (High-Medium-Low). The grade high is given when the project has an approach very similar to EVOTION, i.e. (i) a technological approach proposing new solutions such as Big Data frameworks and sensor/wearable technologies, and (ii) the project aims to address and improve health policies, possibly through policy making tools. The grade medium is given when only one of the two approaches above is addressed. The grade low is given when the project, even if related to electronic health, new technologies and management of big amount of data, has a different approach from EVOTION.

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
EuroHeart, European Heart Health Strategy [16]	EHN - European Heart Network (Yes)	Medium (the project focuses on policies and metrics)	The project relates to EVOTION in its objective n. 2 (Map and analyse national plans, policies and measures impacting on cardiovascular health promotion and cardiovascular disease prevention) and n. 5 (Implement and adapt European guidelines). Also objective n. 4 is relevant (Improve prevention practices at primary care level), but it addresses PHC and not policy makers, as EVOTION does.
QualityAction, 2013-2016 [17]	EU Public Health Programme (Yes)	Low (the project focuses on concrete actions for the policy makers in the HIV field)	One of the objectives of the project is to develop a policy kit that offers policy makers the rationale and concrete actions for integrating quality improvement into HIV prevention policies, strategies and action plans.
SIALON II, 2008-2013 [18]	EC Public Health Programme (Yes)	Low (focus on HIV preventive campaigns)	The project provides insight of prevention needs and an overview of existing preventive campaigns and initiatives as well as of the gaps with respect to HIV/STI prevention.
Equity Action [19]	EU Public Health Programme (Yes)	Low (focus on health inequalities)	The project aims at reducing health inequalities by helping to improve policies at national and regional level. It engages stakeholders, but does not provide tools.

[16] See http://www.ehnheart.org/projects/euroheart/about.html
[17] See http://www.qualityaction.eu
[18] See http://www.sialon.eu/en/home/
[19] See http://www.health-inequalities.eu/projects/past-projects/equity-action/

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
Action-for-Health [20]	EU Public Health Programme (Yes)	Low (focus on good practices)	The project focuses on good practices but it does not propose any new tool.
EUnetHTA Joint Action 2, 2012-2015 [21]	EU Public Health Programme (Yes)	Low (focus on assessments)	Focus on Health Technology Assessment (HTA) to strengthen the practical application of tools.
TOREADOR, TrustwOrthy model-awaRE Analytics Data platform, 2016-2018 [22]	Horizon 2020 (No)	Medium (Big Data approach)	The project has a quantitative approach and focuses on providing Big Data models. However the pilots are not related to the health sector.
BigO, Big data against childhood Obesity, 2016-2018	Horizon 2020 (No)	High (Big Data approach, focus on health policies)	The project focuses the technological achievements in mobile and wearable electronics and Big Data infrastructures. It also aims to reshape policies at a regional, national and European level, through the development of a platform. Similarly to EVOTION this project will reach out to patients (in this case obese children in schools).
PULSE Participatory Urban Living for Sustainable Environments, 2016-2018	Horizon 2020 (No)	High (Big Data approach, focus on health policies)	The project has a clinical focus on respiratory diseases (asthma) and metabolic diseases (Type 2 Diabetes) in adult populations. The project aims at leveraging diverse data sources and big data analytics to transform public health from a reactive to a predictive system
MIDAS, Meaningful Integration of Data, Analytics and Services, 2016-2018	Horizon 2020 (No)	High (Big Data approach, focus on health policies)	The MIDAS consortium involves health authorities in five EU countries and the U.S. and technical big data experts from research institutions and companies. MIDAS aims at developing and delivering an integrated solution for policy makers.
Trillium II, Trillium Bridge II - Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary, 2016-2018	Horizon 2020 (No)	High (Big Data approach, focus on health policies)	Trillium-II aims to bridge, harmonize, evaluate existing patient summary initiatives and guide emerging ones, leading the way toward one International Patient Summary standard by establishing a global community fostering the practice of digital health innovation with robust widely-used interoperability standards and joint pilots. Trillium-II aims also to foster innovation and inform health policy sharing International Patient Summary.

[20] See http://www.action-for-health.eu
[21] See http://www.eunethta.eu/
[22] See http://www.toreador-project.eu

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
EURO-CAS, EU eHealth Interoperability Conformity Assessment Scheme, 2016-2018	Horizon 2020 (No)	Low (focus on business models and regional eHealth programs)	EURO-CAS aims at maintaining and developing the adoption and take-up of testing the interoperability of ICT solutions against identified eHealth standards and profiles defined in the eHealth European Interoperability Framework (eEIF). The project gathers a multi-disciplinary consortium of high-level expertise, including organizations focused on implementing international standards as well as industry stakeholders and healthcare providers.
LIVE INCITE, Lifestyle intervention in the perioperative process through digital service, 2016-2018	Horizon 2020 (No)	Low (focus on ehealth and lifestyle factors)	LIVE INCITE focuses on lifestyle factors of the patient (e.g. smoking, hazardous alcohol drinking and malnutrition) that are proven to be independent risk factors negatively impacting health.
RITMOCORE, Arrhythmias monitoring and comprehensive care, 2016-2018	Horizon 2020 (No)	Medium (the project promotes the use of sensors and devices)	RITMOCORE addresses the evolution in the treatment of elderly patients with arrhythmias using or in need of a pacemaker. Similarly to EVOTION this project promotes the use of remote monitoring of devices, home monitoring of vital signs using wearable, apps and available innovative devices.
NIGHTINGALE, Connecting Patients and Carers using wearable sensor technology, 2016-2018	Horizon 2020 (No)	Medium (the project promotes wearable sensor technologies)	The project challenges industry to develop robust monitoring and communications systems that connect patients, carers and health professionals, provide early warning of acute deterioration in and out of hospital, and learn and adapt to different individuals in different situations. The project promotes wearable sensor technology that allows dynamic monitoring of vital signs that indicate health status and self-learning adaptive algorithms interfaced with Electronic Medical Records can provide reliable early warning.
PROGRESSIVE, Progressive Standards around ICT for Active and Healthy Ageing, 2016-2018	Horizon 2020 (No)	Low (focus on standards, ethical approach)	PROGRESSIVE is rather similar to EVOTION because it provides a dynamic and sustainable framework for standards and standardisation around ICT for Active and Healthy Ageing (AHA). However it does not make use of technological platforms, neither it addresses policymaking. PROGRESSIVE project establishes parameters by which good practice in standards and the standardisation process around ICT for AHA can be identified. A platform is developed to promote

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
			discussion and debate. The work refers more to standards.
SEED, Supporting the Recognition of the Silver Economy in Europe in the Digital Era, 2016-2018	Horizon 2020 (No)	Low (Focus on quality of life of the ageing population)	Also SEED addresses the ageing population. SEED is designed to ensure the successful launching of a highly visible and sustainable European-level award scheme rewarding innovative solutions that demonstrate a significant impact on the quality of life of the ageing population.
IC-Health, Improving digital health literacy in Europe, 2016-2018	Horizon 2020 (No)	Low (focus on improvement of digital health literacy)	IC-Health will provide support for the improvement of digital health literacy in Europe. In particular, the project will design 35 open access online courses (MOOCs), in seven different national languages, for different population cohorts including children, adolescents, pregnant and lactating women, elderly and people affected or susceptible to be affected by type 1 and type 2 diabetes.
ProEmpower, Procuring innovative ICT for patient empowerment and self-management for type 2 diabetes mellitus, 2016-2020	Horizon 2020 (No)	Low (focus on disease self-management solutions)	ProEmpower applies the internationally acclaimed Chronic Care Model to specify support needs for type 2 diabetes at all stages. Self-management and treatment are supported by personalised guidelines and making the best use of clinical data.
EUUSEHEALTHWORK, Mapping Skills and Competencies; Providing Access to Knowledge, Tools and Platforms; and Strengthening, Disseminating and Exploiting Success Outcomes for a Skilled Transatlantic eHealth Workforce, 2016-2018	Horizon 2020, CSA - Coordination and support action (No)	Low (focus on coordination and support actions)	The EUUSEHEALTHWORK Consortium has an overall goal of mapping, quantifying and projecting the need, supply and demand for workforce skills and competences, utilising these results to further develop IT skills and training programmes for the healthcare workforce.
STARS, Empowering Patients by Professional Stress Avoidance and Recovery Services, 2016-2018	Horizon 2020 (No)	Low (focus on Individualized tackling of unnecessary stress)	The project aims to enhance the autonomy and quality of life of many people and yield a significant contribution to self-empowerment, thus relieving careers and related persons from personal assistance. Project challenges start from smart vital signs measuring to wireless real-time transfer of large data amounts to Big Data management.
eHealth Hub, The European Hub for eHealth Business Support, 2016-2019	Horizon 2020 (No)	Low (focus on business opportunities in eHealth)	This project describes the creation of a support system that is cross-border, sustainable, highly specialized on the eHealth vertical, providing long-term support at various stages of development, and addressing all the challenges facing European eHealth SMEs: finding the right

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
			business model, accessing finance, connecting with the demand side and accelerating their commercialization, getting legal and regulatory guidance to develop their solution in compliance with a multi-layer complicated framework.
SIFEM / Semantic Infostructure interlinking an open source Finite Element tool and libraries with a model repository for the multi-scale Modelling and 3d visualization of the inner-ear/ EUR 3.915.461/ 2013-2016[23]	FP7	Medium Assisting the experts to better assess each patient's condition which leads to a more efficient treatment and rehabilitation planning and, in long-term, to personalized healthcare.	The clinical evidence indicates that the number of people with all levels of hearing impairment and hearing loss is rising mainly due to a growing global population and longer life expectancies. Hearing loss caused by pathology in the cochlea or the cochlear nerve is classified as sensorineural hearing loss. The study of the normal function and pathology of the inner ear has unique difficulties as it is inaccessible during life and so, conventional techniques of pathologic studies such as biopsy and surgical excision are not feasible.SIFEM focuses on the development of a Semantic Infostructure interlinking an open source Finite Element Tool with existing data, models and new knowledge for the multi-scale modelling of the inner-ear with regard to the sensorineural hearing loss. The experts will have access to both the data (micro-CT images, histological data) and inner ear models, while the open-source developed tools and the SIFEM Conceptual Model will be contributed to the VPH toolkit enhancing their reusability. These SIFEM open source tools and services enhance and accelerate the delivery of validated and robust multi-scale models by focusing on: (i) Finite Element Models manipulation and development, (ii) cochlea reconstruction and (iii) 3D inner ear models visualization. The final outcome is the development of a functional, 3D, multi-scale and validated inner-ear model that includes details of the micromechanics, cochlea geometry, supporting structures, surrounding fluid environment and vibration patterns. In the open context that the project addresses the results can be used to better identify the mechanisms that are responsible for the highly sensitive and dynamic properties of hearing loss.

[23] http://sifem.ubitech.eu

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
			These result to the description of alterations that are connected to diverse cochlear disorders and assist the experts to better assess each patient's condition leading to more efficient treatment and rehabilitation planning and, in long-term, to personalized healthcare.
EMBALANCE / A Decision Support System incorporating a validated patient-specific, multi-scale Balance Hypermodel towards early diagnostic Evaluation and efficient Management plan formulation of Balance Disorders / EUR 4.740.776/ 2013-2016 / [24]		Medium Integration of a multi-scale and patient-specific Hypermodel, which will be incorporated to a Decision Support System, towards the early diagnosis, prediction and the efficient treatment planning of balance disorders.	Human balance is achieved and maintained by a complex set of sensorimotor systems that include sensory input from vision, proprioception and the vestibular system (motion, equilibrium, spatial orientation); integration of the sensory input; and motor output to the muscles of the eye and body. Failure at the level of the sensory inputs or at the integration of the sensory information by the central nervous system may lead to a variety of age spanning diseases which affect balance. This complexity leads to undiagnosed or under-treated patients with balance disorders for long periods and results in large socio-economic costs. The EMBalance project aims to extend existing but generic and currently uncoupled balance modelling activities leading to a multi-scale and patient-specific balance Hypermodel, which will be incorporated to a Decision Support System, towards the early diagnosis, prediction and the efficient treatment planning of balance disorders. Various data will feed the intelligent system increasing the dimensionality and personalization of the system. Human Computer Interaction techniques will be utilized in order to develop the required interfaces in a user-intuitive and efficient way, while interoperable web-services will enhance the accessibility and acceptance of the system. The vision extends to the experimental and clinical validation of the project outcomes with existing and newly acquired data (by conducting small scale clinical trials), and includes showcases in balance disorders diagnosis, prediction, treatment and follow-up in normal and micro-gravity environments.The final outcome will be a powerful web-based

[24] http://www.embalance.eu

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
			platform provided to primary and secondary care physicians across specialties, levels of training and geographical boundaries, targeting wider clinical acceptance as well as the increased confidence in the developed DSS towards the early diagnostic evaluation, behaviour prediction and effective management planning of balance problems.
CALLIOPE / CALL for InterOPErability: Creating a European coordination network for eHealth interoperability implementation/ EUR 497.500/ 2008-2010 / [25]		High Cooperation of health authorities and organisations representing networks of physicians, community pharmacists, patients, industry and health insurers. It represents a targeted effort aiming to establish an appropriately governed, composed and structured open forum, with the focal goal to support Member States to implement interoperable eHealth solutions, in close collaboration with the key stakeholders, including users, industry and payers.	CALLIOPE - eHealth accross Europe. Collaborative, Interactive initiative for the successful deployment of eHealth in EU The CALLIOPE Network is part of the Open eHealth Initiative, which is driven by Member States health administrations. It has been initiated by 17 health authorities and 10 organisations representing networks of physicians, community pharmacists, patients, industry and health insurers. It represents a targeted effort aiming to establish an appropriately governed, composed and structured open forum, with the focal goal to support Member States to implement interoperable eHealth solutions, in close collaboration with the key stakeholders, including users, industry and payers. CALLIOPE will therefore operate in synergy with cross border eHealth initiatives in Europe, in terms of supporting exchanges within a much broader community and will also be one of the major mechanisms for dissemination and propagation of EU level activities in this area. The Network has the ambition to contribute to standardisation activities through close liaison with relevant standardisation bodies, as well as to provide input to CIP PSP, towards better focusing of future programme funded activities in cross border eHealth. Initially, the network governance and the knowledge infrastructures will be developed and the CALLIOPE Network will be set to operation. As part of its work program, CALLIOPE will then serve a first set of operational objectives i.e., elaboration of a common Interoperability Road map; review and advancement of the

[25] http://www.calliope-network.eu

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
			EU Interoperability Recommendation and; facilitation of pre-standardisation processes through liaison with SDOs. It will furthermore offer a portfolio of targeted support services to be provided on request and by mobilising, to the extent possible, external resources, thus setting the network on track to self sustainability. This set of activities and related deliverables will also put to testing the network processes and the results will comprise part of the independent evaluation at the end of the project.
RENEWING HEALTH / REgioNs of Europe WorkINg toGether for HEALTH / EUR 14.000.000 / 2011-2014/ [26]	ICT Policy Support Programme (ICT PSP)	High Provision of coherent clinical services through ICT that take into proper consideration patients' and professional users' needs, capabilities, risks and benefits. It also implements a new healthcare model that is expected to reduce the cost of chronic patients care to the society by progressively reducing the reliance of these patients on expensive facilities. The project intends to create an organisational model for telemedicine services that	RENEWING HEALTH addresses clinical outcome, patient/user, economic and organisational objectives: Clinical objectives - the project improves the quality of life of patients suffering from diabetes, chronic obstructive pulmonary or cardiovascular diseases. This objective will be achieved by means of removing anxiety about health conditions and reducing the need to use emergency services and hospital stays. Patient/user perspective objectives - the project will provide coherent clinical services through ICT that take into proper consideration patients' and professional users' needs, capabilities, risks and benefits. The actions are planned to implement solutions that support the empowerment of patients and increase their satisfaction. Economic objectives - the project implements a new healthcare model that is expected to reduce the cost of chronic patients care to the society by progressively reducing the reliance of these patients on expensive facilities geared to tackle only the acute episodes of the chronic disease they suffer from and to replace them with more affordable homecare. Organisational objectives - the project intends to create an organisational model for telemedicine services that ensures a safe, clear and efficient pathway for patients in their journey through the

[26] http://www.renewinghealth.eu

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
		ensures a safe, clear and efficient pathway for patients in their journey through the healthcare system by creating standard patients programs for each telemedicine service that take into account the active participation of the patients in the organisational model. The model will also be transferable to other patients groups and healthcare systems.	healthcare system by creating standard patients programs for each telemedicine service that take into account the active participation of the patients in the organisational model. The model will also be transferable to other patients groups and healthcare systems. The achievement of the four objectives described above will be monitored and documented through the use of the European evaluation model developed in the MethoTelemed Study.
epSOS / European Patients: Smart Open Services / EUR 36.5000.000 / 2008-2014/[27]	ICT Policy Support Programme (ICT PSP)	High Development of a practical eHealth framework and ICT infrastructure that enables secure access to patient health information among different European healthcare systems.	epSOS attempts to offer seamless healthcare to European citizens. Key goals are to improve the quality and safety of healthcare for citizens when travelling to another European country. Moreover, it concentrates on developing a practical eHealth framework and ICT infrastructure that enables secure access to patient health information among different European healthcare systems. epSOS can make a significant contribution to patient safety by reducing the frequency of medical errors and by providing quick access to documentation as well as by increasing acessibility of ones prescribed medicine also abroad. In emergency situations, this documentation provides the medical personnel with life-saving information and reduces the (sometimes needless) repetition of diagnostic procedures.

[27] http://www.epsos.eu/

Project acronym and name, start and end dates	Funded by (Yes/No: if project is already present in proposal)	Level of relevance with EVOTION	Comment
			The technical, legal and organizational concepts developed within the framework of the project are subject to an extensive practical testing phase which will last until the end of the project.
PONTE/ Efficient Patient Recruitment for Innovative Clinical Trials of Existing Drugs to other Indications/ EUR 3.276.699/ 2010-2013 / [28]	FP7	Medium Semantic interoperability of clinical care information systems with clinical research information systems and drug and disease knowledge databases, as well as the appliance of advanced data mining techniques and enhanced learning algorithms.	PONTE is a European project standing for Efficient Patient Recruitment for Innovative Clinical Trials of Existing Drugs to other Indications. PONTE provides a platform following a Service Oriented Architecture (SOA) approach that offers intelligent automatic identification of individuals eligible to participate in clinical trials (concerning their safety and clinical trial efficacy). The trials will be designed and planned through a flexible authoring tool, enabling semantic interoperability of clinical care information systems with clinical research information systems and drug and disease knowledge databases, as well as the appliance of advanced data mining techniques and enhanced learning algorithms.

[28] http://www.ponte-project.eu

5. Methodology

5.1. Expectations

This report will obtain the requirements of the users target groups, i.e., Policy Makers, governmental organizations, clinicians, stakeholders and related professionals. The identification of user requirements will be based on focus groups and interviews and will supported by the definition of intuitive use case scenarios, which will highlight features and interactions that users cannot imagine of at present due to the limitation of the existing online platforms.

5.2. Overall Methodology

5.2.1. Process

An iterative process for the elucidation of user requirements has been followed in the EVOTION project, aiming to implement the strategic project decision to bring the target stakeholders, including the policy makers, the clinicians and the HA users, in the forefront of the development process. As such, the user requirements methodology has been evolved around the steps that are described in the following lines and are visually summarized in the below figure.

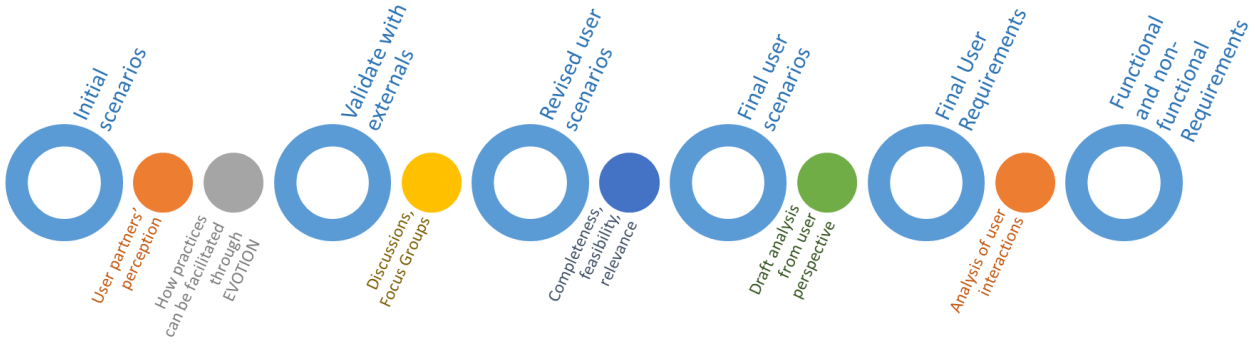

Figure 8: Followed process

In the beginning of the process, a list of representative user scenarios has been identified, which reflects the initial perception of the Consortium user partners on what EVOTION could provide to them and which priorities of their current business practices for policy making and support of clinician in managing their HA patients could be automated and optimized through the technologies offered by the project. In order to dig into the details of these scenarios, the user requirements analysis methodology envisions three scenario groups, namely, for the policy making domain, the clinicians' operations, and the support for HA users.

The initial scenarios produced in this step have been validated within the user partners' centers by engaging stakeholders external to the EVOTION project. To this end, a number of discussions and focus groups were organized, with the aim to discuss the scenarios in these three groups and come up with revisions from the external to the project experts and stakeholders' representatives. By doing so, a first revision of the scenarios was produced.

The revised scenarios were evaluated by the project technical and user teams to collectively decide whether the scenarios can formulate a strong basis for addressing the expectations of the experts and stakeholders' representatives in these three groups. The criteria for scenario evaluation in this first round have been the completeness of the scenarios with respect to the project objectives, the feasibility and/or relevance of the scenarios implementation within the EVOTION lifetime, and the added value for the target stakeholders. The outcome of this evaluation round was the final set of scenarios for the three groups, which involved new scenarios that were not previously introduced.

Subsequently, the updated (final) scenarios were analysed in terms of the user requirements. Again at this phase, the requirements were produced in an iterative process. Thus, a draft set of user requirements were extracted from the analysis of the final scenarios for the three groups. These requirements were validated by the project partners with respect to their relevance to the project scope and their appropriateness for addressing the user scenarios. This process resulted in the specification of the final user requirements, which was the set of the user level perception on what the EVOTION can do for the user groups.

By materializing the user requirements, the EVOTION project team identified the functions that the users expect from the EVOTION platform. These functions relate to the envisaged interactions of the target stakeholders this the front end interfaces of the platform. In that respect, the functional requirements were derived. By elaborating the details of these requirements, the technical team of the project analysed the system level requirements that would ensure the normal operation of the EVOTION platform and the provision of a useful environment for the stakeholders to consume the desired functionalities. The result of this phase was the development of the EVOTION system functional and non-functional requirements.

In Appendix 1, Appendix 2 and Appendix 3 can be found the guidelines on user requirements collection process that have been provided to the relevant partners, focus groups minutes and the dropped draft scenarios.

5.2.2. Scenarios and requirements specification templates

The templates for requirements and scenarios are filled with textual descriptions inspired by a standardized formal language in RFC2119 [114] to describe among others: pre-conditions and post-conditions, rationale, flow of events and keywords. In particular, we often highlight in block letters MUST, SHOULD and COULD/MAY. These should however not be confused with the similar keywords that we use for the priority of accomplishment of a requirements, i.e., “Must have”, “Should have”, “Could have”.

The requirements table template we have defined is as follows:

Field	Description
ID	*A unique ID for this requirement/assumption*
Title	*A title/short name for this requirement/assumption*
Priority of accomplishment	*One of the following: Must have: The system must implement this requirement to be accepted. Should have: The system should implement this requirement: some deviation from the requirement as stated may be acceptable. Could have: The system should implement this requirement, but may be accepted without it.*
Description	*Specify the intention of the requirement/assumption*
Rationale	*If the description is not descriptive enough, this entry gives a justification of the requirement/assumption. Otherwise this entry will be filled with N/A.*
Supporting materials	*If applicable, give a pointer to documents that illustrate and explain this requirement/assumption. Otherwise this entry will be filled with N/A.*
Tentative scheduling	*Tentative scheduling of accomplishment.*

Table 5: Requirement table template

The use case scenarios table template is as follows:

Use Case Id	*A unique id distinguishing this use case from any other. To form use case IDs the following scheme should be used:* *<Prefix>.<number>*

	where *<Prefix> := PHAS | CLIS | PSOS* *The use of the one of the above prefixes should indicate the primary actor of the use case. The intended meaning of the individual values is as follows:* • *PHAS: Public Health Authority Stakeholder* • *CLIS: Clinical Stakeholder* • *PSOS: Patient or Significant Other Stakeholder*
Use Case Name	*A short string indicating the meaning of the use case*
Use Case Summary	*A brief summary outlining the overall purpose of the use case and the interaction taking place between the EVOTION platform and the use case actor(s).*
Actors	*The stakeholders who will interact with the EVOTION platform in the context of the use case. Only actors that have a DIRECT interaction with the EVOTION platform as part of the specific use case should be listed here.*
Preconditions	*All conditions that must be satisfied prior the commencement of the interaction described by the use case.*
Trigger	*The event/circumstance(s) that will trigger the interaction described by the use case.*
Basic Flow	*The typical flow of steps that should be taken to realise the interaction between the EVOTION platform and the use case actors that this use case describes. The steps should be listed in the exact sequence in which they occur and be numbered in a way that indicates this sequence (i.e., 1. (for first step), 2. (for second step) etc.) Steps should be atomic (i.e., a step should be a single action that is taken by either the external actor or the system as part of the interaction) and indicate with clarity who is responsible for taking the step (i.e., the system or an external actor).* *A step may involve the extension of the use case by another use case or the inclusion of another use case within this use case. If this is the case, the step will be an extension or an inclusion point, respectively.* *A use case A needs to be extended by another use case B, if the interaction described by B should take place in the context of A under certain conditions. These conditions must be clearly described.* *A use case A needs to include another use case B, if the interaction described by B should take place in the context of A in all circumstances.* *An extension point will be introduced by the special keyword: EXTENDED BY <use-case-id> UNDER CONDITION <condition>* *An inclusion point will be introduced by the special keyword: INCLUDES <use-case-id>*
Alternate Flows	*Alternatives to the typical steps taken to realise the interaction described by the use case. A use case may have one more alternate flows.* *Each alternate flow may involve one or more alternative steps all of which must be associated with steps in the Basic Flow.* *Alternate flows and their steps must be numbered according to the following scheme:* *AF<number>. AF_STEP<number>.BF.<number>* *Where* • *AF<number> is the unique identifier of the alternate*

	• *AF_STEP<number> is the unique identifier of the individual step within the alternate* • *BF.<number> is the identifier of the step in the basic flow that will be substituted for by the alternate flow step*
Postconditions	*All conditions that must be satisfied upon the completion of the interaction described by the use case.*

Table 6: Use case scenarios table template

5.2.3. Glossary

The glossary of the deliverable consists of Terms, Definitions and Abbreviations which are listed below:

Acronym	Definition
EVOTION	Refers to ancient Greek "εὖ + ὠτίον" meaning "good ear"
ACID	Atomicity, Consistency, Isolation and Durability
AHL	Action on Hearing loss
AES	Advanced Encryption Standard
AES	Advanced Encryption Standard
AIK	Attestation Identity Key
APD	Auditory processing disorders
API	Application programming interface
AT	Auditory training
ATS	Asymptotic threshold shift
AUC	Area Under the ROC
BDA	Platform big data analytics platforms
BIC	Bayesian Information Criterion
BMA	Bayesian Model Averaging
CFHI	Canadian Foundation for Healthcare Improvement
CAPTCHA	Completely Automated Public Turing Test To Tell Computers and Humans Apart
CAs	Certification Authorities
CBAT	Community Based Acute Treatment
CBC	Cipher-block chaining
CBOC	Community Based Outpatient Clinic
CSRF	Cross site request forgery
DSS	Decision-Support System
DStream	Discretized stream
ECDH	Elliptic Curve Diffie-Hellman
EDPS	European Data Protection Supervisor
EU	European Union
G2G	Government-to-Government
GDPR	General Data Protection Regulation
GEMSS	Geospatial Emergency Management Support System
HAs	Hearing Aids
HDFS	Hadoop Distributed File System
HIA	Health Impact Assessment
HL	Hearing Loss
HLs	Hearing levels

HS	High Speed
ICT	Information and communications technology
IDC	Internet Data Center
IFTTT	If This Then That
LTK	Long-Term Key
MITM	Man-in-the-middle
Mllib	Machine Learning library
MPM	Mobile Platform Module
MPL	Modified Power Law
NHS	National Health System
NIHL	Noise induced hearing loss
NGO	Nongovernmental Organization
PHPDM	Public health policy decision making
PCRs	Platform Configuration Registers
PKI	Public Key Infrastructure
RDD	Resilient Distributed Datasets
ROC	Receiver Operating Characteristic
SMS	Short Message Service
SQL	Structured Query Language
SSP	Secure Simple Pairing
SVM	Support Vector Machines
SWOT	Strengths, Weaknesses, Opportunities and Threats
TPM	Trusted platform modules
TTS	Temporary threshold shift
URL	Uniform Resource Locator
VM	Virtual machine
XSS	Cross site scripting
YARN	Yet Another Resource Negotiator
WHO	World Health Organization

Table 7: Acronyms

5.3. Key Stakeholders

All potential user groups, as identified in the EVOTION project description, were involved in the user requirements survey in order to disclose various opinions and views on EVOTION and also provide different suggestions for solving the key issues.

A mix of public bodies' officers, representatives of clinical organizations, HA Users and significant others were approached. Representatives of all these potential target groups took part in the key activities of the collection of user requirements, namely the usage scenarios, the focus group discussions and interviews. In these activities, external audience has been also involved.

The goal was to identify users' opinions and requirements that will be analyzed and incorporated into the EVOTION components addressing their main needs as well as provide the incentives for using and evaluating the EVOTION platform & components in the next phases of the project.

5.4. Risks & Methods to address them

The effectiveness of user requirements analysis in the beginning of a development project depends to a large extent on the type of project. Collecting user requirements for potential consumer products requires much

effort, and the risk to fail is still very high. As long as end users have no idea of the innovative product or service, it will be very difficult for them to state their needs. Creativity of designers is required for the transfer of user requirements into innovative consumer products or services.

For the development of professional applications, precise analysis and identification of user requirements is essential. Professionals often are available to perform the tasks under investigation.

Task analysis is obligatory for the development of safety critical applications. A characteristic of safety critical work domains is that tasks and procedures are precisely defined before new support tools are built. This is a good precondition for the specification of functional and non-functional requirements.

User requirements analysis is an error prone part of the development process. Errors not detected at this stage may lead to expensive system failures later. For this reason, user requirements should be verified as soon as design solutions and prototypes are available.

6. User Scenario & Requirements

In order to create scenarios of stakeholders use, a series of actions took place. Initially, stakeholder EVOTION partners contributed several scenarios spontaneously, according to their point of view and their priorities. A template was provided and used for this contribution and all scenarios in order to have a harmonized structure. Consequently, scenarios were collected together and there a first cycle of internal evaluation was conducted.

This kind of evaluation consisted of two levels: In the first level, each scenario was evaluated in terms of integration, feasibility, expected value and relation to the project. In a second level, an overall evaluation of the range of the scenarios and the proportion of the potential uses of the EVOTION ecosystem was also provided by all partners through indirect and direct (teleconference) way.

Following this, a list of additional scenarios was created, so that all potential uses of the scenario, according to the plans described in description of action and those identified collectively by the partners, would be covered. Additional scenarios were assigned to certain partners and were created. The following step was the creation of a final list of scenarios. Finally, those scenarios were validated, both internally as well as during focus group meetings with experts in the field.

The following sub section presents the user scenarios and the elicited requirements for the three key stakeholders group.

6.1. For Policy Makers

6.1.1. Prognosis of low HA usage

Use Case Id	PHAS.1
Use Case Name	Prognosis of low HA usage.
Use Case Summary	This use case captures scenarios regarding the formation of public health policy for exploring the potential of interventions aimed at preventing the low usage of HAs. The scenario is related to the **initial advocacy phase** according to WHO and is aimed at • Providing evidence regarding the scale of the problem • Investigating potential factors that may be used as predictors of low/ineffective HA usage, including clinical, physiological, life-style, occupational and behavioural patient profiles, environment, personal, behavioural, clinical and physiological data. Such analysis can identify circumstances under which HA are underused with the aim to inform the development of strategies with regards to the provision of HAs and continuous support, alerts and other enablers (special training programmes) to increase the frequency and efficacy of HA usage.
Actors	Public health authority actor PHAA (Ministry of Health, Hearing Aid programme team actors)
Preconditions	
Trigger	Increasing anecdotal evidence regarding low HA usage
Basic Flow	1. PHAA explores the different types of data that can be collected and analysed by the EVOTION platform and select some of them, which are thought to be potential factors for prognosing low HA usage. 2. Following a review of summaries of recent related studies that have been summarised and are available through the EVOTION platform, PHAA selects the following potential factors for prognosing low HA usage: environment (END.1 – END.3), personal (PED.1 – PED.4),

	behavioural (BHD.1 – BHD.3), clinical (CGD.1 – CGD.4), physiological (PHD.1 – PHD.3)) data. 3. PHAA determines whether the data to be used will be retrospective or prospective; the minimal size of the relevant data set; and the sources from which these data will be collected (i.e., the exact hospital repositories). 4. PHAA determines the types of data analysis that will be performed upon the data and the tests that should be applied to establish the sensitivity and the significance of the outcomes of the analysis. 5. PHAA initiates a data analysis session as an initial policy advocacy task using the EVOTION platform. 6. The EVOTION platform records the outcomes of its analysis in reference to the initiated initial policy advocacy task and notifies the owner of the task when the analysis is complete. 7. PHAA uses the EVOTION platform to visualise the outcomes of the analysis. 8. Based on the outcomes of the analysis, PHAA identifies factors of low and promising prognostic value and marks them as such. 9. For factors with promising prognostic value, PHAA may initiate a further analysis task following steps 3-7. As part of this set up, PHAA may also indicate whether subsequent analysis should involve the initial data sets or only the ones, which are newly defined. 10. Based on the outcomes of the additional analysis, PHAA identifies factors of low and promising prognostic value and marks them as such (Several rounds of additional analysis may be requested).
Alternate Flows	
Postconditions	The initial policy advocacy task is recorded in the EVOTION platform along with the outcomes of the successive stages of analysis.

6.1.2. Predicting early retirement due to hearing impairments

Use Case Id	PHAS.2
Use Case Name	Predicting early retirement due to hearing impairments
Use Case Summary	Exploring the potential for public policy interventions aimed at preventing early retirement due to hearing impairments. The scenario is related to the **initial advocacy phase** according to WHO and is aimed at: • Providing evidence regarding the scale of the problem • Investigating potential factors that may be used as predictors of early retirement due to hearing impairments such as clinical, life-style, occupational and behavioral patient profiles; environmental, personal, behavioral data. • Analysing above factors in order to identify circumstances under which early retirement is due to hearing impairments with the aim to inform the development of strategies with regards to the provision of obligatory screening of employees above certain age, provision of incentives for seeking timely assistance, reducing HL-causing factors, etc.
Actors	• Regional structures of the national Ministry of Public Health (in their role as supervising the Committees of Occupational Expert Physicians prescribing early retirement); • Regional Labor Inspectorate (in their role as supervising occupational environments)

	• Regional ENT-specialists' Advisory Committee (in their role as prescribing the use of HAs); • Regional Directorate for Social support (in their role as authorising financial support for purchasing HAs);
Preconditions	• Actors have authority and competences in drafting public health strategies; • EVOTION dashboard is functioning; • Interacting case actors have sufficient knowledge of English
Trigger	Increasing evidence regarding early retirement due to hearing impairments
Basic Flow	1. Case actors identify different types of data that can be collected and analysed by the EVOTION platform and select some of them, which are thought to be potential factors for early retirement due to hearing impairments; 2. Case actors review summaries of recent related studies that have been summarised and made available through the EVOTION platform, and select potential predictive factors for early retirement due to hearing impairments (e.g. occupational (OCD1), cognitive (CGD1-4), environment (END.1–3), personal (PED.1–4, 6), behavioral (BHD.1-5), web and social networks (SWD1-2)) data; 3. Case actors determine whether the data to be used will be retrospective or prospective; the minimal size of the relevant data set; and the sources from which these data will be collected (i.e., the exact repositories); 4. Case actors determine the types of data analyses to be performed and initiate a data analysis session upon the selected data using the EVOTION platform, as an initial policy advocacy task; 5. The EVOTION platform records the outcomes of its analysis in reference to the initiated initial policy advocacy task and notifies the owner of the task when the analysis is complete; 6. Case actors use the EVOTION platform to visualise the outcomes of the analysis; 7. Based on the outcomes of the analysis, Case actors identify factors of low and promising prognostic value and mark them as such; 8. Case actors may initiate a further analysis task following steps 3-7 for factors with promising prognostic value and may also indicate whether subsequent analysis should involve the initial data sets or only the newly defined ones. 9. Based on the outcomes of the additional analysis, Case actors identify factors of low and promising prognostic value and marks them as such (several rounds of additional analysis may be requested).
Alternate Flows	
Postconditions	• The initial policy advocacy task is recorded in the EVOTION platform along with the outcomes of the successive stages of analysis; • Case actors refer their identified factors of prognostic value to the responsible decision-making body; • Possibility for reviewing the identified factors of prognostic value upon acquisition of new evidence.

6.1.3. Predicting urban physical planning based on HL

Use Case Id	PHAS.3
Use Case Name	Predicting urban physical planning based on HL.
Use Case Summary	Exploring the potential for public policy interventions aimed at preventing HL by means of predictive urban physical planning. The scenario is related to the **initial advocacy phase** according to WHO and is aimed at: • Providing evidence regarding the scale of the problem of noise-inducing urban physical infrastructure • Investigating potential factors that may be used as predictors of HL due to noise-inducing urban physical infrastructure such as clinical, life-style, occupational, cognitive and behavioural patient profiles; environmental, personal, behavioural data. • Analysing above factors in order to identify circumstances under which noise-induced HL is due to urban physical infrastructure with the aim to inform the development of strategies with regards to the provision of obligatory regular noise-load measurements, provision of recommendations for specific urban planning (change of pavement materials, provision of noise absorption along motorways in living suburbs, etc.
Actors	Regional structures of the national Ministry of Environment (in their role as supervising the measurements of noise levels); Regional structures of the national Ministry of Public Health (in their role as providing recommendations for interventions affecting public health); Regional Labour Inspectorate (in their role as supervising open-air occupational environments) Local authorities (municipal administrations in their role as urban planning responsibles) Regional ENT-specialists' Advisory Committee (in their role as prescribing the use of HAs); Regional Directorate for Social support (in their role as authorising financial support for purchasing HAs);
Preconditions	• Evidence available indicating higher noise levels measured in the city; • Actors have authority and competences in drafting public health strategies; • EVOTION dashboard is functioning; • Interacting case actors have sufficient knowledge of English
Trigger	Increasing evidence indicating higher noise levels measured in the city
Basic Flow	1. Case actors identify different types of data that can be collected and analysed by the EVOTION platform and select some of them, which are thought to be potential factors for HL due to noise-inducing urban physical infrastructure; 2. Case actors review summaries of recent related studies that have been summarised and made available through the EVOTION platform, and select potential predictive factors for HL due to noise-inducing urban physical infrastructure (ex. occupational (OCD1), environment (END.1–3), cognitive (CGD1-4), clinical (CMD 7), behavioural (BHD.3-5), web and social networks (SWD1-2)) data; 3. Case actors determine whether the data to be used will be retrospective or prospective; the minimal size of the relevant data set;

	and the sources from which these data will be collected (i.e., the exact repositories); 4. Case actors determine the types of data analyses to be performed and initiate a data analysis session upon the selected data using the EVOTION platform, as an initial policy advocacy task; 5. The EVOTION platform records the outcomes of its analysis in reference to the initiated initial policy advocacy task and notifies the owner of the task when the analysis is complete; 6. Case actors use the EVOTION platform to visualise the outcomes of the analysis; 7. Based on the outcomes of the analysis, Case actors identify factors of low and promising prognostic value and mark them as such; 8. Case actors may initiate a further analysis task following steps 3-7 for factors with promising prognostic value and may also indicate whether subsequent analysis should involve the initial data sets or only the newly defined ones. 9. Based on the outcomes of the additional analysis, Case actors identify factors of low and promising prognostic value and marks them as such (several rounds of additional analysis may be requested).
Alternate Flows	
Postconditions	• The initial policy advocacy task is recorded in the EVOTION platform along with the outcomes of the successive stages of analysis; • Case actors refer their identified factors of prognostic value to the responsible decision-making body; • Possibility for reviewing the identified factors of prognostic value upon acquisition of new evidence.

6.1.4. Explore the potential for personalization of HA administration and use follow-up

Use Case Id	PHAS.4
Use Case Name	Explore the potential for personalization of HA administration and use follow-up
Use Case Summary	Eliciting possible public policy interventions aimed at personalization of HA administration and use follow-up for risk groups of patients. Currently, all HL patients under a certain level of economic status are administered a fixed amount of funding for purchasing HAs for a fixed period of time but have different needs in terms of HL change and social status change with time. The scenario is related to the **initial advocacy phase** according to WHO and is aimed at: • Providing evidence regarding the scale of the problem • Studying data to elicit potential factors that may be used as predictors of poor administration and insufficient use of HAs due to lacking personalization follow-up on risk groups of patients (cognitive, medical, life-style, occupational and behavioural patient profiles; personal and behavioural data). • Analysing such factors in order to identify circumstances under which changes in HL result from poor follow-up personalisation of the administration and use of HA with the aim to inform the development of strategies with regards to the provision of personalised follow-up for risk groups of HAs patients, provision of incentives for seeking

	timely personal care, interviewing follow-up visits, running information campaigns for personalized follow-up, etc.
Actors	• Regional ENT-specialists' Advisory Committee (in their role as prescribing the use of HAs); • Regional Directorate for Social support (in their role as authorising financial support for purchasing HAs and performing follow-up on administration and use); • Regional structures of the national Health Insurance Fund (in their role as funding clinical pathways);
Preconditions	• Actors have authority and competences in drafting public health strategies; • EVOTION dashboard is functioning; • Interacting case actors have sufficient knowledge of English
Trigger	Increasing evidence regarding insufficient use of administered HAs among risk groups of patients (low economic or social status)
Basic Flow	1. Case actors identify different types of data that can be collected and analysed by the EVOTION platform and select some of them, which are thought to be potential factors for insufficient use of administered HAs among risk groups of patients of low economic or social status; 2. Case actors review summaries of recent related studies that have been summarised and made available through the EVOTION platform, and select potential predictive factors for insufficient use of administered HAs among risk groups of patients (ex. HA logging HA 1-2, clinical CMD 6-7; occupational (OCD1), cognitive (CGD1-4), personal (PED.5- 6), behavioural (BHD.1-5), web and social networks (SWD1-2)) data; 3. Case actors determine whether the data to be used will be retrospective or prospective; the minimal size of the relevant data set; and the sources from which these data will be collected (i.e., the exact authority repositories); 4. Case actors determine the types of data analyses to be performed and initiate a data analysis session upon the selected data using the EVOTION platform, as an initial policy advocacy task; 5. The EVOTION platform records the outcomes of its analysis in reference to the initiated initial policy advocacy task and notifies the owner of the task when the analysis is complete; 6. Case actors use the EVOTION platform to visualise the outcomes of the analysis; 7. Based on the outcomes of the analysis, Case actors identify factors of low and promising prognostic value and mark them as such; 8. Case actors may initiate a further analysis task following steps 3-7 for factors with promising prognostic value and may also indicate whether subsequent analysis should involve the initial data sets or only the newly defined ones. 9. Based on the outcomes of the additional analysis, Case actors identify factors of low and promising prognostic value and marks them as such (several rounds of additional analysis may be requested).
Alternate Flows	

Postconditions	• The initial policy advocacy task is recorded in the EVOTION platform along with the outcomes of the successive stages of analysis; • Case actors refer their identified factors of prognostic value to the responsible decision-making body; • Possibility for reviewing the identified factors of prognostic value upon acquisition of new evidence.

6.1.5. Policy Formation for Effective Use of Assistive Listening Devices

Use Case Id	PHAS.5
Use Case Name	Policy on Effective Use of Assistive Listening Devices
Use Case Summary	This use case captures scenarios regarding the formation of public health policy for exploring the effectiveness of Hearing Loops. The scenario is aimed at collecting logs of sound transmitted to hearing aids given to participants of the EVOTION projects and the feedback obtained by EVOTION HA users regarding the effectiveness of use of HLs. The collected logs and HA user feedback will be correlated and analysed in reference to the activity supported by HLs (e.g., banking) and the location and noise profile of the overall environment where the HLs are installed in order to establish if HL effectiveness is affected by such factors, as well as by other characteristics of the HA users (e.g., their hearing level, age, overall behavioural and cognitive activity profile etc.) The scenario covers two phases of public health policy formulation, namely: (1) Situation analysis, and (2) Development of action plan
Actors	Public health authority actor PHAA (Authority responsible for occupational medicine, HA user associations)
Preconditions	
Trigger	
Basic Flow	1. PHAA creates a new PHP decision making model to explore the effectiveness of using Hearing Loops (HL). The model is intended to collect: (a) logs of sound transmitted to hearing aids given to participants of the EVOTION projects and (b) feedback from these participants regarding the effectiveness of use of HLs (AUD.7). 2. PHAA defines the types of data to be collected and analysed by the model. These include: (i) logs of sound transmitted to hearing aids given to participants of the EVOTION projects; (ii) the activity supported by HLs (e.g., banking); (iii) the location and noise profile of the overall environment where the HLs are installed; (iv) the level of the hearing loss (as measured by AUD.1, AUD.2, AUD.3 and AUD.4), (v) the behavioural profile of the HA users (i.e., the behavioural and lifestyle data BHP.1, BHP.2, BHP.3, BHP.4 and BHP.5), and (vi) feedback from participants regarding the effectiveness of use of HAs with HLs (AUD.7). 3. PHAA specifies the types of data analysis that will be performed as part of the PHP decision making model. PHAA does so by selecting from pre-defined types of analysis available in the EVOTION platform. The selected analysis types for the model include classic statistical analysis (regression, correlation, ANOVA) between (i)-(v) and (vi) and the use of supervised learning algorithms for building data mining models to predict (vi) from (i)-(v). 4. PHAA specifies the criteria that should be applied to establish the significance of the outcomes of the analysis. These criteria relate: (i) to

	the minimum size of the data set that should be considered, and (ii) the statistical significance of the results. 5. PHAA initiates a data analysis session and specifies that he/she should receive notifications when 25%, 50%, 75% and 100% of the minimal data set has been analysed. 6. The EVOTION platform records partial outcomes of its analysis and notifies the owner of the task as specified in Step 5 above. 7. PHAA uses the EVOTION platform to visualise the outcomes of the different types of analysis. 8. Based on the outcomes of the analysis, PHAA identifies factors that have a significant impact on the effectiveness of HL use. 9. PHAA invites specific stakeholders to participate in an EVOTION-facilitated discussion aimed at formulating a policy on the effective use of HL, and gives them access to the outcomes of the analysis to enable them to form and express their views. 10. The invited stakeholders access the recorded information regarding the factors that appear to be affecting the effective use of HLs and record their views into the EVOTION platform. 11. When enough stakeholders have expressed their views, PHAA requests the EVOTION platform to carry out an analysis of the expressed views and to make suggestions for alternative ways of addressing the effective use of HL based on the views/arguments expressed and the collected evidence. 12. EVOTION makes such suggestions and notifies all stakeholders. 13. All stakeholders including PHAA review the suggestions and express their final positions. 14. If the analysis of the expressed positions indicates that an alternative reaches sufficient majority, EVOTION generates it as a potential policy model for implementation.
Alternate Flows	8.AC1. The outcomes of analysis provide insufficient evidence. 8.AC1.1 PHAA asks the EVOTION platform to continue the collection of data until the originally envisaged data set is doubled. 8.AC2. The outcomes of analysis provide insufficient evidence. 8.AC2.1 PHAA decides to stop the relevant analytic activity and closes the ongoing policy exploration activity. 14.AC1. A model is formulated only if there is consensus. 14.AC2. If the analysis of expressed positions indicates extensive disagreement, EVOTION identifies the “tension points” and presents the outcomes of the analysis to the stakeholders involved.
Postconditions	

6.1.6. Exploration of factors for prevention of cognitive decline

Use Case Id	PHAS.6
Use Case Name	Exploration of factors for prevention of cognitive decline
Use Case Summary	This use case captures scenarios focusing on the exploration of cognitive decline in HA users. This is important as there have been studies suggesting that people with mild (moderate) hearing loss are more likely to develop some form of cognitive decline (e.g., dementia) than people without any HL. The scenario supports the collection and analysis of information to enable the identification of factors that are likely to have an effect on (preventing) cognitive decline and the formation of policies for relevant interventions. In

	particular, it will support the collection and analysis of cognitive data and their correlation with the level and type HL, clinical and medication data, physiological data, personal and medication data, and behavioural/life style data. The scenario covers the first phase of public health policy formulation, namely situational analysis.
Actors	Public health authority actor PHAA (Ministry of Health, Hearing Aid programme team actors)
Preconditions	
Trigger	
Basic Flow	1. PHAA creates a new PHP decision making model focusing on the identification of cognitive decline amongst HA users and factors that may affect it. 2. PHAA defines the types of data to be collected and analysed for this purpose. These include: (i) cognitive data (CGD.1, CGD.2, CGD.4); (ii) data about the level and type of HL (i.e., AUD.1, AUD.2, AUD.3, AUD.4); (iii) physiological data (i.e., PHD.1, PHD.2); (v) clinical and medication data (i.e., CMD.7); (vi) personal data (i.e., PED.1 – PED.6) and (vii) behavioural data (i.e., BHP.1 – BHP.5). 3. PHAA specifies the types of data analysis that will be performed as part of the PHP decision making model. PHAA does so by selecting from pre-defined types of analysis available in the EVOTION platform. The model will include stratified analysis using: (a) classic statistical analysis (regression, correlation, ANOVA) to investigate the presence of effects of (ii)—(vii) onto (i), and (b) supervised learning algorithms for building data mining models to predict (i) from (i)-(v) in (a) demonstrates statistically significant relations. 4. PHAA specifies the criteria that should be applied to establish the significance of the outcomes of the analysis. These criteria refer to: (i) the minimum size of the data set that should be considered, (ii) the time over which data need to be collected in order to be able to form some judgement of the evolution of cognitive capability, and (iii) the statistical significance of the results. 5. PHAA identifies the subjects who will participate in the study, configures the platform to collect data from them, and initiates the execution of the PHP decision making model, i.e., the continuous collection and analysis of data. 6. PHAA uses the EVOTION platform to visualise the outcomes of the different types of analysis, as the study progresses. The platform generates such outcomes on bi-annual basis. 7. At the end of the study, PHAA identifies factors that appear to have a significant impact on the cognitive activity of HA users, and asks the platform to generate a report with the main outcomes of the study. The latter include the factors that have a statistically significant effect on the cognitive activity of HA users and the predictive models that have shown a high prediction accuracy (i.e., can predict cognitive levels with a deviation from actual values of no less than 15%). 8. PHAA requests the platform to store the outcomes of all types of analysis that have been conducted and index them based on the defined PHP making model for future use. He/she also asks the platform to archive the collected primitive data sets in an anonymised and controlled access form.

	9. PHAA gives access rights to other stakeholders for visualising selected outcomes of the study.
Postconditions	1. The outcomes of all types of analysis that have been conducted by the EVOTION platform are recorded in the platform, are indexed based on the PHP making model underpinning for analysis. archiving of the original datasets in an anonymised and controlled access form. 2. The original datasets used in the analysis are archived by the platform in an anonymised and controlled access form.

The elicited requirements from the above scenarios are presented at the below table.

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(PHAS)1	Mechanism for collecting data of different types	Must have	p
FR(PHAS)2	Discover factors of low HA usage	Must have	P
FR(PHAS)3	Identify relevant studies and provide a summary of them	Must have	P
FR(PHAS)4	Filter the relevant studies	Must have	P
FR(PHAS)5	Cluster the relevant studies	Should have	P
FR(PHAS)6	Characterize data to define the size of the dataset	Should have	P
FR(PHAS)7	Support different types of data analysis	Should have	P
FR(PHAS)8	Support different types of data tests	Should have	P
FR(PHAS)9	Produce and manage metrics for the quality of analysis	Could have	P
FR(PHAS)10	Initiate data analysis session	Must have	P
FR(PHAS)11	Administrate (create, update, delete) analysis' outcomes	Must have	P
FR(PHAS)12	Notification when analysis is complete	Must have	P
FR(PHAS)13	Visualizations of the analysis outcome	Must have	P
FR(PHAS)14	Suggest factors of analysis' outcome	Must have	P
FR(PHAS)15	Re-analysing a specific dataset with different factors	Must have	P
FR(PHAS)16	Data analysis, in a statistical way, between different data types	Should have	P
FR(PHAS)17	Support multiple types of analysis' criteria	Must have	P
FR(PHAS)18	Support of progressive notifications and save of the outcomes on data analysis	Should have	P
FR(PHAS)19	Support Online discussions	Must have	P
FR(PHAS)20	Access management features for the analysis outcomes	Must have	P
FR(PHAS)21	Analyze expressed evidence from the online discussions and suggestions	Should have	P
FR(PHAS)22	Notifications with suggestions about alternative ways of addressing the effective use of HL	Must have	P

FR(PHAS)23	Deliberation mechanism on the EVOTION's suggestions	Should have	P
FR(PHAS)24	Identification of the resulting tense and generation of a potential policy model for implementation	Should have	P
FR(PHAS)25	Extend the criteria for the data collection process	Must have	P
FR(PHAS)26	Stop the relevant analytic activity	Must have	P
FR(PHAS)27	Configurable on what consensus on a policy model means	Should have	P
FR(PHAS)28	Visualize comparative policy models for implementation	Should have	P

6.2. For Clinical Users

In the following table, results of the validation during the focus group are presented

6.2.1. Retrieval of HA usage data

Use Case Id	CLIS.1
Use Case Name	Retrieval of HA usage data
Use Case Summary	This use case captures scenario regarding the clinical use of the EVOTION platform in regards to improvement of hearing aid fitting, increased patient satisfaction and upgrade of hearing aid assessment to evidence based on streaming data. The scenario is related to the initial set up of the EVOTION platform to the individual patient and to the follow up visit(s) protocol. According to current *"as is"* scenario, patients have an initial visit in which a standardized protocol is followed in order to achieve optimal hearing aid fitting based on specific features. During follow up visit, problems and constraints of hearing aid used are referred by the patient and generic data of HA usage are displayed in the audiologist, retrieved by HA memory. Important constraints occur, since HA memory is restricted by HA size. Audiologist has access to non-specific data in regards to time periods of HA usage. It is not feasible to know usage time per day and usage time related to environment, noise exposure and activities. Consequently, feedback is subjective and affected by memory bias. This scenario describes how objective data will be retrieved by the EVOTION platform, allowing evidence based evaluation of HA usage.
Actors	Audiologists/audiological scientists performing hearing aid fitting.
Preconditions	Access to EVOTION platform. Use of certain mobile phones by patients. Patient education. Concurrent use of HAs and mobile phones.
Trigger	Need for optimal patient data recording and HA usage
Basic Flow	1. Periods of HA usage are automatically recorded by the EVOTION mobile application 2. Unlimited ratings of HA ease of use (BHD 3) can be provided by the user, right after he or she experiences problems. Ratings will be recorded and will be accessible during follow up visit.

	3. Correlations of HA usage with noise exposure, environment (END 1,2,3) and activities as recorded by the sensors (working, driving, watching TV-BHD 1,2,4,5) are provided. 4. Records are transferred in EVOTION repository 5. Data will be available both in raw format as well as in cumulative format and in diagrams and charts. 6. During follow up visit, Audiologist will have the opportunity to correlate aforementioned HA ratings with these actions and maybe suggest an adaptive change of fitting parameters during these activities 7. Fitting profiles can be increased and optimized. Change of fitting parameters can be programmed to be automatic after detection of change in END or BHD parameters in the future
Alternate Flows	
Postconditions	Audiologist/audiological scientist will use this information in order to have an overview of actual HA usage. This feedback is tremendously useful for HA fitting optimisation.

6.2.2. Transfer Data to clinicians and audiologist

Use Case Id	CLIS.2
Use Case Name	Sudden Deterioration of Hearing
Use Case Summary	During the active use of the EVOTION Hearing Aids sudden hearing alterations can occur. These should be analysed by the clinician and/ or audiologist. It would be very helpful for them to base their analysis on the actual objective data related and recorded at the event (probably some minutes before and after) and not on the subjective impression of the patient. Therefore, a needed functionality would allow the patient to indicate, through the smart-phone application that an event has occurred. This would trigger the transfer of the relevant data (AUD.1) at the time of the event to the clinician and/or audiologist.
Actors	Patient. Clinician/ Audiologist
Preconditions	Concurrent use of HAs and mobile phones.
Trigger	Occurrence of sudden hearing alterations to the patient.
Basic Flow	1. Patient uses EVOTION Hearing Aids and smart-phones. 2. Patient suffers from a sudden hearing alteration. 3. Patient indicates through the smart-phone application that an event has occurred. 4. The relevant data, before, during and after the event are transferred to the Clinician and/or Audiologist. 5. Clinician and/or Audiologist can analyse the event better based on objective real data. Analysis will include pure tone audiometry in quiet, speech audiometry in quiet and auditory evoked potentials).
Alternate Flows	
Postconditions	Better evaluation of sudden hearing alterations.

6.2.3. "Ask the expert" hearing aid fitting (à la Watson)

Use Case Id	CLIS.3
Use Case Name	"Ask the expert" hearing aid fitting (à la Watson)
Use Case Summary	The clinician fitting hearing aids has an option in the fitting software called "ask the expert". When the clinician selects this option, the software takes into account the information the clinician has entered about a specific patient (age, hearing impairment, cognitive status, activity level, etc) to suggest the best hearing aid type and hearing aid settings for that person. These recommendations are based on a large study that tracked the hearing aid usage and outcomes of over 1000 hearing aid users. These recommendations insure that the clinician adheres to best practices and it takes the guessing game out of selecting and adjusting hearing aids for every patient. The clinician can always make changes to the recommendations of "ask the expert" based on the individual patients' preferences. These changes further inform the recommendations the system generates in the future. Patient outcomes are also registered over time to further inform the recommendations the system generates in the future.
Actors	Clinician-audiologist Patient
Preconditions	Big data analytics came to clinically useful recommendations. The clinician-audiologist can obtain the patient required for patient differentiation (eg, age, hearing impairment, is easy but cognitive status, activity level, etc can be difficult). The clinician-audiologist believes in the evidence base and the value of "ask the expert".
Trigger	Clinician-audiologist sees value in "ask the expert".
Basic Flow	1. The clinician fitting hearing aids has an option in the fitting software called "ask the expert". When the clinician selects this option, the software takes into account the information the clinician has entered about a specific patient (age, hearing impairment, cognitive status, activity level, etc) to suggest the best hearing aid type and hearing aid settings for that person. These recommendations are based on a large study that tracked the hearing aid usage and outcomes of over 1000 hearing aid users. These recommendations insure that the clinician adheres to best practices and it takes the guessing game out of selecting and adjusting hearing aids for every patient. 2. The clinician can always make changes to the recommendations of "ask the expert" based on the individual patients' preferences. 3. These changes further inform the recommendations the system generates in the future. 4. Longitude data will also be collected for future use
Alternate Flows	
Postconditions	

6.2.4. Assessment of initial follow up policies

Use Case Id	CLIS.4
Use Case Name	Assessment of initial follow up policies
Use Case Summary	This use case captures scenarios regarding the assessment and formation of protocols for follow up appointments in the initial phase following the fitting of HAs, with the aim to increase the cost effectiveness of such policies. More specifically, the use case is aimed at investigating potential factors that may indicate low/ineffective HA usage within the first 4-6 weeks after the initial

	fitting of the HAs, which is a critical period for the acclimatisation of HA users to HAs. This use case will help to identify profiles of users who would benefit from earlier remote interventions that can reduce the number of physical follow appointments, and maximise the overall satisfaction of HA users.
Actors	Clinical actor (CLINA)
Preconditions	
Trigger	
Basic Flow	1. CLINA explores the different types of data that can be collected and analysed by the EVOTION platform and selects some of them, which are likely to prevent the effective usage of HAs in the first few weeks after HA fitting. 2. Following a review of related studies that are available through the EVOTION platform, CLINA selects the following potential factors for prognosis low initial HA usage: environment (END.1 – END.3), personal (PED.1 – PED.4), behavioural (BHD.1 – BHD.3), clinical (CGD.1 – CGD.4), physiological (PHD.1 – PHD.3)) data. 3. CLINA determines that the analysis will be based on prospective data initially and defines the minimum size of data that should be collected and analysed. 4. CLINA determines the types of data analysis that will be performed upon the data and the tests that should be applied to establish the sensitivity and the significance of the outcomes of the analysis. 5. CLINA initiates a data analysis session using the EVOTION platform. 6. The EVOTION platform records the outcomes of its analysis in reference to the new task. 7. CLINA uses the EVOTION platform to visualise the outcomes of the analysis. 8. Based on the outcomes of the analysis, CLINA identifies factors of low and promising prognostic value and marks them as such. 9. For factors with promising prognostic value, CLINA initiates a further analysis task following steps 3-5. 10. Based on the outcomes of the additional analysis, CLINA identifies factors of low and promising prognostic value and marks them as such. (Several rounds of additional analysis may be requested). 11. If, after considering a data set that exceeds the minimum size set in Step 3, the analysis reveals factors of high prognostic value, CLINA asks EVOTION to produce notifications of patients who would benefit from early interventions (e.g., provision of remote guidelines or early follow up appointments) and patients who would not require physical follow up appointments.
Alternate Flows	
Post conditions	The task and the outcome of the recorded analysis will be recorded in the EVOTION platform for future analysis

6.2.5. Protection of people with hearing impairments from the harmful effects of loud noise: individualized risk assessment

Use Case Id	CLIS5-NIHL
Use Case Name	Protection of people with hearing impairments from the harmful effects of loud noise: individualized risk assessment

Use Case Summary	This use case captures scenario regarding determination of individualised (environmental, physiological) factors associated with increased risk for Temporary Threshold Shift (TTS) or noise induced hearing loss (NIHL) for prevention of further TTS/NIHL episodes.
Actors	Clinical Stakeholder: Audiologist.
Preconditions	Access to EVOTION platform. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. Patient exposure to leisure noise while using HAs and wearing sensors.
Trigger	There is individual susceptibility to TTS/NIHL and legally determined "safe" noise levels may not be safe for all individuals; combination of noise and other potential risk factors may increase risk of TTS/NIHL.
Basic Flow	PATIENT DOES NOT RECORD TTS/NIHL EPISODE OR SEEK MEDICAL HELP; 1. Patient returns for 3 month follow up 2. During follow up visit, Audiologist/audiological scientist accesses automatically recorded data regarding TTS/NIHL 3. Audiologist retests patient 4. Audiologist re-educates patient re NIHL 5. Audiologist records TTS episode retrospectively 6. EVOTION system determines combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes 7. EVOTION system sets automatic alerts to prevent further episodes
Alternate Flows	1. Patient is diagnosed with hearing loss and referred for hearing aid fitting by ENT/AVM/Audiologist. 2. Audiologist/audiological scientist performs initial hearing tests and open mould hearing aid fitting 3. Standard hearing aid usage education is provided by audiologist/audiological scientist 4. Patient is educated to monitor for TTS/NIHL and perform a hearing test as soon as TTS/NIHL noticed (written instructions on EVOTION app) 5. EVOTION HA system records ambient noise level and patient physiological data (oxygen saturation, blood pressure) automatically 6. Patient perceives TTS/NIHL 7. Patient self tests hearing and confirms NIHL 8. EVOTION HA system alerts the patient to seek urgent medical attention 9. PATIENT RECORDS TTS/NIHL EPISODE 10. PATIENT SEEKS MEDICAL HELP AND ENTERS CLINICAL PATHWAY 11. EVOTION system determines combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes 12. EVOTION system sets automatic alerts to prevent further episodes
Postconditions	Audiologist will use this information in order to determine individualised risk factors for TTS/ NIHL and prevent further episodes. The TTS/NIHL episodes and related data (test results, environmental/physiological data) are recorded in the EVOTION platform for several HA users. Successive stages of analysis will inform public health case scenaria.

6.2.6. Individualised auditory training (AT) to optimise HA benefits and prevent or delay cognitive and auditory processing deterioration

Use Case Id	CLIS.6

Use Case Name	Individualised auditory training (AT) to optimise HA benefits and **prevent** or delay **cognitive and auditory processing deterioration**
Use Case Summary	This use case captures scenarios regarding determination of individualized auditory training in cases who do not fulfil "classic" criteria to prescribe AT. AT will be determined on the basis of real life HA user experienced communication difficulties and association of such difficulties with HA usage. Auditory training will aim towards improvement of speech in noise perception, auditory memory and localization abilities of the EVOTION user. To this end, the system will employ a mixture of artificially listening scenarios and dynamically selected real listening scenes that the specific HA user has experienced and found it difficult to cope with, which will be presented to the HA user for training purposes. The training material will include words and non-words and sentences. Current *"as is"* scenario, does not include the auditory training potential for HA users. Implementation of AT in EVOTION platform is expected to increase compliance and adapt AT in specific user's needs.
Actors	Clinical Stakeholder: Audiologist. Patient stakeholder: patient
Preconditions	Access to EVOTION platform. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. Patients engaging with AT. Patients returning for 6 month additional follow up.
Trigger	There is individual susceptibility to TTS/NIHL and legally determined "safe" noise levels may not be safe for all individuals; combination of noise and other potential risk factors may increase risk of TTS/NIHL.
Basic Flow	1. Patient is diagnosed with hearing loss and referred for hearing aid fitting by ENT/AVM/Audiologist. 2. Audiologist/audiological scientist performs initial hearing tests and basic cognitive screening tests, including questionnaires, like the Montreal Cognitive Assessment (MOCA). 3. Audiologist/audiological scientist performs initial open mould hearing aid fitting 4. Patient performs speech in noise tests on mobile phone app 5. Audiologist records MOCA and speech in noise tests as normal 6. Standard hearing aid usage education is provided by audiologist/audiological scientist 7. Patient uses HA and sensors in a variety of environments (single speaker noise, multiple talker noise, non-speech noise). ENDS nand BHD parameters will be recorded. 8. EVOTION HA system records ambient noise level (END 2), duration of noise exposure and patient physiological data (skin conductance, blood pressurePHD 1-5) automatically 9. EVOTION HA system transfers records in cloud service 10. Patient returns for 3 month follow up 11. Audiologist performs outcome measures 12. Patient performs outcome measures on app 13. EVOTION HA system provides data in cumulative diagrams and charts format: skin conductance (listening effort) is increased in certain noise (eg multitalker noise) or in other noisy situations after prolonged noise exposure (need to rely on memory resources) 14. EVOTION system provides HA usage data for different combinations of noise types/levels/duration of exposure 15. Audiologist accesses automatically recorded data 16. Audiologist educates patient in auditory training 17. Audiologist prescribes auditory training dependent on automatically recorded data. This is expected

	18. Patient performs auditory training on a regular basis at home, using words, sentences and other material. 19. Progress in AT is recorded and feedback is provided by the EVOTION platform 20. When certain milestones are reached (discrimination, discrimination in noise), AT steps up in more difficult program. 21. Feedback is also provided by the patient 22. Patient returns for 6 month follow up and performs outcome measures
Alternate Flows	AF16 – Patient does not performs auditory training in a regular basis at home AF16 BF1 Patient returns for 6 month follow up and performs outcome measures
Postconditions	Audiologist will use this information in order to determine individualised AT. Outcome measures (HA use and MOCA in particular) and AT related data (type of training, dosage) are recorded in the EVOTION platform for several HA users. Successive stages of analysis will inform public health case scenario: does AT help improve HA use (and which type/dosage of AT), prevent cognitive decline, improve listening effort

6.2.7. Collection of HL related web and social net-work data

Use Case Id	CLIS.7 (WEB)
Use Case Name	Collection of HL related web and social net-work data
Use Case Summary	This use case captures a scenario in which the EVOTION platform will capture data from social networks This scenario is innovative, since it will capture significant information that was not accessible until social network development and can give valuable feedback for HA usage and users satisfaction. Both direct comments and indirect information will be recorded (related to location, activity, mood etc)
Actors	Patients. Audiologist/audiological scientist, IT.
Preconditions	Access to EVOTION platform. Use of smart mobile phones by patients. Existing social network accounts of patients. Consent of the users that the EVOTION platform collects social network data.
Trigger	Need for objective record of data and additional input extending traditional approach and parameters.
Basic Flow	1. Patient is diagnosed with hearing loss and a hearing aid is recommended by the ENT/AVM physician. 2. Audiologist/audiological scientist performs initial hearing aid fitting 3. Standard hearing aid usage education is provided by the audiologist/audiological scientist 4. Patient is provided with smart mobile phone 5. Patient informs for the existence of social network account and activity 6. Patient gives consent for access to social network information 7. Parameters such as location (smartphone GPS), activity (step count/distance walked smartphone health app), mood (app questionnaires) are recorded. 8. This information can be related with events on the time domain (social network activity) and also be cumulatively correlated with patient satisfaction (primary outcome questionnaire).
Alternate Flows	
Postconditions	Audiologist/audiological scientist will have access to social network data cumulative recordings. Successive stages of analysis will identify parameters

	from social network activity that may predict HA usage. Successive stages of analysis will inform public health case scenaria.

6.2.8. Collection of sensors data and upload to the Cloud

Use Case Id	CLIS.8 (SENSORS)
Use Case Name	Collection of sensors data and upload to the Cloud
Use Case Summary	Throughout the use of the EVOTION platform, data of various types will be collected. Among them are data collected through patient-wearable sensors. Data include: • PHD.1. heart and respiratory rate • PHD.2. blood pressure • PHD.3. temperature • PHD.4. skin conductance • PHD.5. oxygenation In order to gain value from the collection of the data above the following have to be implemented: 1. Data need not only be collected but also stored for further-on analysis. Such storage should be provided in the Cloud. 2. Data should be able to be compared with additional data collected through the HAs, so as to be able to mine possible correlations, etc.
Actors	Patient Stakeholder
Preconditions	Concurrent use of HAs and sensors.
Trigger	Storage of sensors' data can be triggered both: 1. At a periodic basis, e.g. daily at a specific time. At that time the upload of daily gathered data should be made together with data collected through the HAs. 2. At a time of an event. At this particular instance, both sensors' data and HA-collected data (e.g environmental noise, conversations) should be bundled together and uploaded simultaneously to the Cloud for analysis.
Basic Flow	1. Patient is diagnosed with hearing loss and hearing aid is suggested by ENT physician. 2. Audiologist/audiological scientist performs initial hearing aid fitting 3. Standard hearing aid usage education is provided by audiologist/audiological scientist 4. Patient is provided with wearable sensors and uses them throughout the defined period of data collection 5. Data are automatically collected through the sensors and uploaded periodically in the Cloud together with data collected through HAs. Upload happens on an ad hoc basis in case of an event 6. Analysis of all the collected data. 7. Correlation of events recorded with sensors with HL deteriotation and occurence of tinnitus 8. Consideration of protective measures or adaptive antihypertansive therapy, in case of high values of blood pressure

Alternate Flows	
Postconditions	Use of stored data from patients' sensors' to be used for analysis.

6.2.9. Cognitive data

Use Case Id	R-CLIS.9 (COG)
Use Case Name	Cognitive data
Use Case Summary	Patients with hearing impairment are frequently offered hearing aids as part of rehabilitation. The epidemiology of hearing aid use is skewed towards the older adult. It is well recognised that cognitive impairment is increasingly common with older age. Cognitive factors may affect audiological rehabilitation in terms of assessment capability and also in terms of selection of rehabilitation tools. Cognitive impairment can be missed if not specifically sought and can lead to suboptimal auditory rehabilitation.
Actors	Clinician-audiologist
Preconditions	Data is visualised in a meaningful way for all actors. Audiologist able to interact with evotion interface. All conditions that must be satisfied prior the commencement of the interaction described by the use case.
Trigger	Audiology service seeking to improve uptake and maximise efficient use of resources.
Basic Flow	1. Patient presents for hearing aid fitting. 2. Clinician identifies cognitive impairment using standardized assessment tool (as per WP7 clinical evaluation) 3. Clinician inputs cognitive test score into EVOTION platform. Platform flags cognitive impairment and degree of severity (mild, moderate, severe) according to standardized instrument. 4. Patient is fitted with EVOTION hearing aids. 5. EVOTION aids upload real time data to platform. 6. At review, clinician views cognitive scores, real time usage and patient feedback. 7. Clinician can tailor rehabilitation to needs.
Alternate Flows	
Postconditions	Clinician applies information in specific clinical context.

6.2.10. Collection of questionnaire answers through the platform

Use Case Id	CLIS.10 (QUESTIONNAIRES)
Use Case Name	Collection of questionnaire answers through the platform
Use Case Summary	Throughout the period of patients' data collection for the EVOTION platform the patients will need to answer to specific questionnaires in order to facilitate remote assessment of auditory disability, hearing-aid benefit etc. These

	questionnaires can be provided through the smart-phone EVOTION application. The questionnaires should be based on accepted and established assessment methodologies, such as the Glasgow Hearing Aid Benefit Profile. Questionnaires should be uploaded by Clinical Stakeholders and should be short in length so as not to discourage patients from filling them in.
Actors	Patient Stakeholder, Clinical Stakeholder
Preconditions	Concurrent use of HAs and sensors.
Trigger	Patient is notified for the availability of the questionnaire and the need to fill it in through the smartphone application.
Basic Flow	1. Clinical Stakeholder uploads questionnaire 2. Patient is notified of the need to fill-in the questionnaire 3. Patients fills it in 4. Data is transferred to the EVOTION platform where Clinical stakeholder has access to 5. Analysis is performed to provide assessment.
Alternate Flows	
Postconditions	Use of questionnaire-derived data for patient's improved clinical evaluation and assessment.

6.2.11. Diary of HL related event and HA malfunctions and problems

Use Case Id	CLIS.11 (MALFUNCTIONS)
Use Case Name	Diary of HL related event and HA malfunctions and problems
Use Case Summary	This use case captures scenario regarding ability of the EVOTION platform user to record events related to HL as well as problems and malfunctions of the HA. The *as is* scenario (current practice) says that such problems are mentioned during follow up visits and their frequency, duration and significance are subject to memory bias. User will be able to record HA related problems (fitting problems, earache, autophony, whistle sounds, artificial sound perception etc) in a diary. Closed set of most common problems will be available for the user to choose, facilitating data management, whereas open commentary will also be available. Furthermore, level of annoyance will also be recorded, using a 1-5 scale. Both audiologists/audioprosthetists and patients will have access to this information. This scenario describes how HA malfunction data will be recorded and stored by the EVOTION platform.
Actors	Audiologists/audiological scientists performing hearing aid fitting. Hearing aid users.
Preconditions	Access to EVOTION platform. Use of certain mobile phones by patients. Development of an app with closed and open set questions in a diary form. Patient education. Concurrent use of HAs and mobile phones.
Trigger	Need for objective record of HA related problems
Basic Flow	1. Patient is provided with mobile phone

	2. Apps able to record HA and HL related problems are crested and their basic usability is tested. 3. Apps are deigned in a user friendly way, including voice recognition and convenient fonts. 4. Most common sources of annoyance are listed and user can choose more than one option, as many times as he or she wishes. 5. During follow up visit, Audiologist/audiological scientist will have automatic access to this information recorded. 6. Data will be available both in raw format as well as in cumulative format and in diagrams and charts.
Alternate Flows	
Postconditions	Audiologist/audiological scientist will have access to objective recording about HA malfunctions and HL related problems

6.2.12. Performing audiological tests through HA.

Use Case Id	CLIS.12 (TESTS)
Use Case Name	Performing audiological tests through HA.
Use Case Summary	This use case captures scenario regarding the clinical use of the EVOTION platform in regards to remote, platform based performance of audiological tests (pure tone audiogram, speech in noise test, auditory evoked potentials). The scenario is related to the initial set up of the EVOTION platform to the individual patient and to the follow up visit(s) protocol. Currently, there are apps available, able to conduct audiometry. In the context of the EVOTION project, SIN and evoked potential apps will also be developed. Audiological tests will both be performed on demand (after certain events such as noise exposure) or in preset periods, after notification of the user by the platform. This scenario describes how audiological tests data will be recorded and stored by the EVOTION platform.
Actors	Audiologists/audiological scientists performing hearing aid fitting.
Preconditions	Access to EVOTION platform. Use of certain mobile phones by patients. Development of relevant apps and interfaces for PTA, SIN, evoked potentials. Ability of the platform to perform tests online and timely and correctly relate stimuli to response. Patient education. Concurrent use of HAs and mobile phones.
Trigger	Need for performance of audiological tests in order to correlate results with environmental conditions and hearing related events
Basic Flow	1. Patient is diagnosed with hearing loss and hearing aid is 2. Apps able to perform PTA, SIN and evoked potentials are connected to the platform (or developed as a component) 3. Quality control is performed in regards to the tests 4. Calibration procedure is performed prior to tests (preferably automatic) 5. There is interaction between user and apps 6. Audiological tests are performed both in quiet and in noise (platform is able to identify quiet and noisy environments) 7. Records are transferred in cloud service including parameters AUD1-5.

	8. During follow up visit, Audiologist/audiological scientist will have automatic access to this information recorded. 9. Data will be available both in raw format as well as in cumulative format and in diagrams and charts.
Alternate Flows	
Postconditions	Audiologist/audiological scientist will have access to actual audiological test results during periods of HA usage.

The elicited requirements from the above scenarios are presented at the below table.

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(CLIS)29	Mobile app communicates with HA devices	Must have	M
FR(CLIS)30	Mobile app collect data from HA devices	Must have	M
FR(CLIS)31	Mobile app provides a window to rate the HA ease of use	Must have	M
FR(CLIS)32	Mobile app identify problems in the communication with the HA device	Must have	M
FR(CLIS)33	Mobile app sends stream of user ratings to the EVOTION platform	Should have	M
FR(CLIS)34	Manage and visualise the history of ratings on the HA ease	Should have	
FR(CLIS)35	Collect environmental noise and noise coming from user activities and send them to the EVOTION platform	Must have	M
FR(CLIS)36	Correlation of HA usage with collected noise data	Should have	P
FR(CLIS)37	Manage HA usage with problems occurred, ratings provided and corresponding noise recorded	Could have	P
FR(CLIS)38	Different visualization modes of the recorded data	Should have	P
FR(CLIS)39	Allow audiologists to access the recorded data	Must have	P
FR(CLIS)40	Audiologists modifies fitting parameters	Must have	P
FR(CLIS)41	Audiologists modifies fitting parameters	Must have	P
FR(CLIS)42	Analyse END or BHD parameters and automatically respond to them by changing the fitting profile	Must have	P
FR(CLIS)43	Communicate of the new fitting profile to the EVOTION mobile app	Should have	M
FR(CLIS)44	Configure the HA device fitting parameters	Must have	M
FR(CLIS)45	Insert a new event	Must have	M
FR(CLIS)46	Collect timestamped data related to an event for a configurable period between before the event occurrence and after it	Must have	M

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(CLIS)47	Communication of a detected event record to the EVOTION platform	Must have	M
FR(CLIS)48	Manage and visualize a detected event record	Should have	P
FR(CLIS)49	Provide objective real data relevant to the detected event	Must have	P
FR(CLIS)54	Interface with the fitting hearing aids software to allow clinicians to request recommendations	Must have	P
FR(CLIS)55	Select a different device, based on patient's preferences and record this selection	Could have	P
FR(CLIS)56	Visualize a list of data types that are collected in the platform	Must have	P
FR(CLIS)57	Provide a list of studies for inspection	Should have	P
FR(CLIS)58	Select from a list of data types	Must have	P
FR(CLIS)59	Visualize TTS/NIHL data recorded for a selected patient	Must have	P
FR(CLIS)60	Provide aggregated records of TTS episodes from patients from retrospective studies	Must have	P
FR(CLIS)61	Analyse data and suggest combination of factors affecting TTS and NIHL episodes	Must have	P
FR(CLIS)62	Compose alerts for a patient, based on desired values for the factors affecting TTS / NIHL episodes	Must have	P
FR(CLIS)63	Allow TTS/NIHL data monitoring and provide a wizard to guide patients in performing a hearing test on their own	Must have	M
FR(CLIS)64	Mobile app should be able to record noise level and physiological data automatically	Must have	M
FR(CLIS)65	Mobile app allows patients to start a hearing test and declare NIHL events	Must have	M
FR(CLIS)66	Mobile app raises alerts for urgent medical attention	Could have	M
FR(CLIS)67	Mobile app allows patients to manually insert a TTS / NIHL episode	Must have	M
FR(CLIS)68	Record the patient' responses to various standardized questionnaires	Must have	P
FR(CLIS)69	Create record for hearing aid fitting	Must have	
FR(CLIS)70	Provide speech in noise tests and communicate results to the platform	Must have	M
FR(CLIS)71	Categorise the questionnaires responses and the speech in noise test results as patient's initial record	Should have	P
FR(CLIS)72	Record END and BHD data	Must have	M

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(CLIS)73	Mobile app should records ambient noise level data, duration of noise exposure and physiological data	Must have	M
FR(CLIS)74	Mobile app communicates with the platform	Must have	M
FR(CLIS)75	EVOTION platform deployed on the cloud	Should have	P
FR(CLIS)76	EVOTION platform analyse outcome measures	Must have	
FR(CLIS)77	Visualize aggregated data sets	Must have	P-M
FR(CLIS)78	Visualize HA usage data with respect to various noise parameters	Must have	P-M
FR(CLIS)79	Creation of auditory training sessions	Must have	P
FR(CLIS)80	Retrieve respective auditory training sessions	Should have	M
FR(CLIS)81	Mobile app should allow patients to respond to auditory trainings and get assessment from the EVOTION platform	Must have	P
FR(CLIS)82	Analyze the responses to the auditory training tests	Must have	P
FR(CLIS)83	Provide auditory training sessions of various level of difficulty	Must have	P
FR(CLIS)84	Automatically switch between different auditory trainings	Should have	P
FR(CLIS)85	Mobile app records patient feedback on a training	Must have	M
FR(CLIS)86	Maintain results and score of cognitive tests for each patient	Must have	P
FR(CLIS)87	Associate cognitive scores with collected HA usage data and patients' feedback	Must have	P
FR(CLIS)88	Create an initial record with the lifestyle and listening environment requirements per patient	Must have	P
FR(CLIS)89	Connect with the hearing aids software selection service	Should have	P
FR(CLIS)90	Platform and mobile app collects real-time listening environment data and automatically adjust the fitting settings	Must have	P-M
FR(CLIS)91	Mobile app connects to the user profile in the social networks	Must have	M
FR(CLIS)92	Mobile app stores user consent action for accessing social networks	Must have	M
FR(CLIS)93	Mobile app records different data streams	Must have	M
FR(CLIS)94	Analyse patient activity in the social networks and relate it with events captured from the patient's HA and mobile devices	Should have	P-M

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(CLIS)95	Analyse captured events from the patient's devices in relation to the patient responses in the questionnaires	Could have	P
FR(CLIS)96	EVOTION HA BP sensor should be able to calculate when BP exceeds the predefined thresholds	Should have	P-M
FR(CLIS)97	Provide a report about the collected BP values	Should have	P
FR(CLIS)98	Electronically transmits report to patient	Must have	P
FR(CLIS)99	Issue notifications with respect to actions that should be taken on detected BP events	Should have	P
FR(CLIS)100	Compare sensors' data and data collected from HAs	Must have	P-M
FR(CLIS)101	Mobile app should collect data from sensors and upload them to EVIOTION repository in a periodic basis	Should have	M
FR(CLIS)102	Mobile app should collect data from sensors and HAs and upload them to EVIOTION repository in an ad hoc basis in case of an event	Must have	M
FR(CLIS)103	Analyze sensors' and HAs' data	Must have	P
FR(CLIS)104	Manage surveys in order to create, update, delete, publish and assign surveys	Should have	P
FR(CLIS)105	Mobile app should notifies HA users to fill-in a questionnaire	Must have	M
FR(CLIS)106	Mobile app provides questionnaires to be filled-in by HA users and records HA users' answers	Must have	M
FR(CLIS)107	Access to questionnaires' answers	Must have	P
FR(CLIS)108	Analyze questionnaires' answers	Must have	P
FR(CLIS)109	Record HA and HL related problems	Should have	P-M
FR(CLIS)112	Mobile app provides a multi-selection list with the most common sources of annoyance	Must have	M
FR(CLIS)113	Mobile app records interactions of HA user with the multi-selection list of the most common sources of annoyance	Should have	M
FR(CLIS)114	Show interactions of the HA user with the multi-selection list of the most common sources of annoyance in raw format as well as in cumulative format and in diagrams and charts	Should have	P-M
FR(CLIS)115	Access to objective recording about HA malfunctions and HL related problems of HA users	Should have	P

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(CLIS)116	Mobile app supports PTA, SIN and evoked potentials	Could have	M
FR(CLIS)117	HA gets calibrated (preferably automatically) based on HA test's results	Should have	P
FR(CLIS)119	Mobile app performs audiological tests and records the test results (quiet/noisy environment sounds and AUD1-5 parameters)	Must have	M

6.3. For HA users & significant others

6.3.1. Downloading of personal data to a Personal Health Record

Use Case Id	PSOS.1
Use Case Name	Downloading of personal data to a Personal Health Record
Use Case Summary	Throughout the use of the EVOTION platform data will be collected. This kind of data could possibly be useful to a patient, for example if stored and displayed by a Personal Health Record application. As a hearing aid user, I can choose to store my own personal data locally. This functionality should be provided through the smart-phone application. The flow of data to the EVOTION platform will be in no way affected.
Actors	I am the hearing aid user or my carer.
Preconditions	Concurrent use of HAs and mobile phones.
Trigger	I need to store audiological data locally in order to be able to keep track of my hearing health.
Basic Flow	1. I use EVOTION Hearing Aids and smart-phones. 2. I choose to store personal audiological data locally, outside the EVOTION platform, for personal use. Personal use could include the data being used through a PHR, therefore the data should be extracted in an application-friendly standard format. 3. I extract the data locally by functionality provided through the EVOTION's smart-phone application 4. The flow of data to the EVOTION platform is in no way affected.
Alternate Flows	
Postconditions	Use of extracted data for patient's improved future clinical evaluation.

6.3.2. Text-based communication of the Hearing aid user and the Clinician and/or Audiologist through the EVOTION application

Use Case Id	PSOS.2
Use Case Name	Text-based communication of the hearing aid User and the Clinician and/or Audiologist through the EVOTION application

Use Case Summary	In order to facilitate the communication between the Hearing aid user and the Clinician, a text-based functionality of the smart-phone application would provide value. As a hearing aid user, I can send text messages to the Clinician and/or Audiologist and report any kind of problems encountered through the use of the Hearing Aids. The functionality would also add to the attractiveness of EVOTION platform when the latter will enter the commercial market.
Actors	Hearing aid user/significant other. Clinician/ Audiologist
Preconditions	Concurrent use of HAs and mobile phones.
Trigger	Patient who wants to communicate with the Clinician and/or Audiologist through the application.
Basic Flow	1. I (user) have EVOTION Hearing Aids and smart-phones. 2. I have an issue or concern I wish to discuss. 3. I can send text message(s) through the application to my clinician, stating the issue. 4. Messages can be received and answered in real-time.
Alternate Flows	
Postconditions	Better and faster communication between the Hearing aid user and the Clinician and/or Audiologist through the EVOTION application.

6.3.3. Self-testing of hearing and self-adjustment of hearing aids

Use Case Id	PSOS.3
Use Case Name	Self-testing of hearing and self-adjustment of hearing aids
Use Case Summary	The hearing aid user can test their hearing and adjust their hearing aids.
Actors	Patient or carer/Significant other Clinician-audiologist
Preconditions	Self-testing and self-adjustment is possible. Patients and significant others want and can use the self-testing and self-adjustment. Data is visualised in a meaningful way for all actors.
Trigger	Patient / significant other notice hearing change / have some unresolved issues with hearing aids.
Basic Flow	1. The hearing aid user has the possibility to take tests to monitor their hearing over time. These tests are quick, simple, and reliable, and the hearing aid user can access them via their mobile device. Significant others can help the hearing aid users perform these tests. 2. These hearing tests can be either triggered by a) the hearing aid user who decides to take the test or by b) a system that tracks if the hearing aids are unused for long periods or if hearing aid controls are more frequently used. 3. After taking the test, the hearing aid user can see clearly whether their hearing levels are stable or changing over time. 4. If hearing levels have changed, the hearing aid user can adjust their hearing aid settings so they correspond to the new hearing levels. 5. The clinician is made aware of the hearing test results and of any adjustments that the hearing aid user does to the hearing aids.

	6. If the clinician notices that the hearing has changed significantly or that significant new adjustments must be made to the hearing aids, the clinician contacts the hearing aid user to book a face-to-face appointment at the hearing clinic.
Alternate Flows	
Postconditions	Improved hearing outcomes

6.3.4. Mobile hearing coach

Use Case Id	PSOS.4
Use Case Name	Mobile hearing coach
Use Case Summary	The hearing aid user has access to a hearing coach through their mobile device. The coach is like a personal trainer towards hearing fitness. The coach makes the hearing aid user train (eg, listen to words that are increasingly difficult for the hearing aid user to hear), self-manage (eg, identify where the hearing aid user has hearing difficulties even though they are wearing their hearing aids, and propose concrete solutions), helps the hearing aid user involve other people (eg, simulate hearing loss for communication partners to understand what it's like to have a hearing loss), and keeps track of the hearing aid user's achievements so they remain engaged in their training. The coach has many components, which the hearing aid user decides to engage in or not based on individual needs – together with advice from the clinician.
Actors	Patient Significant other Clinician-audiologist
Preconditions	Components of the mobile coach (adaptive auditory training, online rehabilitation, etc) are available and shown to lead to better outcomes. Patients and significant others want and can use the mobile coach. Achievements are visualised in a meaningful way for patients and significant others.
Trigger	Patient / significant other want to self-manage the hearing loss.
Basic Flow	1. The hearing aid user has access to a hearing coach through their mobile device. The coach is like a personal trainer towards hearing fitness. The coach makes the hearing aid user train (eg, listen to words that are increasingly difficult for the hearing aid user to hear). 2. The coach has many components which the hearing aid user decides to engage in or not based on individual needs – together with advice from the clinician. 3. The coach makes the hearing aid user self-manage (eg, identify where the hearing aid user has hearing difficulties even though they are wearing their hearing aids, and propose concrete solutions). 4. The coach helps the hearing aid user involve other people (eg, simulate hearing loss for communication partners to understand what it's like to have a hearing loss), and keeps track of the hearing aid user's achievements so they remain engaged in their training. 5. The coach keeps track of the hearing aid user's achievements so they remain engaged in their training.
Alternate Flows	
Postconditions	

6.3.5. Protection of people with hearing impairments from the harmful effects of loud noise: individualised risk assessment

Use Case Id	PSOS.5
Use Case Name	Protection of people with hearing impairments from the harmful effects of loud noise: individualised risk assessment
Use Case Summary	This use case captures scenarios regarding determination of individualised (environmental, physiological) factors associated with increased risk for Temporary Threshold Shift (TTS) or noise induced hearing loss (NIHL) for prevention of further TTS/NIHL episodes.
Actors	Clinical Stakeholder: Audiologist. Patient stakeholder: hearing aid user or carer
Preconditions	Access to EVOTION platform. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. Patient exposure to leisure or other types of noise while using HAs and wearing sensors.
Trigger	There is individual susceptibility to TTS/NIHL and legally determined "safe" noise levels may not be safe for all individuals; combination of noise and other potential risk factors may increase risk of TTS/NIHL.
Basic Flow	1. Patient is diagnosed with hearing loss and referred for hearing aid fitting by ENT/AVM/Audiologist. 2. Audiologist/audiological scientist performs initial hearing tests and open fit/open-ear hearing aid fitting 3. Standard hearing aid usage education is provided by audiologist/audiological scientist 4. Patient is educated to monitor for TTS/NIHL and perform a hearing test as soon as TTS/NIHL noticed (written instructions on EVOTION app) 5. EVOTION HA system records ambient noise level and patient physiological data (oxygen saturation, blood pressure) automatically 6. Patient perceives TTS/NIHL 7. Patient self-tests hearing and confirms NIHL 8. EVOTION HA system alerts the patient to seek urgent medical attention 9. PATIENT RECORDS TTS/NIHL EPISODE 10. PATIENT SEEKS MEDICAL HELP AND ENTERS CLINICAL PATHWAY 11. EVOTION system determines combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes 12. EVOTION system sets automatic alerts to prevent further episodes
Alternate Flows	AF9 - PATIENT DOES NOT RECORD TTS/NIHL EPISODE OR SEEK MEDICAL HELP; AF9-BF1 - Patient returns for 3 month follow up AF9-BF2- During follow up visit, Audiologist/audiological scientist accesses automatically recorded data regarding TTS/NIHL AF9-BF3 – Audiologist retests patient AF9-BF4- Audiologist re-educates patient re NIHL AF9-BF5 –Audiologist records TTS episode retrospectively AF9-BF6- EVOTION system determines combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes AF9-BF7 - EVOTION system sets automatic alerts to prevent further episodes
Postconditions	Audiologist will use this information in order to determine individualised risk factors for TTS/ NIHL and prevent further episodes. The TTS/NIHL episodes and related data (test results, environmental/physiological data) are recorded in the EVOTION platform for several HA users. Successive stages of analysis will inform public health case scenaria.

6.3.6. Early Support for hearing aid uptake

Use Case Id	PSOS.6
Use Case Name	Improved rehabilitation outcomes – early support after first fit
Use Case Summary	This use case covers issues with hearing aid uptake. A proportion of individuals who could theoretically benefit from hearing aids eventually reject devices. Reasons for this are complex, but can include factors such as sound quality. Individuals who reject hearing aids have limited alternatives to help with hearing health.
Actors	Clinical Stakeholder: Audiologist. Patient stakeholder: patient
Preconditions	Access to EVOTION platform. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. Patient has been identified as potentially suitable for hearing aids.
Trigger	I have concerns about my hearing and it is having an impact on my work, leisure and other activities.
Basic Flow	1. Patient is diagnosed with hearing loss and referred for hearing aid fitting by ENT/AVM/Audiologist. 2. Audiologist/audiological scientist performs initial hearing tests and offers hearing aid. Hearing aid is accepted by patient. 3. Patient in early stage of use can record all issues, concerns and problems with hearing aid via smartphone app. 4. Customised support can be offered at the critical early stage via the mobile app prior to the initial review appointment. 5. With this support, the successful uptake of hearing aids is increased. Outcome is better for the individual in terms of hearing health.
Alternate Flows	
Postconditions	There are measurable cost effectiveness benefits of greater uptake of hearing aids.

6.3.7. Better hearing for better health globally in older age

Use Case Id	PSOS.7
Use Case Name	Longer term benefit of hearing rehabilitation
Use Case Summary	This use case covers longer term benefits of hearing aid use in relation to both individuals and more broadly to populations.
Actors	Clinical Stakeholder: Audiologist. Patient stakeholder: patient. Public health
Preconditions	Access to EVOTION platform. Concurrent use of HAs, mobile phones and apps. Patient education and engagement. It is assumed that good hearing health and auditory training are associated with health benefits in older age. It is assumed that health promotion interventions will be effective in improving uptake of rehabilitation interventions.
Trigger	Use of EVOTION platform to promote long term health
Basic Flow	1. Patient is diagnosed with hearing loss and referred for hearing aid fitting by ENT/AVM/Audiologist. 2. Audiologist/audiological scientist performs initial hearing tests and fits EVOTION hearing aid 3. EVOTION offers auditory training in conjunction with other rehabilitation components. 4. EVOTION delivers up-to-date hearing research and health promotion information to end-users via the smartphone app 5. EVOTION is used to promote hearing health messages

	6. Hearing function, cognitive function and mental health are better preserved into older adult life.
Alternate Flows	
Postconditions	Benefits of improved hearing health can be translated into measurable benefits in terms of public health.

6.3.8. Hearing health as a part of general health

Use Case Id	PSOS.8
Use Case Name	Integrating hearing health with other needs
Use Case Summary	Many hearing aid users have additional health needs. Commonly these include visual impairment, mobility problems, manipulative (fine motor co-ordination) problems, mental health conditions, cognitive disorders. Hearing aid services and devices need to take into account the range of needs of users rather than be focused exclusively on auditory aspects of health.
Actors	Clinical Stakeholder: Audiologist. Patient stakeholder: patient. Public health stakeholders
Preconditions	Access to EVOTION platform – patients share data about medical co-morbidities that can be analysed by service providers
Trigger	Promotion of hearing aid services that meet the needs of the served population
Basic Flow	Hearing aid users need services which can adapt to their other health needs. The EVOTION platform collects data on the co-morbidities and additional health needs of hearing aid users. This information is used to develop services which can meet the hearing health needs of patients in the context of their other health needs.
Alternate Flows	
Postconditions	

The elicited requirements from the above scenarios are presented at the below table.

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(PSOS)120	Mobile app extracts personal data in an application-friendly standard format	Must have	M
FR(PSOS)121	Support peer-2-peer real-time text messaging	Must have	P-M
FR(PSOS)122	Mobile app communicates with the HA device in order to request simple tests to monitor users' hearing over time	Must have	M
FR(PSOS)123	Mobile app triggers hearing tests to take	Must have	M
FR(PSOS)124	Hearing tests trigger to be taken	Must have	P
FR(PSOS)125	Track if the hearing aids are unused for long periods or if hearing aid controls are more frequently used	Must have	P
FR(PSOS)126	Mobile provides clearly the hearing testing results over time (for a selected period)	Must have	M
FR(PSOS)127	Mobile app sends HA adjustments and hearing test results to EVOTION platform	Must have	M
FR(PSOS)128	Present hearing test results and HA adjustments of HA users	Must have	P

Functional Requirement ID	Title	Priority of accomplishment	Related to Platform (P) or/and Mobile (M)
FR(PSOS)129	Recognize significant adjustments of HA	Must have	P
FR(PSOS)130	Send selected training material (words into sound) to EVOTION mobile app	Must have	P-M
FR(PSOS)131	Mobile app should be able to play training material (words into sound)	Must have	M
FR(PSOS)132	Mobile app provides the functionality to select the available training material	Must have	M
FR(PSOS)133	Mobile app provides instructions to monitor TTS/NIHL and instructions to perform hearing test	Must have	M
FR(PSOS)134	Record ambient noise level and patient physiological data (oxygen saturation, blood pressure)	Must have	P
FR(PSOS)135	Mobile app provides hearing self-tests to HA users	Must have	M
FR(PSOS)136	Mobile app alerts HA users to seek urgent medical attention	Must have	M
FR(PSOS)137	Mobile app (automatically/manually) records TTS/NIHL episodes	Should have	M
FR(PSOS)138	Mobile app provides a list of the available medical help for urgent circumstances	Must have	M
FR(PSOS)139	Determine combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes	Must have	P
FR(PSOS)140	Automatic alerts for urgent hearing TTS/NIHL episodes	Must have	P-M
FR(PSOS)141	Record TTS episode retrospectively	Must have	
FR(PSOS)142	Mobile app records issues, concerns and problems with hearing aid	Must have	M
FR(PSOS)144	Analyse issues, concerns and problems with hearing aid reported by HA users	Must have	p
FR(PSOS)145	Mobile app provides up-to-date hearing research and health promotion information to HA user	Must have	M
FR(PSOS)146	Record up-to-date hearing research and health promotion information	Must have	P
FR(PSOS)147	Record data on the co-morbidities and additional health needs of hearing aid users	Must have	P

7. System Requirements

System requirements are detailed specifications describing the functions the system needs to do.

7.1. Functional

Functional Requirements "should define the fundamental actions that must take place in the software in accepting and processing the inputs and in processing and generating the outputs" [130]. They can be partitioned into sub-functions or sub-processes if appropriate. The partitioning does not imply decisions for the design of the software. A required software function could be strongly connected to the data that the function should process as well as to the interface that a user or admin of the software needs to use the function. The complete set of functional requirements for EVOTION can be described as follows below categorized per stakeholders' group.

7.1.1. Policy Makers

FR(PHAS)1 - Mechanism for collecting data of different types

Field	Description
ID	FR(PHAS)1
Title	Mechanism for collecting data of different types
Priority of accomplishment	Must have
Description	EVOTION platform should provide a mechanism for collecting data of different types, as well as geo-located data (PHAS.5, Step 2)
Rationale	Elicited from: • PHAS.1, Step 1 • PHAS.2, Step 1 • PHAS.3, Step 1 • PHAS.4, Step 1 • PHAS.5, Step 1 • PHAS.5, Step 2
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)2 - Discover factors of low HA usage

Field	Description
ID	FR(PHAS)2
Title	Discover factors of low HA usage
Priority of accomplishment	Must have
Description	EVOTION platform should be able to select several types of data to analyze them and discover factors of low HA usage
Rationale	Elicited from: • PHAS.1, Step 1 • PHAS.2, Step 1 • PHAS.3, Step 1 • PHAS.4, Step 1
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)3 - Identify relevant studies and provide a summary of them

Field	Description
ID	FR(PHAS)3
Title	Identify relevant studies and provide a summary of them
Priority of accomplishment	Must have
Description	EVOTION platform should identify relevant studies, order them by date, and provide a summary of them
Rationale	Elicited from: • PHAS.1, Step 2 • PHAS.2, Step 2 • PHAS.3, Step 2 • PHAS.4, Step 2
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)4 - Filter the relevant studies

Field	Description
ID	FR(PHAS)4
Title	Filter the relevant studies
Priority of accomplishment	Must have
Description	EVOTION platform should be able to filter the relevant studies based on selected factors for: i) prognosing low HA usage ii) early retirement iii) HL iv) insufficient use of administered HAs among risk groups of patients
Rationale	Elicited from: • PHAS.1, Step 2 • PHAS.2, Step 2 • PHAS.3, Step 2 • PHAS.4, Step 2
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)5 - Cluster the relevant studies

Field	Description
ID	FR(PHAS)5
Title	Cluster the relevant studies
Priority of accomplishment	Should have
Description	EVOTION platform should cluster the relevant studies based on potential factors for: i) prognosing low HA usage ii) early retirement iii) HL iv) insufficient use of administered HAs among risk groups of patients
Rationale	Elicited from: • PHAS.1, Step 2

	• PHAS.2, Step 2 • PHAS.3, Step 2 • PHAS.4, Step 2
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)6 - Characterize data to define the size of the dataset

Field	Description
ID	FR(PHAS)6
Title	Characterize data to define the size of the dataset
Priority of accomplishment	Should have
Description	EVOTION platform should provide a mechanism to characterize data, based on the study period and the source of origin, as well as to define the size of the dataset, depending on factors like the time frame of the data to be retrieved (from –to), etc.
Rationale	Elicited from: • PHAS.1, Step 3 • PHAS.2, Step 3 • PHAS.3, Step 3 • PHAS.4, Step 3
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)7 - Support different types of data analysis

Field	Description
ID	FR(PHAS)7
Title	Support different types of data analysis
Priority of accomplishment	Should have
Description	EVOTION should be able to support different types of data analysis.
Rationale	Elicited from: • PHAS.1, Step 4 • PHAS.2, Step 3 • PHAS.3, Step 3 • PHAS.4, Step 3
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)8 - Support different types of data tests

Field	Description
ID	FR(PHAS)8
Title	Support different types of data tests
Priority of accomplishment	Should have
Description	EVOTION should be able to allow the selection of the type of test to be performed on the data.
Rationale	Elicited from: • PHAS.1, Step 4

	• PHAS.2, Step 4 • PHAS.3, Step 4 • PHAS.4, Step 4
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)9 - Produce and manage metrics for the quality of analysis

Field	Description
ID	FR(PHAS)9
Title	Produce and manage metrics for the quality of analysis
Priority of accomplishment	Could have
Description	EVOTION should be able to produce and manage metrics for the quality of analysis
Rationale	Elicited from: • PHAS.1, Step 4 • PHAS.2, Step 4 • PHAS.3, Step 4 • PHAS.4, Step 4
Supporting materials	*N/A*
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)10 - Initiate data analysis session

Field	Description
ID	FR(PHAS)10
Title	Initiate data analysis session
Priority of accomplishment	Must have
Description	EVOTION platform should be able to initiate data analysis session. In more details to: i. Implement a policy advocacy workflow; ii. Manage this flow; iii. Trigger this flow through user intervention.
Rationale	Elicited from: • PHAS.1, Step 6 • PHAS.2, Step 6 • PHAS.3, Step 6 • PHAS.4, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)11 - Administrate (create, update, delete) analysis' outcomes

Field	Description
ID	FR(PHAS)11
Title	Administrate (create, update, delete) analysis' outcomes
Priority of accomplishment	Must have
Description	EVOTION platform should be able to administrate (create, update, delete) initial policy advocacy tasks along with the analysis' outcomes
Rationale	Elicited from: • PHAS.1, Step 6

	• PHAS.2, Step 6 • PHAS.3, Step 6 • PHAS.4, Step 6 • PHAS.1, PostConditions
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)12 - Notification when analysis is complete

Field	Description
ID	FR(PHAS)12
Title	Notification when analysis is complete
Priority of accomplishment	Must have
Description	EVOTION platform should notify end-users when a analysis is complete
Rationale	Elicited from: • PHAS.1, Step 6 • PHAS.2, Step 6 • PHAS.3, Step 6 • PHAS.4, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)13 - Visualizations of the analysis outcome

Field	Description
ID	FR(PHAS)13
Title	Visualizations of the analysis outcome
Priority of accomplishment	Must have
Description	EVOTION platform should be able to provide visualizations of the analysis outcome
Rationale	Elicited from: • PHAS.1, Step 7 • PHAS.2, Step 7 • PHAS.3, Step 7 • PHAS.4, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)14 - Suggest factors of analysis' outcome

Field	Description
ID	FR(PHAS)14
Title	Suggest factors of analysis' outcome
Priority of accomplishment	Must have
Description	EVOTION platform should provide a mechanism to suggest factors of analysis' outcome
Rationale	Elicited from: • PHAS.1, Step 8 • PHAS.2, Step 8 • PHAS.3, Step 8 • PHAS.4, Step 8

Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)15 - Re-analysing a specific dataset with different factors

Field	Description
ID	FR(PHAS)15
Title	Re-analysing a specific dataset with different factors
Priority of accomplishment	Must have
Description	EVOTION platform should allow re-analysing a specific dataset with different factors (or selecting from a list of factors)
Rationale	Elicited from: • PHAS.1, Step 9 • PHAS.2, Step 9 • PHAS.3, Step 9 • PHAS.4, Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)16 - Data analysis, in a statistical way, between different data types

Field	Description
ID	FR(PHAS)16
Title	Data analysis, in a statistical way, between different data types
Priority of accomplishment	Should have
Description	EVOTION platform should be able to provide data analysis, in a statistical way, between different data types
Rationale	Elicited from: • PHAS.5, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)17 - Support multiple types of analysis' criteria

Field	Description
ID	FR(PHAS)17
Title	Support multiple types of analysis' criteria
Priority of accomplishment	Must have
Description	EVOTION platform should provide multiple types of analysis' criteria
Rationale	Elicited from: • PHAS.5, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)18 - Support of progressive notifications and save of the outcomes on data analysis

Field	Description
ID	FR(PHAS)18

Title	Support of progressive notifications and save of the outcomes on data analysis
Priority of accomplishment	Should have
Description	EVOTION platform should be able to send progressive notifications and save the outcomes accordingly when (25%, 50%, 75% and 100% of the) minimal data set has been analysed
Rationale	Elicited from: • PHAS.5, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)19 - Support Online discussions

Field	Description
ID	FR(PHAS)19
Title	Support Online discussions
Priority of accomplishment	Must have
Description	EVOTION platform should implement a mechanism to invite and allow individual stakeholders to participate into online discussions to express their views regarding the formulation of a HL policy
Rationale	Elicited from: • PHAS.5, Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)20 - Access management features for the analysis outcomes

Field	Description
ID	FR(PHAS)20
Title	Access management features for the analysis outcomes
Priority of accomplishment	Must have
Description	EVOTION platform should be able to provide features of access management for the analysis outcomes related to a policy formulation process. Outcomes should be able to be accessed by individual stakeholders, who should be able to express their views regarding the analysis outcome
Rationale	Elicited from: • PHAS.5, Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)21 - Analyze expressed evidence from the online discussions and suggestions

Field	Description
ID	FR(PHAS)21
Title	Analyze expressed evidence from the online discussions and suggestions
Priority of accomplishment	Should have

Description	EVOTION platform should be able to analyze expressed views and evidence from the online discussions and to provide suggestions based of the analyzed input
Rationale	Elicited from: • PHAS.5, Step 11
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)22 - Notifications with suggestions about alternative ways of addressing the effective use of HL

Field	Description
ID	FR(PHAS)22
Title	Notifications with suggestions about alternative ways of addressing the effective use of HL
Priority of accomplishment	Must have
Description	EVOTION platform should be able to send notifications with suggestions about alternative ways of addressing the effective use of HL to PHAA and the involved in the discussion stakeholders
Rationale	Elicited from: • PHAS.5, Step 12
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)23 - Deliberation mechanism on the EVOTION's suggestions

Field	Description
ID	FR(PHAS)23
Title	Deliberation mechanism on the EVOTION's suggestions
Priority of accomplishment	Should have
Description	EVOTION platform should provide a mechanism to PHAA and individual in order to deliberate, such as vote (agree/disagree), on the EVOTION's suggestions about alternative ways of addressing the effective use of HL
Rationale	Elicited from: • PHAS.5, Step 13
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)24 - Identification of the resulting tense and generation of a potential policy model for implementation

Field	Description
ID	FR(PHAS)24
Title	Identification of the resulting tense and generation of a potential policy model for implementation
Priority of accomplishment	Should have
Description	EVOTION platform should provide the mechanism to finalize the deliberation process on EVOTION's suggestions, identify the resulting tense and generate a potential policy model for implementation
Rationale	Elicited from:

	• PHAS.5, Step 14
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)25 - Extend the criteria for the data collection process

Field	Description
ID	FR(PHAS)25
Title	Extend the criteria for the data collection process
Priority of accomplishment	Must have
Description	EVOTION platform should be able to extend the criteria (i.e. time frame, sources) for the data collection process until the originally envisaged data set is doubled
Rationale	Elicited from: • PHAS.5, Step 8.AC1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)26 - Stop the relevant analytic activity

Field	Description
ID	FR(PHAS)26
Title	Stop the relevant analytic activity
Priority of accomplishment	Must have
Description	EVOTION platform should provide the feature to stop the relevant analytic activity of a policy exploration activity
Rationale	Elicited from: • PHAS.5, Step 8.AC2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)27 - Configurable on what consensus on a policy model means

Field	Description
ID	FR(PHAS)27
Title	Configurable on what consensus on a policy model means
Priority of accomplishment	Should have
Description	EVOTION platform should be configurable on what consensus on a policy model means
Rationale	Elicited from: • PHAS.5, Step 14.AC1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PHAS)28 - Visualize comparative policy models for implementation

Field	Description
ID	FR(PHAS)28
Title	Visualize comparative policy models for implementation
Priority of accomplishment	Should have

Description	EVOTION platform should be able to visualize comparative policy models for implementation
Rationale	Elicited from: • PHAS.5, Step 14.AC2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

7.1.2. Clinicians

FR(CLIS)29 - Mobile app communicates with HA devices

Field	Description
ID	FR(CLIS)29
Title	Mobile app communicates with HA devices
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to communicate with HA devices.
Rationale	Elicited from: • CLIS.1, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)30 - Mobile app collect data from HA devices

Field	Description
ID	FR(CLIS)30
Title	Mobile app collect data from HA devices
Priority of accomplishment	Must have
Description	EVOTION mobile app should periodically collect patient data from HA devices
Rationale	Elicited from: • CLIS.1, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)31 - Mobile app provides a window to rate the HA ease of use

Field	Description
ID	FR(CLIS)31
Title	Mobile app provides a window to rate the HA ease of use
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to provide the user with a window to rate the HA ease of use, once a problem is reported (either automatically or manually)
Rationale	Elicited from: • CLIS.1, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)32 –Mobile app identify problems in the communication with the HA device

Field	Description
ID	FR(CLIS)32

Title	Mobile app identify problems in the communication with the HA device
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to identify problems in the communication with the HA device and/or to allow the user to report a problem experienced with the device. The occurrence time of the reported problem must be recorded in the app
Rationale	Elicited from: • CLIS.1, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)33 - Mobile app sends stream of user ratings to the EVOTION platform

Field	Description
ID	FR(CLIS)33
Title	Mobile app sends stream of user ratings to the EVOTION platform
Priority of accomplishment	Should have
Description	EVOTION mobile app should be able to send the stream of user ratings to the EVOTION platform.
Rationale	Elicited from: • CLIS.1, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)34 - Manage and visualise the history of ratings on the HA ease

Field	Description
ID	FR(CLIS)34
Title	Manage and visualise the history of ratings on the HA ease
Priority of accomplishment	Should have
Description	EVOTION platform should be able to manage and visualise the history of ratings on the HA ease if use.
Rationale	Elicited from: • CLIS.1, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)35 - Collect environmental noise and noise coming from user activities and send them to the EVOTION platform

Field	Description
ID	FR(CLIS)35
Title	Collect environmental noise and noise coming from user activities and send them to the EVOTION platform
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to collect environmental noise and noise coming from user activities and send them to the EVOTION platform.

Rationale	Elicited from: • CLIS.1, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)36 - Correlation of HA usage with collected noise data

Field	Description
ID	FR(CLIS)36
Title	Correlation of HA usage with collected noise data
Priority of accomplishment	Should have
Description	EVOTION platform should be able to correlate the HA usage with the collected noise data.
Rationale	Elicited from: • CLIS.1, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)37 - Manage HA usage with problems occurred, ratings provided and corresponding noise recorded

Field	Description
ID	FR(CLIS)37
Title	Manage HA usage with problems occurred, ratings provided and corresponding noise recorded
Priority of accomplishment	Could have
Description	EVOTION platform should be able to manage HA usage with problems occurred, ratings provided and corresponding noise recorded.
Rationale	Elicited from: • CLIS.1, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)38 - Different visualization modes of the recorded data

Field	Description
ID	FR(CLIS)38
Title	Different visualization modes of the recorded data
Priority of accomplishment	Should have
Description	EVOTION platform should be able to provide different visualization modes of the recorded data, both on a single and an aggregated level.
Rationale	Elicited from: • CLIS.1, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)39 - Allow audiologists to access the recorded data

Field	Description
ID	FR(CLIS)39
Title	Allow audiologists to access the recorded data

Priority of accomplishment	Must have
Description	EVOTION platform should allow audiologists to access the recorded data.
Rationale	Elicited from: • CLIS.1, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)40 - Audiologists modifies fitting parameters

Field	Description
ID	FR(CLIS)40
Title	Audiologists modifies fitting parameters
Priority of accomplishment	Must have
Description	EVOTION platform should be able to provide audiologists a way to modify the fitting parameters
Rationale	Elicited from: • CLIS.1, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)41 - Audiologists modifies fitting parameters

Field	Description
ID	FR(CLIS)41
Title	Audiologists modifies fitting parameters
Priority of accomplishment	Must have
Description	EVOTION platform should be able to manage fitting profiles.
Rationale	Elicited from: • CLIS.1, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)42 - Analyse END or BHD parameters and automatically respond to them by changing the fitting profile

Field	Description
ID	FR(CLIS)42
Title	Analyse END or BHD parameters and automatically respond to them by changing the fitting profile
Priority of accomplishment	Must have
Description	EVOTION platform should be able to analyse END or BHD parameters and automatically respond to them by changing the fitting profile.
Rationale	Elicited from: • CLIS.1, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)43 - Communicate of the new fitting profile to the EVOTION mobile app

Field	Description

ID	FR(CLIS)43
Title	Communicate of the new fitting profile to the EVOTION mobile app
Priority of accomplishment	Should have
Description	EVOTION platform should be able to communicate the new fitting profile to the EVOTION mobile app.
Rationale	Elicited from: • CLIS.1, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)44 - Configure the HA device fitting parameters

Field	Description
ID	FR(CLIS)44
Title	Configure the HA device fitting parameters
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to configure the HA device fitting parameters
Rationale	Elicited from: • CLIS.1, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)45 - Insert a new event

Field	Description
ID	FR(CLIS)45
Title	Insert a new event
Priority of accomplishment	Must have
Description	EVOTION mobile app should allow patients to insert a new event.
Rationale	Elicited from: • CLIS.2, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)46 - Collect timestamped data related to an event for a configurable period between before the event occurrence and after it.

Field	Description
ID	FR(CLIS)46
Title	Collect timestamped data related to an event for a configurable period between before the event occurrence and after it.
Priority of accomplishment	Must have
Description	The EVOTION mobile app should be able collect timestamped data related to this event for a configurable period between before the event occurrence and after it.
Rationale	Elicited from: • CLIS.2, Step 4
Supporting materials	N/A

Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)47 - Communication of a detected event record to the EVOTION platform

Field	Description
ID	FR(CLIS)47
Title	Communication of a detected event record to the EVOTION platform
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to communicate the detected event record to the EVOTION platform.
Rationale	Elicited from: • CLIS.2, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)48 - Communication of a detected event record to the EVOTION platform

Field	Description
ID	FR(CLIS)48
Title	Manage and visualize a detected event record
Priority of accomplishment	Should have
Description	EVOTION platform should be able to manage and visualize the detected event record
Rationale	Elicited from: • CLIS.2, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)49 - Provide objective real data relevant to the detected event

Field	Description
ID	FR(CLIS)49
Title	Provide objective real data relevant to the detected event
Priority of accomplishment	Must have
Description	EVOTION platform should be able to provide objective real data relevant to the detected event
Rationale	Elicited from: • CLIS.2, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)54 - Interface with the fitting hearing aids software to allow clinicians to request recommendations

Field	Description
ID	FR(CLIS)54
Title	Interface with the fitting hearing aids software to allow clinicians to request recommendations
Priority of accomplishment	Must have

Description	EVOTION platform should be able to interface with the fitting hearing aids software to allow clinicians to request recommendations
Rationale	Elicited from: • CLIS.3, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)55 - Select a different device, based on patient's preferences and record this selection

Field	Description
ID	FR(CLIS)55
Title	Select a different device, based on patient's preferences and record this selection
Priority of accomplishment	Could have
Description	EVOTION platform should allow clinicians select a different device, based on patient's preferences and record this selection
Rationale	Elicited from: • CLIS.3, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)56 - Visualize a list of data types that are collected in the platform

Field	Description
ID	FR(CLIS)56
Title	Visualize a list of data types that are collected in the platform
Priority of accomplishment	Must have
Description	EVOTION platform should be able to visualize a list of data types that are collected in the platform.
Rationale	Elicited from: • CLIS.4, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)57 - Provide a list of studies for inspection

Field	Description
ID	FR(CLIS)57
Title	Provide a list of studies for inspection
Priority of accomplishment	Should have
Description	EVOTION platform should be able to provide a list of studies for inspection
Rationale	Elicited from: • CLIS.4, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)58 - Select from a list of data types

Field	Description
ID	FR(CLIS)58
Title	Select from a list of data types
Priority of accomplishment	Must have
Description	EVOTION platform should be able to allow clinicians to select from a list of data types, those that are of interest for them.
Rationale	Elicited from: • CLIS.4, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)59 - Visualize TTS/NIHL data recorded for a selected patient

Field	Description
ID	FR(CLIS)59
Title	Visualize TTS/NIHL data recorded for a selected patient
Priority of accomplishment	Must have
Description	EVOTION platform should be able to visualize TTS/NIHL data recorded for a selected patient.
Rationale	Elicited from: • CLIS.5, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)60 - Provide aggregated records of TTS episodes from patients from retrospective studies

Field	Description
ID	FR(CLIS)60
Title	Provide aggregated records of TTS episodes from patients from retrospective studies
Priority of accomplishment	Must have
Description	EVOTION platform should be able to provide aggregated records of TTS episodes from patients from retrospective studies.
Rationale	Elicited from: • CLIS.5, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)61 - Analyse data and suggest combination of factors affecting TTS and NIHL episodes

Field	Description
ID	FR(CLIS)61
Title	Analyse data and suggest combination of factors affecting TTS and NIHL episodes.
Priority of accomplishment	Must have
Description	EVOTION platform should be able to analyse data and suggest combination of factors affecting TTS and NIHL episodes.
Rationale	Elicited from:

	• CLIS.5, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)62 - Compose alerts for a patient, based on desired values for the factors affecting TTS / NIHL episodes

Field	Description
ID	FR(CLIS)62
Title	Compose alerts for a patient, based on desired values for the factors affecting TTS / NIHL episodes.
Priority of accomplishment	Must have
Description	EVOTION platform should be able to compose alerts for a patient, based on desired values for the factors affecting TTS / NIHL episodes.
Rationale	Elicited from: • CLIS.5, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)63 - Allow TTS/NIHL data monitoring and provide a wizard to guide patients in performing a hearing test on their own

Field	Description
ID	FR(CLIS)63
Title	Allow TTS/NIHL data monitoring and provide a wizard to guide patients in performing a hearing test on their own
Priority of accomplishment	Must have
Description	EVOTION mobile app should allow TTS/NIHL data monitoring and provide a wizard to guide patients in performing a hearing test on their own.
Rationale	Elicited from: • CLIS.5, Alternative Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)64 - Mobile app should be able to record noise level and physiological data automatically

Field	Description
ID	FR(CLIS)64
Title	Mobile app should be able to record noise level and physiological data automatically
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to record noise level and physiological data automatically.
Rationale	Elicited from: • CLIS.5, Alternative Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)65 - Mobile app allows patients to start a hearing test and declare NIHL events

Field	Description

ID	FR(CLIS)65
Title	Mobile app allows patients to start a hearing test and declare NIHL events
Priority of accomplishment	Must have
Description	EVOTION mobile app should allow patients to start a hearing test and declare NIHL events
Rationale	Elicited from: • CLIS.5, Alternative Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)66 - Mobile app raises alerts for urgent medical attention

Field	Description
ID	FR(CLIS)66
Title	Mobile app raises alerts for urgent medical attention
Priority of accomplishment	Could have
Description	EVOTION mobile app should be able to raise alerts for urgent medical attention
Rationale	Elicited from: • CLIS.5, Alternative Step 8
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)67 - Mobile app allows patients to manually insert a TTS / NIHL episode

Field	Description
ID	FR(CLIS)67
Title	Mobile app allows patients to manually insert a TTS / NIHL episode
Priority of accomplishment	Must have
Description	EVOTION mobile app should allow patients to manually insert a TTS / NIHL episode
Rationale	Elicited from: • CLIS.5, Alternative Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)68 - Record the patient' responses to various standardized questionnaires

Field	Description
ID	FR(CLIS)68
Title	Record the patient' responses to various standardized questionnaires
Priority of accomplishment	Must have
Description	EVOTION platform should be able to record the patient' responses to various standardized questionnaires
Rationale	Elicited from: • CLIS.6, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)69 - Create record for hearing aid fitting

Field	Description
ID	FR(CLIS)69
Title	Create record for hearing aid fitting.
Priority of accomplishment	Must have
Description	EVOTION platform should be able to create the record for the hearing aid fitting.
Rationale	Elicited from: • CLIS.6, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)70 - Provide speech in noise tests and communicate results to the platform

Field	Description
ID	FR(CLIS)70
Title	Provide speech in noise tests and communicate results to the platform
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide speech in noise tests and communicate results to the platform
Rationale	Elicited from: • CLIS.6, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)71 - Categorise the questionnaires responses and the speech in noise test results as patient's initial record

Field	Description
ID	FR(CLIS)71
Title	Categorise the questionnaires responses and the speech in noise test results as patient's initial record
Priority of accomplishment	Should have
Description	EVOTION platform should be able to categorise the questionnaires responses and the speech in noise test results as patient's initial record
Rationale	Elicited from: • CLIS.6, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)72 - Record END and BHD data

Field	Description
ID	FR(CLIS)72
Title	Record END and BHD data
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to record END and BHD data
Rationale	Elicited from: • CLIS.6, Step 7

Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)73 - Mobile app should records ambient noise level data, duration of noise exposure and physiological data

Field	Description
ID	FR(CLIS)73
Title	Mobile app should records ambient noise level data, duration of noise exposure and physiological data
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to record ambient noise level data, duration of noise exposure and physiological data
Rationale	Elicited from: • CLIS.6, Step 8
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)74 - Mobile app communicates with the platform

Field	Description
ID	FR(CLIS)74
Title	Mobile app communicates with the platform
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to communicate with the platform
Rationale	Elicited from: • CLIS.6, Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)75 - EVOTION platform deployed on the cloud

Field	Description
ID	FR(CLIS)75
Title	EVOTION platform deployed on the cloud
Priority of accomplishment	Should have
Description	EVOTION platform will be probably deployed on the cloud.
Rationale	Elicited from: • CLIS.6, Step 9 • CLIS.8, User Case Summary
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)76 - EVOTION platform analyse outcome measures

Field	Description
ID	FR(CLIS)76
Title	EVOTION platform analyse outcome measures
Priority of accomplishment	Must have

Description	EVOTION platform should be able to analyse outcome measures
Rationale	Elicited from: • CLIS.6, Step 12
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)77 - Visualize aggregated data sets

Field	Description
ID	FR(CLIS)77
Title	Visualize aggregated data sets
Priority of accomplishment	Must have
Description	EVOTION platform and EVOTION mobile app should be able to visualize aggregated data sets
Rationale	Elicited from: • CLIS.6, Step 13
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)78 - Visualize HA usage data with respect to various noise parameters

Field	Description
ID	FR(CLIS)78
Title	Visualize HA usage data with respect to various noise parameters
Priority of accomplishment	Must have
Description	EVOTION platform and EVOTION mobile app should be able to visualize HA usage data with respect to various noise parameters
Rationale	Elicited from: • CLIS.6, Step 14
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)79 - Creation of auditory training sessions

Field	Description
ID	FR(CLIS)79
Title	Creation of auditory training sessions
Priority of accomplishment	Must have
Description	EVOTION platform should be able to create auditory training sessions
Rationale	Elicited from: • CLIS.6, Step 17
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)80 - Retrieve respective auditory training sessions

Field	Description
ID	FR(CLIS)80

Title	Retrieve respective auditory training sessions
Priority of accomplishment	Should have
Description	EVOTION mobile app should be able to retrieve respective auditory training sessions
Rationale	Elicited from: • CLIS.6, Step 18
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)81 - Mobile app should allow patients to respond to auditory trainings and get assessment from the EVOTION platform

Field	Description
ID	FR(CLIS)81
Title	Mobile app should allow patients to respond to auditory trainings and get assessment from the EVOTION platform
Priority of accomplishment	Must have
Description	EVOTION mobile app should allow patients to respond to auditory trainings and get assessment from the EVOTION platform
Rationale	Elicited from: • CLIS.6, Step 19
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)82 - Analyze the responses to the auditory training tests

Field	Description
ID	FR(CLIS)82
Title	Analyze the responses to the auditory training tests
Priority of accomplishment	Must have
Description	EVOTION platform should be able to analyse the responses to the auditory training tests.
Rationale	Elicited from: • CLIS.6, Step 19
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)83 - Analyze the responses to the auditory training tests

Field	Description
ID	FR(CLIS)83
Title	Provide auditory training sessions of various level of difficulty
Priority of accomplishment	Must have
Description	EVOTION platform should be able to provide auditory training sessions of various level of difficulty
Rationale	Elicited from: • CLIS.6, Step 20
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)84 - Automatically switch between different auditory trainings

Field	Description
ID	FR(CLIS)84
Title	Automatically switch between different auditory trainings
Priority of accomplishment	Should have
Description	EVOTION platform should be able to automatically switch between different auditory trainings
Rationale	Elicited from: • CLIS.6, Step 20
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)85 - Mobile app records patient feedback on a training

Field	Description
ID	FR(CLIS)85
Title	Mobile app records patient feedback on a training
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to record the patient feedback on a training as well as to recognize patient's speech
Rationale	Elicited from: • CLIS.6, Step 21
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)86 - Maintain results and score of cognitive tests for each patient

Field	Description
ID	FR(CLIS)86
Title	Maintain results and score of cognitive tests for each patient
Priority of accomplishment	Must have
Description	EVOTION platform must maintain the results and the score of cognitive tests for each patient
Rationale	Elicited from: • CLIS.9, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)87 - Associate cognitive scores with collected HA usage data and patients' feedback

Field	Description
ID	FR(CLIS)87
Title	Associate cognitive scores with collected HA usage data and patients' feedback.
Priority of accomplishment	Must have
Description	EVOTION platform should be able to associate cognitive scores with collected HA usage data and the patients' feedback.
Rationale	Elicited from:

	• CLIS.9, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)88 - Create an initial record with the lifestyle and listening environment requirements per patient

Field	Description
ID	FR(CLIS)88
Title	Create an initial record with the lifestyle and listening environment requirements per patient
Priority of accomplishment	Must have
Description	EVOTION platform should be able to create an initial record with the lifestyle and listening environment requirements per patient
Rationale	Elicited from: • CLIS.10, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)89 - Connect with the hearing aids software selection service

Field	Description
ID	FR(CLIS)89
Title	Connect with the hearing aids software selection service
Priority of accomplishment	Should have
Description	EVOTION platform should be able to connect with the hearing aids software selection service
Rationale	Elicited from: • CLIS.10, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)90 - Platform and mobile app collects real-time listening environment data and automatically adjust the fitting settings

Field	Description
ID	FR(CLIS)90
Title	Platform and mobile app collects real-time listening environment data and automatically adjust the fitting settings
Priority of accomplishment	Must have
Description	EVOTION platform and mobile app should be able to collect real-time listening environment data and automatically adjust the fitting settings
Rationale	Elicited from: • CLIS.10, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)91 - Mobile app connects to the user profile in the social networks

Field	Description

ID	FR(CLIS)91
Title	Mobile app connects to the user profile in the social networks
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to connect to the user profile in the social networks
Rationale	Elicited from: • CLIS.7, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)92 - Mobile app stores user consent action for accessing social networks

Field	Description
ID	FR(CLIS)92
Title	Mobile app stores user consent action for accessing social networks
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to store the user consent action for accessing social networks
Rationale	Elicited from: • CLIS.7, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)93 - Mobile app records different data streams

Field	Description
ID	FR(CLIS)93
Title	Mobile app records different data streams
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to record different data streams
Rationale	Elicited from: • CLIS.7, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)94 - Analyse patient activity in the social networks and relate it with events captured from the patient's HA and mobile devices

Field	Description
ID	FR(CLIS)94
Title	Analyse patient activity in the social networks and relate it with events captured from the patient's HA and mobile devices
Priority of accomplishment	Should have
Description	EVOTION platform should be able to analyse the patient activity in the social networks and relate it with the events captured from the patient's HA and mobile devices
Rationale	Elicited from:

	• CLIS.7, Step 8
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)95 - Analyse captured events from the patient's devices in relation to the patient responses in the questionnaires

Field	Description
ID	FR(CLIS)95
Title	Analyse captured events from the patient's devices in relation to the patient responses in the questionnaires
Priority of accomplishment	Could have
Description	EVOTION platform should be able to analyse the captured events from the patient's devices in relation to the patient responses in the questionnaires
Rationale	Elicited from: • CLIS.7, Step 8
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)96 - HA BP sensor should be able to calculate when BP exceeds the predefined thresholds

Field	Description
ID	FR(CLIS)96
Title	EVOTION HA BP sensor should be able to calculate when BP exceeds the predefined thresholds
Priority of accomplishment	Should have
Description	EVOTION HA BP sensor should be able to calculate when BP exceeds the predefined thresholds
Rationale	Elicited from: • CLIS.12, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)97 - Provide a report about the collected BP values

Field	Description
ID	FR(CLIS)97
Title	Provide a report about the collected BP values
Priority of accomplishment	Should have
Description	EVOTION platform should be able to provide a report about the collected BP values for a specific time period, an assessment on the arisen BP events and a notification for actions
Rationale	Elicited from: • CLIS.12, Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)98 - Electronically transmits report to patient

Field	Description

ID	FR(CLIS)98
Title	Electronically transmits report to patient
Priority of accomplishment	Must have
Description	EVOTION platform should be able to electronically transmit this report to the patient
Rationale	Elicited from: • CLIS.12, Step 9
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)99 - Issue notifications with respect to actions that should be taken on detected BP events

Field	Description
ID	FR(CLIS)99
Title	Issue notifications with respect to actions that should be taken on detected BP events
Priority of accomplishment	Should have
Description	EVOTION platform should be able to issue notifications with respect to actions that should be taken on detected BP events
Rationale	Elicited from: • CLIS.12, Step 13
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)100 - Compare sensors' data and data collected from HAs

Field	Description
ID	FR(CLIS)100
Title	Compare sensors' data and data collected from HAs
Priority of accomplishment	Must have
Description	EVOTION platform should be able a mechanism to compare sensors' data and data collected from HAs
Rationale	Elicited from: • CLIS.12, Use Case Summary
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)101 - Mobile app should collect data from sensors and upload them to EVIOTION repository in a periodic basis

Field	Description
ID	FR(CLIS)101
Title	Mobile app should collect data from sensors and upload them to EVIOTION repository in a periodic basis
Priority of accomplishment	Should have
Description	EVOTION mobile app should collect data from sensors and upload them to EVIOTION repository in a periodic basis
Rationale	Elicited from: • CLIS.12, Trigger 1
Supporting materials	N/A

Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)102 - Mobile app should collect data from sensors and HAs and upload them to EVIOTION repository in an ad hoc basis in case of an event

Field	Description
ID	FR(CLIS)102
Title	Mobile app should collect data from sensors and HAs and upload them to EVIOTION repository in an ad hoc basis in case of an event
Priority of accomplishment	Must have
Description	EVOTION platform should be able to analyze sensors' and HAs data
Rationale	Elicited from: • CLIS.8, Trigger 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)103 - Analyze sensors' and HAs data

Field	Description
ID	FR(CLIS)103
Title	Analyze sensors' and HAs data
Priority of accomplishment	Must have
Description	EVOTION platform should be able to analyze sensors' and HAs data
Rationale	Elicited from: • CLIS.8, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)104 - Manage surveys in order to create, update, delete, publish and assign surveys

Field	Description
ID	FR(CLIS)104
Title	Manage surveys in order to create, update, delete, publish and assign surveys
Priority of accomplishment	Should have
Description	EVOTION platform should provide a mechanism to manage surveys in order to create, update, delete, publish and assign surveys
Rationale	Elicited from: • CLIS.10, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)105 - Mobile app should notifies HA users to fill-in a questionnaire

Field	Description
ID	FR(CLIS)105
Title	Mobile app should notifies HA users to fill-in a questionnaire

Priority of accomplishment	Must have
Description	EVOTION mobile app should notify HA users to fill-in a questionnaire
Rationale	Elicited from: • CLIS.10, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)106 - Mobile app provides questionnaires to be filled-in by HA users and records HA users' answers

Field	Description
ID	FR(CLIS)106
Title	Mobile app provides questionnaires to be filled-in by HA users and records HA users' answers
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to provide questionnaires to be filled-in by HA users and record HA users' answers
Rationale	Elicited from: • CLIS.10, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)107 - Access to questionnaires' answers

Field	Description
ID	FR(CLIS)107
Title	Access to questionnaires' answers
Priority of accomplishment	Must have
Description	EVOTION platform should provide access to questionnaires' answers
Rationale	Elicited from: • CLIS.10, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)108 - Access to questionnaires' answers

Field	Description
ID	FR(CLIS)108
Title	Analyze questionnaires' answers
Priority of accomplishment	Must have
Description	EVOTION platform should be able to analyze questionnaires' answers
Rationale	Elicited from: • CLIS.10, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)109 - Record HA and HL related problems

Field	Description

ID	FR(CLIS)109
Title	Record HA and HL related problems
Priority of accomplishment	Should have
Description	EVOTION platform and mobile app should be able to record HA and HL related problems
Rationale	Elicited from: • CLIS.11, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)112 - Mobile app provides a multi-selection list with the most common sources of annoyance

Field	Description
ID	FR(CLIS)112
Title	Mobile app provides a multi-selection list with the most common sources of annoyance
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide a multi-selection list with the most common sources of annoyance
Rationale	Elicited from: • CLIS.11, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)113 - Mobile app records interactions of HA user with the multi-selection list of the most common sources of annoyance

Field	Description
ID	FR(CLIS)113
Title	Mobile app records interactions of HA user with the multi-selection list of the most common sources of annoyance
Priority of accomplishment	Should have
Description	EVOTION mobile app should be able to record the interactions of the HA user with the multi-selection list of the most common sources of annoyance
Rationale	Elicited from: • CLIS.11, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)114 - Show interactions of the HA user with the multi-selection list of the most common sources of annoyance in raw format as well as in cumulative format and in diagrams and charts

Field	Description
ID	FR(CLIS)114
Title	Show interactions of the HA user with the multi-selection list of the most common sources of annoyance in raw format as well as in cumulative format and in diagrams and charts
Priority of accomplishment	Should have

Description	EVOTION platform and mobile app should be able to show the interactions of the HA user with the multi-selection list of the most common sources of annoyance in raw format as well as in cumulative format and in diagrams and charts
Rationale	Elicited from: • CLIS.11, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)115 - Access to objective recording about HA malfunctions and HL related problems of HA users

Field	Description
ID	FR(CLIS)115
Title	Access to objective recording about HA malfunctions and HL related problems of HA users
Priority of accomplishment	Should have
Description	EVOTION platform should provide access to objective recording about HA malfunctions and HL related problems of HA users
Rationale	Elicited from: • CLIS.11, Postconditions
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)116 - Mobile app supports PTA, SIN and evoked potentials

Field	Description
ID	FR(CLIS)116
Title	Mobile app supports PTA, SIN and evoked potentials
Priority of accomplishment	Could have
Description	EVOTION mobile app should be able to support PTA, SIN and evoked potentials
Rationale	Elicited from: • CLIS.12, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)117 - HA gets calibrated (preferably automatically) based on HA test's results

Field	Description
ID	FR(CLIS)117
Title	HA gets calibrated (preferably automatically) based on HA test's results
Priority of accomplishment	Should have
Description	EVOTION HA should be able to get calibrated (preferably automatically) based on HA test's results
Rationale	Elicited from: • CLIS.12, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(CLIS)119 - Mobile app performs audiological tests and records the test results (quiet/noisy environment sounds and AUD1-5 parameters)

Field	Description
ID	FR(CLIS)119
Title	Mobile app performs audiological tests and records the test results (quiet/noisy environment sounds and AUD1-5 parameters)
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to perform audiological tests and record the test results (quiet/noisy environment sounds and AUD1-5 parameters)
Rationale	Elicited from: • CLIS.12, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

7.1.3. HA Users & significant others

FR(PSOS)120 - Mobile app extracts data in an application-friendly standard format

Field	Description
ID	FR(PSOS)120
Title	Mobile app extracts personal data in an application-friendly standard format
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to extract, in an application-friendly standard format (ie. txt, csv, xls, etc.), personal data such as data being used through a PHR
Rationale	Elicited from: • PSOS.1, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)121 - Support peer-2-peer real-time text messaging

Field	Description
ID	FR(PSOS)121
Title	Support peer-2-peer real-time text messaging
Priority of accomplishment	Must have
Description	EVOTION platform (mobile app for Patients and dashboard for Clinicians) should provide a mechanism of peer-2-peer (Patien-2-Clinitian & Clinician-2-Patient) real-time text messaging between Patients and Clinicians
Rationale	Elicited from: • PSOS.2, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)122 - Mobile app communicates with the HA device in order to request simple tests to monitor users' hearing over time

Field	Description
ID	FR(PSOS)122
Title	Mobile app communicates with the HA device in order to request simple tests to monitor users' hearing over time
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to communicate with the HA device in order to request simple tests to monitor users' hearing over time
Rationale	Elicited from: • PSOS.3, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)123 - Mobile app triggers hearing tests to take

Field	Description
ID	FR(PSOS)123
Title	Mobile app triggers hearing tests to take
Priority of accomplishment	Must have
Description	EVOTION mobile app users should be able to trigger hearing tests to take
Rationale	Elicited from: • PSOS.3, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)124 - Hearing tests trigger to be taken

Field	Description
ID	FR(PSOS)124
Title	Hearing tests trigger to be taken
Priority of accomplishment	Must have
Description	EVOTION platform should be able to trigger hearing tests to take
Rationale	Elicited from: • PSOS.3, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)125 - Track if the hearing aids are unused for long periods or if hearing aid controls are more frequently used

Field	Description
ID	FR(PSOS)125
Title	Track if the hearing aids are unused for long periods or if hearing aid controls are more frequently used
Priority of accomplishment	Must have
Description	EVOTION platform should be able to track if the hearing aids are unused for long periods or if hearing aid controls are more frequently used

Rationale	Elicited from: • PSOS.3, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)126 - Track if the hearing aids are unused for long periods or if hearing aid controls are more frequently used

Field	Description
ID	FR(PSOS)126
Title	Mobile provides clearly the hearing testing results over time (for a selected period)
Priority of accomplishment	Must have
Description	EVOTION mobile app should be provide clearly the hearing testing results over time (for a selected period)
Rationale	Elicited from: • PSOS.3, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)127 - Mobile app sends HA adjustments and hearing test results to EVOTION platform

Field	Description
ID	FR(PSOS)127
Title	Mobile app sends HA adjustments and hearing test results to EVOTION platform
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to send HA adjustments and hearing test results to EVOTION platform
Rationale	Elicited from: • PSOS.3, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)128 - Present hearing test results and HA adjustments of HA users

Field	Description
ID	FR(PSOS)128
Title	Present hearing test results and HA adjustments of HA users
Priority of accomplishment	Must have
Description	EVOTION platform (dashboard) should be able to present hearing test results and HA adjustments of HA users
Rationale	Elicited from: • PSOS.3, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)129 - Recognize significant adjustments of HA

Field	Description

ID	FR(PSOS)129
Title	Recognize significant adjustments of HA
Priority of accomplishment	Must have
Description	EVOTION platform should be able to recognize significant adjustments of HA
Rationale	Elicited from: • PSOS.3, Step 6
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)130 - Send selected training material (words into sound) to EVOTION mobile app

Field	Description
ID	FR(PSOS)130
Title	Send selected training material (words into sound) to EVOTION mobile app
Priority of accomplishment	Must have
Description	EVOTION platform should be able to send selected training material (words into sound) to EVOTION mobile app
Rationale	Elicited from: • PSOS.4, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)131 - Mobile app should be able to play training material (words into sound)

Field	Description
ID	FR(PSOS)131
Title	Mobile app should be able to play training material (words into sound)
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to play training material (words into sound)
Rationale	Elicited from: • PSOS.4, Step 1
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)132 - Mobile app provides the functionality to select the available training material

Field	Description
ID	FR(PSOS)132
Title	Mobile app provides the functionality to select the available training material
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide the functionality to select the available training material
Rationale	Elicited from: • PSOS.4, Step 2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)133 - Mobile app provides instructions to monitor TTS/NIHL and instructions to perform hearing test

Field	Description
ID	FR(PSOS)133
Title	Mobile app provides instructions to monitor TTS/NIHL and instructions to perform hearing test
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide instructions to monitor TTS/NIHL and instructions to perform hearing test
Rationale	Elicited from: • PSOS.5, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)134 - Record ambient noise level and patient physiological data (oxygen saturation, blood pressure)

Field	Description
ID	FR(PSOS)134
Title	Record ambient noise level and patient physiological data (oxygen saturation, blood pressure)
Priority of accomplishment	Must have
Description	EVOTION platform should be able to record ambient noise level and patient physiological data (oxygen saturation, blood pressure)
Rationale	Elicited from: • PSOS.5, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)135 - Record ambient noise level and patient physiological data (oxygen saturation, blood pressure)

Field	Description
ID	FR(PSOS)135
Title	Mobile app provides hearing self-tests to HA users
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide hearing self-tests to HA users
Rationale	Elicited from: • PSOS.5, Step 7
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)136 - Mobile app alerts HA users to seek urgent medical attention

Field	Description
ID	FR(PSOS)136
Title	Mobile app alerts HA users to seek urgent medical attention
Priority of accomplishment	Must have

Description	EVOTION mobile app should provide a mechanism to alert HA users to seek urgent medical attention
Rationale	Elicited from: • PSOS.5, Step 8
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)137 - Mobile app records TTS/NIHL episodes

Field	Description
ID	FR(PSOS)137
Title	Mobile app (automatically/manually) records TTS/NIHL episodes
Priority of accomplishment	Should have
Description	EVOTION mobile app should provide the functionality to (automatically/manually) record TTS/NIHL episodes
Rationale	Elicited from: • PSOS.5, Step 9 • PSOS.5, AF9-BF2
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)138 - Mobile app provides a list of the available medical help for urgent circumstances

Field	Description
ID	FR(PSOS)138
Title	Mobile app provides a list of the available medical help for urgent circumstances
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide a list of the available medical help for urgent circumstances
Rationale	Elicited from: • PSOS.5, Step 10
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)139 - Determine combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes

Field	Description
ID	FR(PSOS)139
Title	Determine combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes
Priority of accomplishment	Must have
Description	EVOTION platform should provide a mechanism to determines combination of factors (noise levels, duration of exposure, other physiological data) associated with TTS/NIHL episodes
Rationale	Elicited from: • PSOS.5, Step 11
Supporting materials	N/A

Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)140 - Automatic alerts for urgent hearing TTS/NIHL episodes

Field	Description
ID	FR(PSOS)140
Title	Automatic alerts for urgent hearing TTS/NIHL episodes
Priority of accomplishment	Must have
Description	EVOTION platform should provide automatic alerts for urgent hearing TTS/NIHL episodes
Rationale	Elicited from: • PSOS.5, Step 12
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)141 - Record TTS episode retrospectively

Field	Description
ID	FR(PSOS)141
Title	Record TTS episode retrospectively
Priority of accomplishment	Must have
Description	EVOTION platform should provide a mechanism to record TTS episode retrospectively
Rationale	Elicited from: • PSOS.5, AF9-BF5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)142 - Mobile app records issues, concerns and problems with hearing aid

Field	Description
ID	FR(PSOS)142
Title	Mobile app records issues, concerns and problems with hearing aid
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide a mechanism to record issues, concerns and problems with hearing aid
Rationale	Elicited from: • PSOS.6, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)143 - Mobile app provides customized support to HA user

Field	Description
ID	FR(PSOS)143
Title	Mobile app provides customized support to HA user
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide customized support to HA user
Rationale	Elicited from: • PSOS.6, Step 4

Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)144 - Analyse issues, concerns and problems with hearing aid reported by HA users

Field	Description
ID	FR(PSOS)144
Title	Analyse issues, concerns and problems with hearing aid reported by HA users
Priority of accomplishment	Must have
Description	EVOTION platform should be able analyse issues, concerns and problems with hearing aid reported by HA users
Rationale	Elicited from: • PSOS.6, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)145 - Mobile app provides up-to-date hearing research and health promotion information to HA user

Field	Description
ID	FR(PSOS)145
Title	Mobile app provides up-to-date hearing research and health promotion information to HA user
Priority of accomplishment	Must have
Description	EVOTION mobile app should provide up-to-date hearing research and health promotion information to HA user
Rationale	Elicited from: • PSOS.7, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)146 - Record up-to-date hearing research and health promotion information

Field	Description
ID	FR(PSOS)146
Title	Record up-to-date hearing research and health promotion information
Priority of accomplishment	Must have
Description	EVOTION platform should be able to record up-to-date hearing research and health promotion information
Rationale	Elicited from: • PSOS.7, Step 4
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

FR(PSOS)147 - Record data on the co-morbidities and additional health needs of hearing aid users

Field	Description
ID	FR(PSOS)147
Title	Record data on the co-morbidities and additional health needs of hearing aid users

Priority of accomplishment	Must have
Description	EVOTION platform should be able to record data on the co-morbidities and additional health needs of hearing aid users
Rationale	Elicited from: • PSOS.8
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

7.2. Non-Functional (Security, Privacy, Performance.)

Security requirements "specify the factors that protect the software from accidental or malicious access, use, modification, destruction, or disclosure" [130]. Examples are the usage of cryptographic techniques, assignation of certain functions to different modules, restriction of the communication between some areas of the program, and checking the data integrity for critical variables. **Legal requirements** cover any constraints through legal regulation, e.g. licenses, laws, patents, etc. **Performance requirements** "specify both the static and the dynamic numerical requirements placed on the software or on human interaction with the software as a whole" [130]. Dynamic numerical requirements specify an amount of actions that are done in a certain time period, e.g. amount of web pages that are captured in one hour. Hence, dynamic requirements can be encapsulated in the sub-category of speed/performance requirements. Static numerical requirements will be specified mainly under the sub-category of capacity and scalability requirements. They define how much or how many the system must be able to process or to store. Examples are how many users can access the system at the same time how much storage capacity must be managed by the system [130]. Another subcategory is reliability and availability requirements. Performanc, Legal and Security Requirements for EVOTION can be described as follows.

Field	Description
ID	PPSR1
Title	Users security
Priority of accomplishment	Must have
Description	EVOTION shall provide a system and its tools that respects users security and discourages data loss and misuse of data for fraudulent or other acts.
Rationale	Elicited from: • State of the art section
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

Field	Description
ID	PPSR2
Title	Users privacy and confidentiality
Priority of accomplishment	Must have
Description	EVOTION shall provide a system that respects users privacy and confidentiality.

Rationale	Elicited from: • D7.1 Study protocol and Ethics Approval Application Report
Supporting materials	D7.1 Study protocol and Ethics Approval Application Report
Tentative scheduling	*Tentative scheduling of accomplishment.*

Field	Description
ID	PPSR3
Title	System capacity
Priority of accomplishment	Must have
Description	The performance of EVOTION platform and it components should not degrade with an increase in the number of the users or/and the available datasets.
Rationale	-
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

Field	Description
ID	PPSR3
Title	Meet high usability
Priority of accomplishment	Must have
Description	EVOTION platform and mobile app should be designed to meet high usability
Rationale	Elicited from: • CLIS.11, Step 3
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

Field	Description
ID	PPSR4
Title	Mobile app interacts with the HA user (need of mobile UI)
Priority of accomplishment	Must have
Description	EVOTION mobile app should be able to interact with the HA user (need of UI)
Rationale	Elicited from: • CLIS.12, Step 5
Supporting materials	N/A
Tentative scheduling	*Tentative scheduling of accomplishment.*

Field	Description
ID	PPSR5
Title	Mobile app supports voice recognition
Priority of accomplishment	Must have
Description	EVOTION mobile app should support voice recognition
Rationale	Elicited from: • CLIS.11, Step 3
Supporting materials	N/A

Tentative scheduling	*Tentative scheduling of accomplishment.*

8. Constraints

8.1. Design

EVOTION platform and its components needs to be accessible on multiple platforms and browsers and from remote locations. Also, as the set of EVOTION features are intended to be research based, the design shall be influenced by research needs and obtaining usage statistics.

8.2. Hardware and OS

Concerning scalability of the system, the system that hosts EVOTION platform and its components should be able to be scaled and increased EVOTION's demands. EVOTION's underlying operating system should be adjusted to handle and resolve concurrent transactions with the end users.

8.3. Project Schedule

There is a time constrain of thirty-three-month timeframe to implement a platform and its components for the EVOTION platform and mobile app, where users are not only to discover relevant information but also to remix it with diverse and dynamic functionality.

8.4. Documentation

Official project's documents should contain several parts: a description of the audience(s) for the document, a detailed outline giving the structure and contents of the document. Thus, there may other managerial information, such as number of pages allocated for each section, and so forth. In the workplace, formal document specifications serve three important functions: economy of effort, work planning, and writing organization.

9. Conclusion

A fundamental challenge for technology-oriented enterprises is to meet user expectations when developing online applications and services. Due to strong competition, a successful approach should be the design of applications on the basis of the current state-of-the-art. In this direction, user requirements analysis is the foundation of a user-centered approach, creating applications that appeal to and meet user needs at the highest level.

This document presented the process followed by the EVOTION project to capture, analyse and record the requirements for the EVOTION platform, as expressed by users who belong to the targeted groups. The methodology used to achieve these objectives have been described along with the results the consortium reached and will be later employed in the system design process. As such, a unified approach in the collection of the stakeholders' opinions has been followed in order to collect data from various target groups with different backgrounds and from different localities.

More specifically, scenarios have been drafted by the pilot users. Additionally, focus group discussion and structured interviews were organised to collect feedback and opinions, which would better identify the necessary features of the system.

The deliverable constitutes a user requirements analysis that provides descriptions of the functionality and quality demanded by prospective users. For the identification of user needs, the user perspectives have been taken into account and result in:

- Functional requirements (what the users want the system to do)
- Non-functional requirements (restrictions on the types of solutions to meet the functional requirements)

Functional requirements include what the desired user activities, constraints and preferences are, and how the user would trade-off between different software capabilities. The goals that users want to reach and the tasks they intend to perform by the new system must be determined. The important point to note is that "WHAT is wanted" is specified, and not HOW it will be delivered.

The specification of non-functional requirements incorporates performance aspects such as response time, security, and generally criteria that judge the operation of the system. The reported user requirements will be translated into the Technical specifications based on which the initial design of the system architecture will be delivered. This part of the analysis will be presented in the deliverable "D2.2 EVOTION architecture and detailed design".

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Appendices

Appendix 1 Dropped Draft Scenarios

Hearing aid rejection

Use Case Id	DR-CLIS.3
Use Case Name	Hearing aid rejection
Use Case Summary	Patients with hearing impairment are frequently offered hearing aids as part of rehabilitation. In a proportion of these, the hearing aids are rejected by the user. The reasons for this rejection are complex and sometimes difficult to discern in an individual. The outcome is undesirable in terms of a poor outcome from rehabilitation for the individual and wasted resources of the organization (hardware, staffing time, etc). Audiologists may use the evotion platform to identify factors which are associated with hearing rejection in particular patient populations and target intervention appropriately.
Actors	Clinician-audiologist
Preconditions	Data is visualised in a meaningful way for all actors. Audiologist able to interact with evotion interface. All conditions that must be satisfied prior the commencement of the interaction described by the use case.
Trigger	Audiology service seeking to improve uptake and maximise efficient use of resources.
Basic Flow	1. Clinician identifies need for improved hearing aid uptake 2. Clinician identifies key characteristics of this population 3. Clinician interrogates database for associated features. 4. Clinician identifies possible targets for intervention or high risk groups to target resources.
Alternate Flows	
Postconditions	Clinician applies information in specific clinical context.

Behavioural data

Use Case Id	CLIS.10 (LIFE)
Use Case Name	Behavioural data
Use Case Summary	Patients with hearing impairment are frequently offered hearing aids as part of rehabilitation. Hearing aids may be required to cope with a range of different listening environments depending on individual lifestyles. Common environments could include using screens/tablets, watching television, attending meetings, and driving. Individual hearing aid users may have different listening experiences in different environments. The clinician needs to collect this information to develop customised rehabilitation programmes for individual patients,
Actors	Clinician-audiologist

Preconditions	Data is visualised in a meaningful way for all actors. Audiologist able to interact with evotion interface. All conditions that must be satisfied prior the commencement of the interaction described by the use case.
Trigger	Audiology service seeking to improve uptake and maximise efficient use of resources.
Basic Flow	1. Patient presents for aural rehabilitation. 2. Clinician assesses lifestyle and listening environment requirements for individual and issues Evotion compatible hearing aids. 3. Patient uses Evotion hearing aid and app to trial aid in real-life setting. 4. Evotion platform automatically collects behavioural usage data 6. At review, hearing aid settings can be adapted based on real-time listening environment feedback obtained via app. 7. Improved user satisfaction.
Alternate Flows	
Postconditions	Clinician applies information in specific clinical context.
Use Case Id	CLIS.10 (LIFE)
Use Case Name	Behavioural data
Use Case Summary	Patients with hearing impairment are frequently offered hearing aids as part of rehabilitation. Hearing aids may be required to cope with a range of different listening environments depending on individual lifestyles. Common environments could include using screens/tablets, watching television, attending meetings, and driving. Individual hearing aid users may have different listening experiences in different envinroments. The clinician needs to collect this information to develop customised rehabilitation programmes for individual patients,
Actors	Clinician-audiologist
Preconditions	Data is visualised in a meaningful way for all actors. Audiologist able to interact with evotion interface. All conditions that must be satisfied prior the commencement of the interaction described by the use case.
Trigger	Audiology service seeking to improve uptake and maximise efficient use of resources.
Basic Flow	1. Patient presents for aural rehabilitation. 2. Clinciian assesses lifestyle and listening environment requirements for indivudal using standard Evotion tools. 3. Clinician inputs to Evotion the outputs from the individual assessment of behavioural and environmental data. 4. Clinician uses Evotion generated outputs to identify appropriate rehabilitation tools from among a range of inputted options. 5. Patient uses Evotion hearing aid and app to trial aid in real-life setting. 6. At review, hearing aid settings can be adapted based on real-time listening environment feedback obtained via app. 7. Improved user satisfaction.

Alternate Flows	
Postconditions	Clinician applies information in specific clinical context.

Adverse event

Use Case Id	CLIS 12 (ADVERSE)
Use Case Name	Adverse event
Use Case Summary	This use case captures a scenario related to an adverse event.
Actors	Clinical Stakeholder: Audiologist. Patient stakeholder: patient
Preconditions	Access to EVOTION platform. Concurrent use of HAs, mobile phones and blood pressure monitoring sensor. Communication between BP sensor and app. Patient education and engagement.
Trigger	
Basic Flow	1. Patient is diagnosed with hearing loss and referred for hearing aid fitting by ENT/AVM/Audiologist. 2. Audiologist/audiological scientist performs initial hearing tests 3. Audiologist/audiological scientist performs initial hearing aid fitting 4. Hearing aid usage education is provided by audiologist/audiological scientist 5. Patient uses HA and sensors 6. EVOTION HA BP sensor records BP exceeding safety limits (over 140/90) 7. BP sensor flashes red light to alert patient about raised BP. Patient takes steps to address this (contact GP; take a tablet). Patient mutes BP alarm 8. EVOTION HA system transfers BP records in cloud service 9. Patient BP recording over a week period is emailed to patient with raised BP events highlighted and the suggestion that the patient contacts their GP 10. Patient returns for 3 month follow up 11. EVOTION HA system provides data will in cumulative diagrams and charts format for BP 12. Audiologist/audiological scientist accessess automatically recorded data provided in to this information recorded. 13. Audiologist asks patient if action has been taken regarding BP control and advises patient to contact GP for such ction
Alternate Flows	
Postconditions	All conditions that must be satisfied upon the completion of the interaction described by the use case. BP raised adverse events are aborted. BP data are recorded in the EVOTION platform for several HA users. Successive stages of analysis will identify if BP factors predict HA usage and inform public health case scenario:

Appendix 2 Focus Groups details

Policy Makers focus group 1 minutes

WP2, T2.1 – Public Policy user (PRA)

Executive Summary

Representatives of 4 public policy institutions (described in detail in the *Detailed Minutes* underneath) participated in the initial FG meeting and the follow-up E-mail contacts for scenario validation. Three draft scenarios (PHAS2, PHAS3 and PHAS4) were elaborated by PRA as an outcome to the implemented Focus Group/workshop methodology (the latter also described in detail underneath) and PHAS1 was also added to these three for the validation exercise. The latter was carried out in the period 5-14 Dec. over the E-mail and telephone. URL for the online questionnaire for Public Policy users was sent to additional 6 public policy stakeholders (also described in the *Detailed Minutes* underneath)**,** and assistance was offered by PRA's internal EVOTION team for filling-in.

The following general points came up as feedback and suggestions for further analysis:

- Opinion across the entire Focus group is that similar tools for support of public decision-making processes are not available nor familiar to policy makers here – so far they have only used regulations/decrees, guidelines and/or methodological instructions;
- Again, the opinion across the entire group is that EVOTION could be beneficial for its intended purpose as a public health policy-making support tool (all institutions represented in the FG have advisory competences and are authorized to deliver opinions on draft legislation/regulations);
- However, the majority of participants expressed skeptical opinions on the availability of local "big data" in Bulgaria; statistics and record-keeping here are insufficient, especially focused on HL and HAs use. Therefore, it may be necessary to use background EVOTION data analyses for the generation of possible measures/interventions in specific user cases. But will these reflect the local specificities?
- Alternative solution would be to organize targeted collection of relevant local data to be fed into the EVOTION platform if the functionality would allow this. However, this might eventually involve too much time, effort and collaboration with different stakeholders thus, making the decision-making process too tedious;
- A suggestion was made to consider involving the business of HA suppliers/producers as well since here they are responsible for making individual fitting-in of HAs and also, for follow-up adjustments and maintenance

Scenario PHAS.1 - Prognosis of low HA usage

Pros:

- very relevant;

- review of related studies could help for determining the types, size, etc. of data, types of data analyses and prognostic factors;
- the change in patients' life and in the efficiency of HL treatment/rehabilitation will be significant ;
- economies for the public health budget for HL treatment/rehabilitation;
- will help clinicians improve treatment/rehabilitation
- benefits for the economy from reduction in early HL retirement.

Cons:

- collecting some types of data (real time, etc.) might require substantial investment in equipment and research time and effort;
- if auditory training is selected as a suggested measure this would be difficult to adopt as a policy intervention because it is private HAs suppliers/producers who will have to provide such training and hence, this might involve additional personnel demand and costs to them

Scenario PHAS.2 - Predicting early retirement due to hearing impairments

Pros:

- the economies for the public budget and economy in general would be of scale;
- will help prolong active economic activities of people;

Cons:

- not large number of population to be affected by eventually adopted policy interventions – the cost-benefit should be weighed

Scenario PHAS.3 - Predicting urban physical planning based on HL

Pros:

- good idea to give consideration to the effects urban infrastructure has on hearing from the early stage of planning
- would be easier to take further than the initial advocacy phase the EVOTION suggested policy measures for policy adoption at local level by municipal urban planning departments and municipal councils; they are more flexible than national policy-makers
- national and EU funding programmes promote investment in infrastructure for the benefit of public health
- large number of population will be affected by eventual adopted policy measures

Cons:

- will be hard to test the sensitivity and significance of the outcomes of the analyses because noise-induced HL resulting specifically from poor urban infrastructure would be hard to distinguish from other factors influencing HL;
- territory coverage will be limited only to large cities due to fixed measurement points

Scenario PHAS.4 - Explore the potential for personalization of HA administration and use follow-up

Pros:

- could help allocate public funds in a more targeted and efficient way while distributing such funds according to personal needs;
- could have a positive effect on individualizing HL treatment and rehabilitation as well;
- could help reduce health inequalities.

Cons:

- analyses will have to rely largely on qualitative/subjective data;
- only a risk group of patients will be affected;
- unlikely to be taken further from the initial advocacy phase for policy adoption due to the fact that it will involve a lot of resource, both financial and human.

Detailed Minutes

During PRA's internal EVOTION team discussions on the tasks due in WP2 we came up with a decision to proceed with the process of requirements identification and analysis for EVOTION by identifying Focus Group participants and inviting them for a first workshop in order to establish their needs as potential users of the platform.

Initial **FG participants** identified were the directors of:

1. the regional structure of the national Ministry of Public Health as follows:

- The Regional Health Inspectorate - in their role as supervising the Regional ENT-specialists' Advisory Committee (issuing use of HAs) and the Committee of Occupational Expert Physicians (issuing early retirement decisions);

2. the regional structure of the National Health Insurance Fund :

– the Regional Health Insurance Fund (in their role as managing public funding for clinical pathways).

3. the regional structure of the national Agency for Social Support (belonging to the national Ministry of Labour and Social Policies):

– the Regional "Social Support" Directorate - in their role as authorising financial support for purchasing HAs and performing administrative follow-up on HA use.

An invitation letter was sent to all three persons above and the first **FG meeting was held on 30th November, 2016 in PRA's offices**. **Present at the meeting were also the Regional Governor and two public policy planning experts from PRA**. After the introductory presentation of the EVOTION project, PRA's involvement and the purpose of the Focus Group an open discussion was held with all participants as actual potential users. Our target was to identify their current procedures and workflows for implementing national policies focused on HL and HA use as well as their role and activities in the policy decision-making processes. Also, we established their priorities and experienced difficulties and constraints in order to gain as much as possible additional information for creating the user requirements towards the EVOTION system . Thus we managed to collect opinions and ideas and raise interest for further collaboration. This gave us the basis to very briefly draft example scenarios and questions for the questionnaire which the PRA team further elaborated and drafted to fit into the template provided by the WP Leader. These final drafts were then circulated by E-mail to all FG participants for additional input, comments and validation. E-mail was also used to put general questions on their opinion about the EVOTION platform

and how and when they could use it, as well on other services they would like to be included and if they knew similar tools or applications. An executive summary of the feedback to these is included in the beginning of the present material.

Eventually, when the online questionnaire was made available and functional the URL address for "Public policy stakeholders" was also circulated by E-mail and we offered assistance for filling it in.

In the course of the meeting it was suggested that we should **consider inviting additionally representatives of the Regional Labour Inspectorate (in their role as supervising occupational environments) and of the local authorities (12 municipal administrations** in their role as urban planning responsibles). Both these actors have their share to contribute to some of drafted scenarios. Also, it was considered beneficial to **involve as Focus Group participants major nationally-representative regional structures of HL patients/HA users in their specific advisory role in drafting national public health policies focused on HL**. As a first step we sent these three types of stakeholders the URL to the Public Policy users' questionnaire. We plan to involve them in Focus Group meetings later in process (especially in the evaluation in WP7).

Policy Makers focus group 2 minutes (Location: Ministry of Health of the Republic of Croatia, Zagreb, Croatia, Date: January 16 2017)

Executive Summary: Validation of the 6 scenarios for Public policy makers, **third** FG meeting.

First scenario: Prognosis of low HA usage

To determine the scale of the problem Ministry of Health (MoH as PHAA) will open communication channel with the Croatian Public Health Insurance Company (CPHIC) and try to collect all recorded HL patient data in last 10 years (more or less). IPH will determine of HA usage on all healthcare level (primary and secondary level) and their cost. This data will not become part of EVOTION database but will be useful for EVOTION data analysis.

There is possibility of obstruction in obtaining this data coming from CPHIC.

According to the EVOTION outcomes MoH will consider entirely public health policy of HA usage and possible re-determination of the minimum standard of HAs.

Second scenario: Predicting early retirement due to hearing impairments

MoH will try to open communication channel to Croatian Pension Insurance Institute (CPII) to link data of HL patients, already existing in CIPH database and patient's retirement status. IPH will determine the scale of the problem of retirement and hearing impairments. This data will not become part of EVOTION database but will be useful for EVOTION data analysis.

There is possibility of obstruction in obtaining this data coming from CPII.

Third scenario: Predicting urban physical planning based on HL

MoH monitors noise-inducing urban physical infrastructure through sanitary inspection. This intervention could be improved a lot depending on EVOTION outcomes by making of new legislation harmonized with other PHAA. In this scenario, MoH stresses a limited role in relation to other PHAA (Ministry of Environment, municipalities…).

Fourth scenario: Explore the potential for personalization of HA administration and use follow-up

MoH is aware that current model of assistance based solely on the provision of free devices to every patient is very rigid, regardless to personal characteristics and environment where patient lives and (possibly) works in the community. According to the EVOTION outcome, economic analysis and expenses are possible to adopt laws and regulations to the all or selected group of HPs over time.

Fifth scenario: Policy formation for effective use of assistive listening

MoH believes that local communities should participate predominantly in this scenario. There is no experience in Croatia for effective use of assistive listening.

Sixth scenario: Exploration of factors for prevention of cognitive decline

MoH believes that exploration of this factors is time-consuming compared with project duration, but can satisfy situational analysis.

Detailed Minutes

During the third FG meeting participants invited were representatives of:

1. Ministry of Health, Administration for health improvement, Department of health projects and programs, Zagreb
2. The Regional Labour Inspectorate, Ministry of Labour
3. The Regional Sanitary Inspection, Ministry of Health
4. Municipality of Osijek, Department of Social Welfare and Health

Regards to PHPM process, MoH believes that one workshop will be very important for improving cross-sectoral collaboration and harmonization of PHAA from different countries to achieve goals in development of public health policies and EVOTION.

Policy Makers focus group 3 minutes (Collected user requirements in PRA's Focus Group according to the Proposed New Plan for the Delivery of D2.1-EVOTION WP2 requirements and design)

Executive Summary

Representatives of 5 public policy institutions (described in detail in the *Detailed Minutes* underneath) participated in the second FG meeting for the validation of the updated and finalized by CITY draft scenarios for Public policy makers. The two new draft scenarios (PHAS5 and PHAS6) were discussed according to the Focus Group/workshop methodology (the latter also described in detail underneath).
The following points came up as feedback and suggestions for further analysis:

Scenario PHAS.5 - Policy on Effective Use of Assistive Listening Devices

Pros:

- the change in the quality of public service provision and in HL patients' life will be valuable;
- could help reduce health inequalities in delivering public services;
- improved efficiency of HLoops could result in economies for the public health budget;
- will help fitters/audiologists HA improve servicing.

Cons:

- HLoops are not widely used in Bulgaria and there are no regulatory requirements to install them even in public institutions, hence not a large number of the population to be affected by eventually adopted policy interventions – the cost-benefit should be weighed;
- collecting such types of data might require substantial investment in equipment, research time and effort;

Scenario PHAS.6 - Exploration of factors for prevention of cognitive decline

Pros:

- will help prolong active life and economic activities of people;
- the economies for the public budget would be of scale;

Cons:

- will be hard to test the sensitivity and significance of the outcomes of the analyses because there are a variety of factors affecting cognitive decline in addition to the specific data types to be collected within the EVOTION context;
- the scenario covers only the situational analysis stage of the policy-making process and hence, will provide only partial support for effective public policy formulation;
- the cost involved in collecting all such data should be considered against the above partial solution.

Detailed Minutes

During the second **FG meeting participants** invited were representatives of:

1. the regional structure of the national Ministry of Public Health: The *Regional Health Inspectorate* - in their role as supervising the Regional ENT-specialists' Advisory Committee (issuing use of HAs) and the Committee of Occupational Expert Physicians (issuing early retirement decisions);

2. the regional structure of the National Health Insurance Fund : the *Regional Health Insurance Fund* (in their role as managing public funding for clinical pathways).

3. the regional structure of the national Agency for Social Support (a structure within the national Ministry of Labour and Social Policies): the *Regional "Social Support" Directorate* - in their role as authorising financial support for purchasing HAs and performing administrative follow-up on HA use.

4. the regional structure of the national "Labour Inspectorate" Executive Agency: *the Regional Labour Inspectorate* in Pazardzhik (in their role as supervising occupational environments);

5. Pazardzhik Regional Administration – EVOTION partner: Present at the meeting were also the Regional Governor and two public policy planning experts (EVOTION internal PRA staff)

An invitation letter was sent to all four institutional stakeholders above and the second round of the **FG meeting was held on 5th January, 2017 in PRA's offices**. After the introductory presentation of the updated PHAS scenarios and of the purpose of the Focus Group meeting an open discussion was held with all participants as actual potential EVOTION users. Thus, we collected their opinions, comments and ideas. An executive summary of their feedback to these is included in the Executive Summary in the beginning of the present material.

In the course of the meeting it was again suggested that we should **consider inviting additionally representatives of the local nationally-representative regional structure of HL patients/HA users organisation (The Union of Deaf People in Bulgaria)** in their specific advisory role in drafting national public health policies focused on HL. As a first step we sent them the URL to the Public Policy users' questionnaire and we plan to approach them individually in the next Focus Group rounds.

Clinicians focus group 1 minutes

Particpants	UoA-Audiologist 1	UoA Audiologist 2	UoA-Otolaryngologist
Location	1st Otolaryngology University Clinic, Athens, Greece		
Date	19 January 2017		
Participant	Clinician UoA Gender: Male Age: 50	Clinician UoA Gender: Female Age: 40	Clinician UoA Gender: Female Age: 30

		Education: Masters of audiology Years of work experience: 26 Current work setting: Head of hearing aid fitting centres	Education: Speech therapist, Audioprosthetist Years of work experience: 15 Current work setting: Audioprosthetist, private	Education: MD, Otolaryngologist Years of work experience: 2 Current work setting: ENT resident
	EXECUTIVE SUMMARY	**DETAILLED MINUTES**		
Scenario 1. Retrieval of HA usage data	• Scenario with 8/10 • Pros: 1. Makes possible objective monitoring of valuable data 2. Increases reliability and facilitates counselling • Cons: 1. Needs patient education	• It would be a very nice feature • Misunderstandings and non-reliable information are common and this would be a way to reduce related problems • Objective data are far more reliable compared to subjective descriptions	• Although data recording is present in most of hearing aids, this is an innovative and very interesting scenario • In my experience, a significant constraint would be that many elderly people do not own an Android • It would be very nice to visualize results and talk with the patient based on these during counselling	• Very nice scenario • Needs patient education
Scenario 2. Transfer data to clinicians and audiologist	• Scenario ranked 6/10 • Pros: 1. Patients are always concerned	• Scenario targets sudden hearing loss but most commonly patients concerns are about non	• Other problems (whistling, mold related problems, tinnitus alternations	• Difficult to establish diagnosis of

	regarding various events and this could be a tool to reduce workload Cons: 1. Medical related issues considerations	clinically significant issues • It would be beneficial to provide instructions about hearing aid care, protection and handling • Consider giving the patient the opportunity to refer problems manually • Consider videos in mobile app describing hearing aid care	etc) are more common indeed • It could significantly reduce workload in hearing aid fitting units • Also a valuable tool to estimate overall performance of the hearing aid. • Consider open and closed label set of problems to be reported.	sudden hearing loss remotely • A concern is that many false positive findings may arise • Requires very careful calibration and patient education
Scenario 3. Hearing aid rejection	• Scenario ranked 7/10 • Pros: 1. Addresses a major and maybe underestimated issue • Cons: 1, Expectation are of profound importance and cannot be identified with this scenario	• Although factors related to rejection are more or less well known, this scenario could be helpful to personalize • Patient expectations are very important for hearing aid rejections and this kind of data cannot be monitored with this scenario. • It is very important to connect with scenario 1	• In our case, socioeconomic status is very important and this relation could e easily monitored by a simple audit • Hence, other factors could be identified via this scenario • Very important to	• Not very clear scenario as described • Many patients do not even try a hearing aid and maybe data collected from people who actually tries a hearing aid might be misleading.

		and try to convince patients not to reject.		
Scenario 5. "Ask the expert" hearing aid fitting (à la Watson)	• Scenario ranked 5.7/10 • Pros: 1. Potentially improves hearing aid fitting and patient satisfaction Cons: 1. Concerns about technology used 2. Risk of audiologists relying too much on this.	• Not sure whether this scenario is feasible at all, since enormous data are required to produce reasonable results • It could never replace the audiologist • Current DSSs are evidence based, I wonder whether this can be characterizes as such. •	• Nice scenario, especially since data that will be collected are objective and therefore reliable. • Current algorithms are almost 30 years old and consequently reliable. Hence, technology is growing rapidly and it is reasonable to expect significant progress ion relatively short periods, as achieved in many other fields.	• Sounds interesting, but should never replace the audiologist's duty of care.
Scenario 6. Assessment of initial follow up policies	• Scenario ranked 7.7/10 • Pros: 1. Ensures equality for HA users 2. Reduces number of F/U visits	• Very important for people from distant places • Consider online video consultation • Consider eliminating some F/U visits if a checklist is OK. • Some problems can be resolved remotely.	• This is a nice tool for my office to reduce time on people who are doing well and increase time to those who need it. It will be evidence based time management. • Decision for F/U is multifactorial and a	• Nice idea, not sure whether it will reduce or increase workload

		Hence, this could be equally time consuming, especially during the initial phases.	structured way to decide upon is helpful	
Scenario 7. Protection of people with hearing impairments from the harmful effects of loud noise: individualized risk assessment	• Scenario ranked 7/10 • Pros: 1. Very common problem, most of the times underdiagnosed • Cons: 1. False positives 2. Needs education	• Similar systems have also be implemented in other HAs • HAs reduce noise automatically and this might affect measurements reliability • Many times exposure to loud noises happens when the patients does not use the HA. It would be nice to record noise levels all the time via the mobile and perform a PTA as soon as the user wear HA again.	• It is essential to have objective data instead of subjective histories • It would be intere4sting to have noise exposure data (dBs, duration) • More useful for people who work in noisy environments • Might cause concern in some people, so notification system should be very carefully designed • Difficult to ensure that PTAs will be performed all times, due to every day constraints and thus there will be a lot of missing data that might mislead conclusions	• Compound of noise is always a mystery in HL pathophysiology • Detection is not enough, protection should also be implemented • Could also be interesting for research purposes

Scenario 8. Individualised auditory training (AT) to optimise HA benefits and prevent or delay cognitive and auditory processing deterioration	• Scenario ranked 7/10 • Pros 1. Promising and innovative field 2. Excellent opportunity to test effectiveness in adults Cons 1.Requires education and commitment 3. Not sure whether trade-off is positive	• Auditory training is considered potentially helpful in the first place • AT is an intervention for selected patients. Who are motivated and are willing to commit • It is an opportunity to test effectiveness •	• Most of the patients will not be willing to do it or get tired soon • Hence, elderly patients have time and are sometimes motivated, provided that a good reasoning will be given during consultation • Consider using an award system to motivate patients	• Nice idea, it could also improve cognition
Scenario 9. **Collection of cognitive data**	• Scenario ranked 6/10 Cons 1. Very difficult to commit 2. Time consuming	• Elderly people do have cognitive failure but, at least in their minds, this cannot be connected to HL • Very small proportion will allocate time for this • They might even find this annoying or insulting, since most of them do not think they have any kind of problem.	• Addresses very important issue • Difficult to know whether the measurements will be done properly and this is not "professional" • Could work as screening	• Cognitive screening is very important but should be performed in person

			• Important to send notifications to relatives	
Scenario 11. **Collection of HL related web and social network data**	Ranked 5/10 Cons: 1. Confidentiality issues 2. Most elderly do not use social media	• Very limited target group, could lead to misleading results • Consider creating groups with similar problems/needs	• This is more public health related • Vast majority does not have a social media account anyway • Very difficult to gain consent	• Confidentiality issues should be taken into account
Scenario 15 Diary of HL related events and HA malfunctions	Ranked 8/10 Pros: 1. Summarizes problems 2. Objective	• Nice to have a timel;ine and possibly correlate with events • During F/U visits, it is very diffivult to be sure about frequency of problems	• Nice scenario • Consider of giving instructions remotely • User guide should also include solutions	• Not clear whether data will be collected automatically or by the user.
Scenario 16 **Performing audiological tests through HA.**	Ranked 8/10 Pros: 1. Can give a different perspective 2. Can improve HA fitting	• Very nice idea • Calibration is a very important issue • SIN test is maybe more important than PTA for fitting • Very important for children	• My opinion is that patients will perform the tests, people love to be tested • Nice to have raw data	• Very good scenario. Will capture fluctuations, especially in subgroups (e.g. Meniere disease)

Clinicians focus group 2 minutes

		OTC-CLIS1	OTC-CLIS2
	Location	Eriksholm Research Centre, Oticon A/S, Denmark	
	Date	8 December 2016	9 December 2016
	Participant	Clinician OTC-CLIS1 Gender: Female Age: 26 Education: Masters of audiology Years of work experience: 2 Current work setting: Research centre of hearing instrument manufacturer	Clinician OTC-CLIS2 Gender: Female Age: 27 Education: Masters of audiologopedics Years of work experience: 2.5 Current work setting: Research centre of hearing instrument manufacturer
	EXECUTIVE SUMMARY	**DETAILLED MINUTES**	
Scenario 1. Retrieval of HA usage data	• Scenario ranked #4 out of 8 • Pros: 1. Supports patient-centred care and individualisation of care based on patient needs / here, based on hearing aid usage of every patient 2. Can support research / evidence collection • Cons: 1. Could be time consuming for clinicians	• Good idea, would help me in my work to identify cause of problems when hearing aid users are reporting less satisfaction • Data would make it easier for me to personalise my rehabilitation as at the moment it's based on averages – in this scenario data would be based on the actual hearing aid user • This scenario would help to set a specific user aid user's problems in context	• This scenario is a "nice to have", but not a "need to have", as most clinicians have limited time and will not have time to look at the HA usage data. Most clinicians would be interested to see that data if they had time, but they don't have that time • Very interesting for my work in a research setting, would give interesting information • Data would have to be displayed at the patient level – a cumulative average across users would have no value for me
Scenario 2. Transfer data to clinicians and audiologist	• Scenario ranked #3 out of 8 • Pros: 2. Helps identify problems with hearing (sudden hearing alterations) as	• In public hearing clinics (in hospitals), hearing aid users usually go 4 years without appointments -> would be good for the audiologist to keep an	• This is a very good idea, as it solves the problem that it's difficult for users to describe their sound experiences with words

	well as problems with hearing aids without having to rely solely on patient report, which is not always informative 3. Keeps the clinician informed of any problems, so they can address them – this is a positive thing, as these problems could otherwise be unaddressed for a long period of time	eye on the patient, if there is a sudden hearing deterioration, hearing aids could stop being used, and then the audiologists would be able to address this problem rather than having to wait for 4 years before discovering that there is a problem • This scenario is more relevant if it can lead to prevention of sudden hearing alteration	• Would be great for users to be able to send that information to their clinician • The scenario can be expanded beyond sudden hearing alterations, but also to other problems users experience, for example users could help identify what makes the hearing aid feedback (whistling because the sound of the hearing aid speaker is being picking up by the hearing aid microphone) • This scenario would help me to translate the hearing aid user's experience into problems I can solve • Also relevant to track the user's hearing levels over time
Scenario 3. Hearing aid rejection	• Scenario ranked #5 out of 8 • Pros: 1. Recommendations could help individualise care on a patient level, before care commences • Cons: 1. Attempts to replace the clinical judgement of the clinician	• For this scenario to be interesting, I would need to have access to this information on a patient basis (not based on averages /populations as is described in the scenario) in advance, before the patient comes to see me for the first time • Then this would help me meet the patients' needs, for example not start discussing candidacy for hearing aids with the patient and scare them off	• I don't think this scenario would work and I don't think I would use it – there are too many factors involved in hearing aid rejection versus hearing aid acceptance. I prefer to ask patients directly and to use my instinct in the clinic rather than asking a database. • I know in advance the factors that make it more difficult to use hearing aids (for example, comorbidities like poor finger dexterity) and I look for those in my patients

		if they are not mentally ready for hearing aids • In the example above, the scenario would have benefits for me as audiologist as well as the patient • Would be a good help to personalise the contents of the meetings • It would help me ”meet the patients where they are”	• From a sales and marketing perspective, this scenario could help understand what makes people not buy hearing aids and address these factors to improve hearing aid sales
Scenario 4. Use of auditory training	• Scenario ranked #8 out of 8 (lowest ranking) • Cons: 1. Limited scientific evidence to show the benefits of auditory training in adult hearing aid users 2. Requires significant motivation from the patients, high drop-out / low adherence likely	• I do not think auditory training would be beneficial • If patients cannot hear a s, they cannot hear a s! It’s about audibility. Auditory training will not make a difference. It cannot be trained. • I have experience with auditory training with cochlear implant patients, but I doubt that auditory training works for people with hearing aids. I am not sure when I should use it / with which patients. • That the auditory training would be personalised is a good feature	• The idea is good, but I wonder how well this would work in practice – would only work for some few patients • It requires that patients are very motivated and have a good understanding of their hearing loss and the importance of training – many patients see hearing aids as getting new glasses, they expect immediate benefits, they do not want to take part in auditory training that will require work • I would recommend auditory training to my patients, but I don’t think that most people would use it – only the very keen ones
Scenario 5. “Ask the expert” hearing aid fitting (à la Watson)	• Scenario ranked #1 out of 8 (highest ranking) • Pros:	• This is great. At the moment it’s random which hearing aid selection and fitting we use,	• Very very good idea, especially for audiologists with limited work experience

	2. Supports the clinicians by helping them solve concrete patient problems, whilst retaining the clinician's central role 3. Teaches clinicians / gives them skills which they can apply with future patients	would be great to have evidence to base this on • Good to learn from my own and from other people's experiences • This scenario makes me think of the "Fitting Assistant" available in Oticon's fitting software and other manufacturers' fitting software • I would also like to use this scenario for the initial hearing aid selection and fitting, but also for solving problems at follow-up / fine-tuning • Would this scenario make me lazy and stop thinking as audiologist and leave it to the computer? I don't think so. The scenario would still allow me to be critical about the recommendations, and that's important.	• It makes me think of the guide currently available in the fitting software, that lists common reported problems and ways to address these problems by doing hearing aid adjustments – I used that guide a lot when I started as audiologist and I learnt a lot out of using the guide • Would be best if the scenario came as a visual recommendation, eg frequency areas relevant if patients report a specific problem became highlighted in the fitting software - so I can learn from the recommendations of the system and implement these recommendations by myself in the future • I really like that the system would be "living" and that it can learn, that it's not static in its recommendations
Scenario 6. Assessment of initial follow up policies	• Scenario ranked #2 out of 8 • Pros: 3. Supports patient-centred care and individualisation of care based on patient needs 4. Helps free clinical time for patients who need extra care	• This is similar to Scenario 3 • This scenario could save time on patients that don't require follow up and use that time on patients that need help, which would be great • If the scenario allowed to predict for which patients only small things would require fixing at the follow up, I could	• I completely agree that it's not important for all patients to come for a follow-up • I already make my own decision rules for providing follow-up appointment or not providing follow-up appointment as sometimes it's a waste of time for some patients to come in for a follow-up appointment

		conduct the follow up online (tele-health) or provide online information to address the small things like videos on how to change hearing aid batteries	• I base my decisions on whether a) it's a first hearing aid fitting or an experienced hearing aid user and b) if I fit hearing aids that are similar to the previous hearing aids the patient had or not (eg, new hearing aid signal processing platform or new hearing aid style) • I don't think this scenario would be helpful as I already have my own method for deciding whether patients should come in for a follow-up appointment
Scenario 7. Protection of people with hearing impairments from the harmful effects of loud noise: individualized risk assessment	• Scenario ranked #6 out of 8 • Cons: 1. High risk for false alarms – difficult to have good sensitivity / specificity to identify the important cases and only the important cases 2. Most people don't want to be told what to do when it comes to recreational noise exposure, it is a personal choice that they made to expose themselves 3. Only relevant for very specific and rare patient groups: Patients	• I would not offer this scenario to all patients, as I think it would be counterproductive for many patients • To use an analogy, it's like a person weighing themselves all the time, when there is some measurement variability that make this constant weighing a waste of time. This scenario would be counterproductive for some patients who would always want to test their hearing. As soon as the system would record a small change (eg if they have a cold, if been to concerts), they would call me and I would have to address their concerns	• This scenario seems very ambitious – it requires that the patients actively use the system. It also requires that the patients see the system as an authority and that they would follow the advice coming from the system when they are in potentially harmful situations because of loud noise. I don't think this would be the case. I think most patients would say: "I am having fun at a party, I don't need an app telling me that I should leave" • I doubt patients would find the system cool and socially acceptable • The system goes against people's freedom of choice, eg

	who take ototoxic medication (high risk of hearing loss) and patients working in noisy environments	• This would create doubt/panic in the patient's mind, when these fluctuations are normal and within the measurement variability (measurement error) of the system. A system that would only alert of major changes would be more relevant, but then would not be sensitive enough • Would require more appointments, would mean more waiting times for people who really need my help rather than these "false alarms" • The system would not help in identifying the cause of hearing deterioration, I think it would be unclear most of the time • This scenario could be relevant for specific patient groups: 1. People who take ototoxic medication (high risk of hearing loss) 2. People working in noisy environments	to be where they want to be and to engage in the activities they want to engage in • Could be more relevant when listening to music/videos on mobile phone/computer, eg when playing video games, as it's easier to decide to stop playing video games or to reduce the volume of the video games, than it is to leave a concert or a party. In the video game example, the system could inform the user on safe listening levels. That could be valuable for young people.
Scenario 8. Individualised auditory training (AT) to optimise HA benefits and prevent or delay cognitive and auditory	• Scenario ranked #7 out of 8 • Cons: 4. Limited scientific evidence to show the benefits of auditory training in adult hearing aid users	• This is similar to Scenario 4 • Limited value • Could be relevant to counsel hearing aid users who report specific hearing problems even when wearing their hearing aids: could track and visualise with data their performance –	• Sounds complicated • Sounds good in theory, but creates a lot from the audiologist: an understanding of cognition, which is not the case of most people who fit hearing aids – would require new training for the clinicians

processing deterioration	5. Requires significant motivation from the patients, high drop-out / low adherence likely	could help hearing aid users become more aware of their hearing limitations and what hearing aids can and cannot do for them	so they can explain cognition properly • I use a lot patient's self-report / observations as the experience of the patient is more important than what this system could measure – for me it's important to remember that every patient is different and that I must listen to what they prefer

Patients focus group minutes

Patient information

	Patient 1	**Patient 2**	**Patient 3**	**Patient 4**
Location	Eriksholm Research Centre, Oticon A/S, Denmark			
Date	9 December 2016	12 December 2016	13 December 2016	13 December 2016
Gender	Female	Male	Female	Male
Age	73	77	67	70
HL-degree	Moderate-severe	Severe	Moderate	Moderate-severe
HA-experience	10 years	13 years	12 years	19 years
Smartphone-experience	No	Yes – Basic user	Yes - Basic	Yes – Proficient user

No stakeholder analysis was done at UK' due to ethics requirements constraints.

Scenario 1. Downloading of personal data to a Personal Health Record

Executive Summary

It seems like the patients would use this App for general information regarding their hearing aids. For example, they would use it to get information regarding repair, warranty and contact information. The patients would not use it to seek information regarding their hearing loss.

Detailed Minutes

Patient 1	**Patient 2**	**Patient 3**	**Patient 4**
Information regarding hearing loss as well as what kind of hearing aids I have, how old are they, warranty, etc. could be relevant for me.	Could be nice to have access to useful information regarding my hearing aids. In addition, it could be useful to have a list of contacts in specific cases, e.g. if your hearing aids doesn't function anymore. Information regarding my hearing loss is not that important to me. There is too much technical terminology.	I do not see myself using this App. I would rather go to my clinician. If I had to use it, I would use it for practical information, like who to contact in specific situations, e.g. where to send my hearing aids if they do not function anymore.	Wouldn't be of any use to me. I'm getting all this information from my clinicians.

Scenario 2. Text-based communication of the Patient and the Clinician and/or Audiologist through the EVOTION application

Executive Summary

The patients think that this opportunity sounds like something they would make use of. They see it as a nice way to get in touch with the clinician in a quick and easy way.

Detailed Minutes

Patient 1	**Patient 2**	**Patient 3**	**Patient 4**
Sounds like a really good idea. Then you know that you can always get an answer. For example, if something unexpected happened to your hearing aid, then there is always someone you can contact and ask for help or advice.	Would use it in case there is something wrong with the hearing aid. This reminds me of those "online chats" you see everywhere. My experience is that online chats work well, I can get the help I need from them.	It would be easier to get in touch with my clinician. I always have to look for their phone numbers and with this App, it would be so much easier to get in touch with a clinician.	Excellent idea! Quick and easy. Direct communication between the patient and clinician.

Scenario 3. Self-testing of hearing and self-adjustment of hearing aids

Executive Summary

In general, the patients like the thought of it. They like the idea of being able to test their hearing on their own. The same goes for the option of being able to adjust their hearing aids without seeing a clinician.

Detailed Minutes

Patient 1	Patient 2	Patient 3	Patient 4
This would be brilliant! If my hearing has changed, it would be nice being able to adjust my hearing aid by myself.	Can be risky. This is for the younger generation. People of my age can have difficulties using this kind of technology. If you are able to adjust your hearing aid without a clinician, it can be risky because many things can go wrong. E.g., too much gain.	Sounds exciting and easy. It is a good idea before attending a test. As a research participant at Oticon's research centre, I often have to get a new hearing test before participating in a research project. It could be much easier if we could do this at home.	Great idea. However, I would not want this to replace my visits to the clinician. Great to be able to self-test your hearing and self-adjust your hearing aids. In case of big changes in my hearing, I would always contact my clinician.

Scenario 4. My mobile hearing coach

Executive Summary

In general, the patients think it is a good way to involve other people and make them more aware of what it is like to have a hearing loss, and what kind of difficulties people with hearing loss can experience. One patient says that being able to contact a clinician when experiencing a problem could be a nice thing. The patients report that it is not always easy for them to explain the problems they experience. If they had the opportunity to get in touch in the given situation, it is an excellent way to get tools on "how to solve" the problem.

Detailed Minutes

Patient 1	Patient 2	Patient 3	Patient 4
I would simulate a hearing loss and show it to my hairdresser, where I am not wearing my hearing aids and where there is noise in the background. In this way, she can experience how it is to have a hearing loss and in general make people around me more aware of hearing loss and its consequences.	A sort of help-desk. In this way, you can show others what kind of difficulties you experience as a user of hearing aids.	Personally, I do not need an App to show people what it is like to have a hearing loss. This is more an App to people who have many meetings (e.g. at their workplace) and experience problems with hearing what other people say. In this case, it could be nice for them to get the opportunity to get in touch with a clinician and get some advice in each given situation.	Brilliant idea. Sometimes it can be difficult to explain what the exact problem is. In this way, you can do something about it while you are in it. Also a good way in involving other people. E.g. I think it would be very useful for my wife!

Scenario 5. Protection of people with hearing impairments from the harmful effects of loud noise: individualized risk **assessment**

This scenario not presented to the patients as it not relevant to this population group who are rarely exposed to harmful loud noise.

Appendix 3 Guidelines on User Requirements process

Introduction

User Requirements Capture is the process by which user desires, needs and expectations are gathered in order to establish what the users will actually use the application for.

Essentially, User Requirements Analysis is about refining the application so that it meets customer needs, as opposed to simply meeting their specification.

Once identified, the user requirements effectively lay the foundation for developers, testers, and implementers to begin determining the functionality, responsiveness, and interoperability required for that system. Unfortunately, many people consider gathering user requirements as a waste of time. However, the strategy is crucial to a project's success for developers and project managers to obtain accurate user requirements as well as increase the level of end-user involvement in the project.

Expectations

User requirements analysis provides precise descriptions of the content, functionality and quality demanded by prospective users. For the identification of user needs the user perspective must be assumed and result in:

- **Functional requirements** (What the users want the system to do)

The goals that users want to reach and the tasks they intend to perform with the new software must be determined. By recognizing the Functional Requirements, we understand the tasks that involve the abstraction of why the user performs certain activities, what his constraints and preferences are, and how the user would make trade-offs between different software applications. The important point to note is that **WHAT is wanted is specified**, and not HOW it will be delivered.

- **Non-functional requirements** (The restrictions on the types of solutions that will meet the functional requirements)

Specification of non-functional requirements includes the categorization of the users, the description of user characteristics such as prior knowledge and experiences, the possible special needs of users, subjective preferences, and the description of the users' environment, in which the product or service will be used. Legal issues, intellectual property rights, security and privacy requirements are also an issue.

EVOTION end-users

The below end-users will be involved in the elicitation of the EVOTION requirements:

1. Policy Makers
2. Clinicians
3. HA users/Groups

Methods for capturing user requirements within EVOTION

For carrying out the process of requirements identification and analysis for EVOTION the following tools will be used in a complementary way.

Focus Groups / Workshops: a cross-section of users with different background in discussion group format using:

1. **Draft Example Scenario / Usage Scenario**: detailed realistic examples of how users may carry out their tasks in a specified context with the targeted system
2. **User Surveys / Questionnaires (online):** a set of written questions to a sample population of users. Surveys can help determine needs, current work practices and attitudes to the new system ideas

EVOTION Scenarios

The Scenarios for the EVOTION project requirements gathering purposes correspond to the following four organizations participating as end users in the EVOTION consortium, namely **CITY, UOA, OTC, GST, IPH** and **PRA**.

The Usage scenario is a free text (around 1 page) describing how you «visualize" the EVOTION solution. In order to produce a usage scenario, you can follow the below steps:

1. Step 1: describe the problem we are solving within the EVOTION project
2. Step 2: describe how this problem is being solved within your Organisation (as-is scenario)
3. Step 3: describe how this problem will be solved with EVOTION (to-be scenario using the Draft Example Scenario)

Then the as-is and to-be scenarios must be further analyzed by elaborating on the exact processes and steps currently followed in your daily tasks and where EVOTION is involved.

EVOTION Focus Groups / Workshops

The Focus Group Process

What is a Focus Group

Focus groups[29] can take many forms, but most frequently, they are a series of structured discussions around a Draft Example Scenario and a specific set of questions that are explored with small groups of 5 to 10 people. The sessions typically last about two hours and are led by an impartial moderator.

Focus Groups are not polls, but in-depth, qualitative interviews with a small number of carefully selected people. Qualitative data derived from focus groups are extremely valuable when vivid and rich descriptions are needed. In fact, Focus Groups are an increasingly popular way to learn about opinions and attitudes.

Unlike the one-way flow of information in a one-on-one interview, Focus Groups generate data through the "give and take" of group discussion. Listening as people share and compare their different points of view provides a wealth of information – not just about what they think, but also why they think the way they do. Among the advantages of the Focus Groups are that a wide range of information can be gathered in a relative short time span and that related unanticipated topics can be explored, as they arise during the discussion.

[29] http://bosr.unl.edu/focus_groups.html

Purpose of the EVOTION Focus Group

The goal of each of the EVOTION Focus Group is to uncover the needs of the potential users, so that the consortium can design the necessary tools and technologies within the project in the most efficient way. Throughout the open discussions with the actual users, we target to identify their priorities and constraints and gain as much as possible additional information for creating the user requirements towards the system specification process.

Furthermore, the EVOTION Focus Groups aim at building a common understanding and approach for the project between the consortium members which are organizations of different backgrounds and focus. In other words, on one hand **the current workflows of the end user organizations** should be made clear to the technical partners and on the other hand **the project scope and objectives should be clearly explained to the end users.** Following that, all consortium members will search and find ways to design a tool in line with the project orientation and the end users expectations.

Set up a focus group

Step 1. Set your goals. It is important to identify the information you expect at the completion of the focus group. It is easy to end a focus group with a muddle of opinions that don't form a cohesive part of a marketing strategy without setting goals first.

Step 2. Limit your questions. A common mistake many focus group novices make is trying to cram too many questions into a session. A 90-minute focus group with 5-10 participants shouldn't have more than five or six principal questions. Each question needs to be fully discussed, and will likely involve drilling down on particular ideas and comments. Plan on spending about 10 minutes on each topic.

Step 3: Start with open-ended questions. Your first set of questions should be designed to gain the big-picture insight. Open-ended questions ask for ideas and opinions, not simple one- or two-word responses. It is easy for a focus group to be steered by the questions, which can cause skewed results and disingenuous opinions.

Step 4: Follow up with specific questions. Once your group has voiced their unprompted views, it is acceptable to ask specific questions.

Step 5: Quantify. Focus groups offer opportunities to learn why people hold certain opinions. Your questions should try to capture the opinions of the entire group. It is easy for one or two vocal attendees to drive the conversation of the session. To avoid this, probe to find out who within the group shares a particular opinion. Asking who prefers red and who prefers blue provides an opportunity for less vocal group members to weigh in on a discussion. Some insight can be gained if the opinions are universal across all participants or if opinions vary considerably.

Provisional agenda and moderation of EVOTION Focus Groups

The Focus Groups for the EVOTION project requirements gathering purposes correspond to the following six organizations participating in the EVOTION consortium, namely **CITY, UOA, OTC, GST, IPH** and **PRA**.

The session will be approximately **two hours** in duration and will be divided into the following parts:

- Welcome note and introduction of the moderator.
- Introduction of participants.
- Short explanation of the purpose of the Focus Group.

- Introduction of the EVOTION project. Explanation of the motivation, the innovation, the target and the approach to be followed by EVOTION.
- Quickly going through example draft scenarios and the questionnaire (focus on specific questions, quick conclusions, etc.).
- Questions – Discussion.
- End user vision about the project. Open discussion about what they would expect ideally.
- General / Final Overview.
- Briefing / Conclusions.
- End note.

Discussion process and moderation

- Welcome (Introduce moderator and assistant)
- Overview of topic
  - Introduction of the EVOTION project.
    - The results of this focus group will be used for identifying in which characteristics to focus and what kind of applications to develop.
  - Ground rules
    - No right or wrong answers, only differing points of view
    - We're taking notes, one person speaking at a time
    - We're on a first name basis
    - You don't need to agree with others, but you must listen respectfully as others share their views
    - My role as moderator will be to guide the discussion
    - ……..
  - Opening Question (round robin)
    - Name, organization and responsibilities of each participant
  - Introductory Question
    - What is the main mission of your organization? Which are the main services that you provide?
  - Present the draft example usage scenarios of the platform and proceed with the following example questions:
    - What do you think about the EVOTION platform?
    - How and when would you like to use the EVOTION platform?
    - What other services would you like to be included in the EVOTION platform?
    - If you had to pick only one factor that was most important to you, what would it be? You can pick something that you mentioned or something that was said by others. (Key Question)
    - Do you know (partially) similar applications? Can you provide us with some examples? How do you use them?
    - Suppose that you were in charge and could make one change that would make the EVOTION better. What would you do? (Key Question)
    - Of all the things we've talked about, what is most important to you? (Ending Question)

- Three Step Conclusion
    - Summarize with confirmation
    - Review purpose and ask if anything has been missed
    - Thanks and dismissal

Output format

The output from each focus group should include the following parts:

- Executive summary (basic points to be used for further analysis)
- Location
- Date
- Participants (who and why have been selected)
- Questions & Detailed Minutes