



AHEAD – Augmented Hearing Experience and Assistance for Daily life



D5-1 Business Development Model Analysis

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1 Executive summary

Deliverable 5.1 deals with the potential business models of partners to have an anchor for further business planning. This document is the foundation for a consortium decision on a business option to go for exploitation during the project and after the project.

Several business approaches for sections of AHEAD are presented and an overall concept is stated called social business approach. Also an overview over the European market situation especially for hearing aids is given.

For developing a product, that is supposed to win recognition after a market launch (in different EU countries with different health systems and cultures at optimum), it is necessary to generate a business development strategy or plan, that defines aims as well as possible barriers and approaches to overcome those in an early stage. AHEAD will only be a success if all stakeholders are aligned and both qualitative and quantitative effects are taken into account. A stakeholder analysis looks at drivers and barriers per stakeholder. To make the benefits of AHEAD explicit for all stakeholders a business evidence model has been developed that takes into account costs, benefits (not only financial ones) and reimbursement.

On the stage of development factors like costs, usability, usefulness and product's appeal in addition to the quality of the product must be taken into account. This is the draft and first step in an iteration of documents until the end of the project. But here is the first step to success.

2 Introduction

AHEAD provides health-related and communication services on a hearing glasses system for elderly people with hearing impairments but elderly in general will be suitable of using AHEAD services . The main goal of the AHEAD project is the integration of a voice-user-interface (VUI) supported by a smartphone graphical-user-interface (GUI) connected to hearing glasses system to support elderly people in their everyday life management. The hearing glasses system consist of traditional eye glasses and hearing aids - two devices elderly people are already familiar with -, together with integrated physiological sensors. Voice-based interaction allows the elderly user to interact naturally with the system without the need to learn new and complex interaction techniques.

2.1 Purpose, context and scope of this deliverable

For developing a product, that is supposed to win recognition after a market launch (in different EU countries with different health systems and cultures at optimum), it is necessary to generate a business development strategy or plan, that defines the aims as well as possible barriers and approaches to overcome those from an early stage.

AHEAD is going to be a success if stakeholders are compliant with qualitative and quantitative effects of service development and business development. To show the use and the potential service model to potential beneficiaries, a business evidence model will be available at the end of the project. This model includes costs and benefits beside the financial thinking. Reimbursement is also considered to be a social return of investment.

2.1.1 Background

2.1.1.1 Market Overview

The potential market for the AHEAD outcomes t is huge. Practically all elderly people could benefit by the use of the AHEAD system to increase their quality of life. For this firsts project period nevertheless two factors have been chosen to limit the initial target group. The main focus lies on people with hearing impairment that also need for glasses. This focus decision has several reasons:

- minimise the entrance barrier for the user
 - o the target group already wears glasses
 - o the target group is also used to hearing device
 - o the target group mostly can get additional funding for AHEAD devices and services (by health insurances or state)
 - o no additional separate devices (e.g. for the microphone, sensors or additional technology)
- maximise the effect for the user
 - o users with need of several aspects of the AHEAD system will profit stronger by the variety of possibilities the project can offer
- practical reasons
 - o better possibilities to shape the right device t to the needs of a specific target group
 - o better feasibility to integrate technology in a hearing glass setup

2.2 Hearing Aid Market

2.2.1 Hearing aid market trends

According to hearing aid manufacturer William Demant the hearing aid industry is experiencing an overall future growth with a compound annual growth rate (CAGR) of 4%. The market size during the last seven years is indicated in the below table:

	2006	2007	2008	2009	2010	2011	2012
Unit sales (mio)	8.2	8.7	9.0	9.4	9.8	10.3	10.7

Table 1: The table shows the sales of the hearing aid industry,

Geographically, the majority of the sales takes place in the developed economies, where demographic development is a strong driver, but also the less developed economies are growing in line with increases in purchasing power and changes in the composition of the population. The European market makes up 41% of the Global hearing aid sales:



Figure 1 Global map showing the percentages per continent of the hearing aid sales.

The hearing aid market is segmented into a number of technological solutions as shown in the below table. The growth potential and estimated market value is indicated for each segment:

Styles	Description	Growth potential	Market value
BTE	Preferred choice in more complex cases and in developing markets	Stable	USD 4bn (whole sale)
ITE	Stabilized at the current share of total market	Stable	
RITE	Preferred choice in many countries – best performance/size ratio	Good	
IIC/extended wear	A niche market for cosmetically	Good	

	oriented users		
Cochlear implants	An underpenetrated market with strong growth opportunities	Strong	USD 1bn
Bone anchored systems	A market with strong growth, but limited size of market	Strong	USD 125m
OTC amplifiers	Fragmented market with lack of fitting and follow-up support	Good	USD 50m

Table 2

The 10-11 million annual hearing aid sales goes through four major distribution channels as shown in the below figure. There are however, quite big variances from market to market:

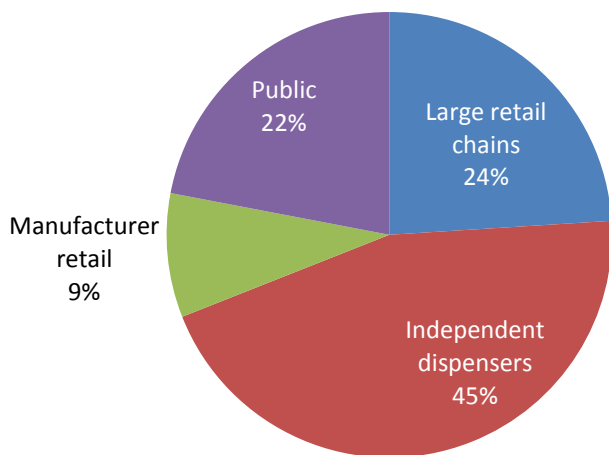


Figure 2: Hearing Aids by sales area

The typical hearing aid end-users are characterized by:

- +10% of population in OECD countries suffer from hearing loss
- 35-40% of population aged +65 are hearing impaired
- Just above 20% of the hearing impaired use a hearing aid
- Average age of first-time user is 69 years (USA)
- Average age of all users is 72 years (USA)

Even the patient has recognized a need for a hearing aid it is only a small fraction of those with an established hearing loss that actually gets a hearing aid. The below figure shows the drop-out rates during the hearing loss verification process in e.g. Germany:

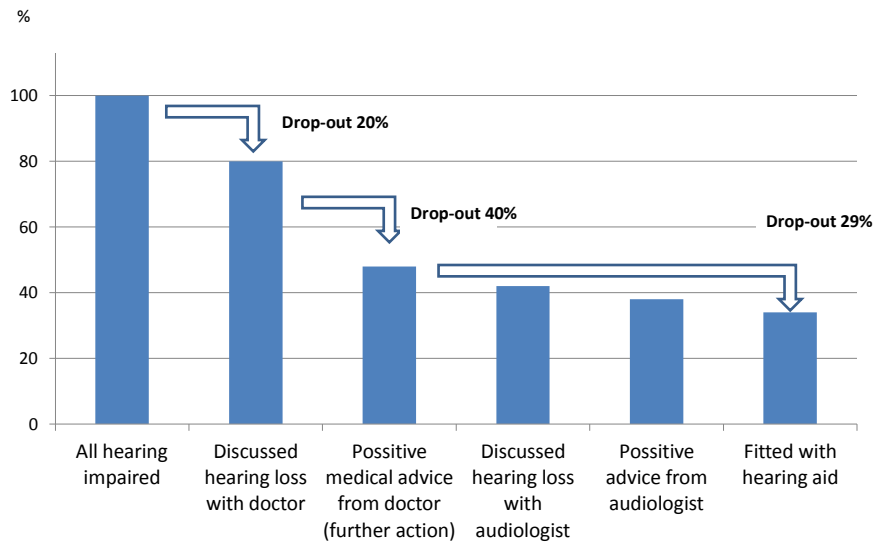


Figure 3: Potential vs. Usage

3 Business Development Models

3.1 Sensor Business Models



Business model

Core competence of cosinuss°:

1. HW & SW Development
2. Marketing

Production with third parties:

- > Components production/ assembly by specialists.
- > First in europe, later on in asia.

Sales via cosinuss°-App, onlineshop, partner (Manufacturer of sporting goods or apps). Later on additionally in specialist shops.

- > 2015: D 2016: EU 2017: USA

Marketing with conventions, magazines, testimonials, sponsoring, TV, Youtube und Google

cosinuss° is a company expert on in-ear Wearable Technologies, developing hardware as well as software components. Also marketing of the sensors is part of the core activities. Marketing includes attending conventions, publishing in magazines and working with testimonials, Youtube, Google as well as events.

Production is organized and steered by cosinuss° but conducted by third party specialists. Sales will be pushed via the cosinuss° online shop and in cooperation with online and offline partners. Accompanying market entry of each sensor a cosinuss° app and new functions will be provided.

3.2 Social Business Model

Organizations like the Johanniter are driven by values for a better living in a social community and not by profit. But the work of these organizations has to be paid and employees have to have a salary worth making a living from it. There is a responsibility not just for a full society but also for the community within the organization. Social business has to take both directions into account. The actions focused in social impact have to cover the costs of the inner expenses of the organization as the financial background of the founders cannot be expected to be infinite.

To allow a non-profit organization to go for innovations and to develop new services, it is necessary to be aware of risks and return-of-investment-cycles. But these are not following the profit oriented methodologies but social expectancies and policy making. The return of investment is not just on a direct financial level but is affecting the organization in all service branches.

This chapter should provide a short perspective in social business for Non-profit-organizations on a practical perspective for developing new services as a follow up of research projects.

3.3 Principals

3.3.1 Definition

Social business is defined as driven by the urge to cope with community problems and providing social appealing solutions to improve the situation for all related stakeholders and individuals.

The gained profit of these activities stays within the organization and supports non-profitable branches and helps to set up new developments or to secure the existence of the organizations. Another aspect is that investors are not looking for financial benefits of the organization but for social benefits (Muhammad, 2008).

The difference to existing non-profit models is that the organizations are supposed to run profitable, as the profits are supporting the growth and development of services. By this, the quality of services is improved and provided to a bigger group of beneficiaries. This guarantees financial sustainability. Social Businesses can evolve typically from three kinds of institutions: Foundations, Non-Profit-Organizations and classical SMEs and LSEs which are starting a corporate social responsibility. The major difference between a NPO and a social business is that NPOs mainly consist of volunteers, as the social business has a majority of employees in its organization structure.

3.3.2 Profit is more

As Social Businesses are profit oriented, the term profit has to be aligned.

Profit is more than just a financial statement that proves that there is a higher income than expenses. Profit is a convolute of ecological, economical and social benefits (Deutscher Bundestag, 1998). These three pillars are representing a sustainability model based on the Brundtland-Report from 1987 (Hauff, 1999) and secures business for more than just one generation. Ecological aspects within business models are protecting environment and saves resources. Economical aspects keep the expenses within a range that can be dealt within the active period of the responsible people. So the debts that are made within one generation have to be covered by this generation as well. Debts shall not be carried by the next generation. To put it blank: First earn it, than spend it.

Within this model social aspects are understood as to decrease social tensions between income levels and between minorities and majority. Social peace is a pillar for sustainable societies and sustainable business.

This three pillar model is not without drawbacks. Innovation cycles are slowed down. The reaction time of such organizations is very long to go through a hierarchy and changes need a lot of time.

But an organization like this is also living through decades and centuries. A very prominent example is the catholic church between 800.A.C and 1680.A.C.

3.4 Value-based Business model

Social business models have been developed further to a value-based business model. Bieger & Reinhold are proposing a 6-Step Model for representing value-based business models:

Value Proposition

The value proposition is the initial phase of defining the values supported by certain actions for a special target group. These services are as well material as immaterial products such as social services, communication or combinations of values and service. An example for this would be the promise of security as a value of the target group of seniors combined with the alert system of a personal home alert system.

3.4.1 Value Creation

The second phase describes the way how the promised values are taken into action for the clients. By this added values and cross selling actions can be a part of setting up services. Following the example of the personal home alert system, this would be the combination of emergency medical service with the command center and the alarm server. All three services could be available as single services but are brought together to fulfill the holistic approach of personal home alerts.

3.4.2 Value Communication and Transfer

Within the third phase it is stated in which way and by which channels the target group will be attended. Internal channels as well as external channels are available for this. It is all about communication of values from service provider to client and from client to service provider.

3.4.3 Value Capture

The fourth phase defines in which way the revenue can be captured. This can be a direct financial value, a gain of reputation, public outreach, policymaking processes etc.

3.4.4 Value Dissemination

The fifth phase defines in how gained value is distributed among investors, departments, etc. to secure the sustainable business model for all who are involved.

3.4.5 Value Development

The last phase is also the closing loop of the iterative process. Here the evaluation of the process is done and the improvement is initialized. This can be the starting point for new innovation processes.

3.5 Telemonitoring-based Business Models

The emerging demographic situation in Europe and the challenge of delivering quality care services to all its citizens necessitate changes in the way healthcare is delivered

Centred users services and the development of sophisticated personal wearable and portable devices can improve not only quality of life but also the management of chronic conditions such as hearing impairing considerably. It is important, however, that sophisticated and innovative devices, including medical devices which can be used by people at home or outdoors-, are developed according to the needs and demands of both users, informal and professional caregivers. Intelligent devices must be interoperable allowing them to interact with other devices and services making platforms scalable and easy to integrate in the different healthcare systems. AHEAD proposed solutions are comprehensive set of applications designed to improve daily life of elderly with hearing impairments, some having additional complications associated to aging, supporting them be more active and independent in their daily lives. If poorly managed, these patients may develop further social complications, resulting in further physical deterioration implying higher cost to the healthcare systems.

Hearing impaired patients will be offered a suite of AHEAD services providing remote monitoring of, e.g., physiological measurements and physical activity using a range of relevant medical and non-medical sensors.

The identified actors and stakeholders include users, audiologist, general practitioners and caregivers Healthcare Regions, Ministry of Health and Prevention and Service Providers. The revenue model in AHEAD is not still decided but it would be based on a mix of fixed subscription fees, fees per user and transaction fees. This will much depend on the reimbursement system in each country/region.

The business drivers are better management of users with several necessities, early detection of risk situation and comprehensive protection against complications and co-morbidities. Both primary and secondary healthcare providers benefit from these services, but the business case aggregates all savings in the Healthcare public authority. The additional cost of new reimbursement fees for these services such as for remote calibration of user's hearing devices are more than compensated by savings significant amounts of time and by a better quality of service.

The outstanding issue in this business case is how the purchase of hearing glasses and the devices for remote monitoring is going to be financed. A fictional actor, the "*National Service Provider*", has been introduced to make room for flexibility in the way the devices and services are initially provided. This "NSP" could be a public operator at national or regional level or an independent insurance company with long term interest.

Anyhow, the structures of European healthcare systems are diverse and it is therefore necessary to be aware of fundamental differences in order to be able to commercially exploit the AHEAD solutions successfully across the fragmented healthcare market in Europe

Healthcare services in Europe are provided mainly by the public sector and financed either via taxes, via statutory health insurance or through a mixture of the two systems. Together to the public system there are private healthcare providers in this case financed through voluntary insurances. For both the tax-based and the social health insurance-based system the public funds account for the majority of total health expenditure; private expenditure is generally low, though usually somewhat higher for insurance-based systems.

The public and private expenditure on health as a percentage of the gross domestic product in the EU Member States averaged 8.3% in 2008, varying between 11.1% (France) and 7.4% (Hungary) for the countries considered in this report.

3.5.1 Cross-border healthcare

Open borders is always a key point in European roadmaps and is a central part of the Digital Agenda.

The legal aspects of cross-border healthcare are covered, specifically in the context of legal safeguards that should accompany patients using mobile health technologies when travelling, social security coordination between healthcare systems and policies in the area of reimbursement, and Electronic Health Records and the risks associated with the systematic flow of personal health data.

3.5.2 National healthcare systems

The main findings are summarised in **Error! Reference source not found.**Table 3.

As the table shows, there are great national differences in the way healthcare is provided, both in terms of administrative responsibility and decision making, funding, reimbursement methods and healthcare coverage.

Though funding falls in three categories, tax-based, social insurance-based or a mixture of these, no two healthcare systems are the same.

Total private health expenditure, which covers out-of-pocket payments and private health insurance, also varies considerably, from 15.5% in Denmark to 40.7% in Switzerland. In Greece, at 39.7%, it is the largest part of funding of healthcare, with National Health Insurance (NHI) and taxes making up approx. 30% each.

In addition to the financing and reimbursement mechanisms being very diverse we found that financing and reimbursement of AHEAD services such as telemonitoring are practically non-existent

Country	Main admin level for primary healthcare	Main funding	Healthcare coverage	GP payment mode	Hospital Payment scheme	ICT Rank
Austria	Regions	NHI/taxes	Multiple insurers	Fees/capitation	Per case/DRG	17
Belgium	Regions	NHI	Multiple insurers	Fees	Per case/procedure/drugs	23
Denmark	Regions	Taxes	Local services	Fees/capitation	Global budget/per case/DRG	4
Finland	Municipal	Taxes	Local services	Salary/fees/capitation	Per case/DRG	12
France	Regions	NHI	Multiple insurers	Fees	Per case/DRG	18
Germany	Regions	NHI	Multiple insurers	Fees	Per case/DRG	13
Greece	Regions	Private/NHI/taxes	Multiple insurers	Salary	Per diem + costs	30
Hungary	Municipal	NHI	Local services	Capitation	Per case/DRG	34
Italy	Central	Taxes	National services	Capitation	Per case/DRG	28
Netherlands	Central	NHI	Multiple insurers	Fees/capitation	Global budget/per case/DRG	5
Slovakia	Central	NHI	3 insurers	Capitation	Per case/DRG	38
Spain	Regions	Taxes	Local services	Salary/capitation	Line-item budget	25
Sweden	Regions	Taxes	Local services	Salary	Per case/DRG/Global budget	1

Switzerland	Regions	NHI/Private/ taxes	Multiple insurers	Fees	Per case/DRG or Global budget	7
UK	Regions	Taxes	National services	Salary/ capitation/ fees	Per case/DRG/ Global budget	10

3.5.3 Interoperability and compliance with standards

In order to successfully deploy AHEAD services in Europe, the following concepts should be addressed by the project:

3.5.3.1 Interoperability

Both European and international strategies emphasise the importance of interoperability between health systems, services and technologies. This is a complex issue, involving more than simply technical factors. It also has legal, ethical, economical and organisational implications which need to be resolved. While this is accepted by the global community in general, agreeing on a common approach is another matter. Recent outcomes from a joint ITU-WHO Workshop on e-Health Standards and Interoperability in Geneva in April 2012 include an ITU-T Watch Report¹, which lists 5 prerequisites for transforming healthcare with ICT standards, and a National eHealth Strategy Toolkit².

Within the Ambient Assisted Living context, AHEAD provides a platform that provides access to health technology by using a smartphone for pairing multiple devices. So the smartphone is used as a hub and by this allows an easy linkage between devices that are not core features of AHEAD but could be an expansion. Further development and further services approaching after the project, would be adjustable with not much effort and make the system interoperable with future developments. By this it is also possible to integrate AHEAD in existing AAL Solutions as well.

3.5.3.2 Standards

Numerous organisations influence and drive developments in the healthcare area; of particular relevance for products like AHEAD in terms of standardisation are:

3.5.3.3 Continua Health Alliance (CHA)

CHA is a not-for-profit Alliance with more than 240 members worldwide focused on creating a system of interoperable personal healthcare devices. The Alliance works to set Guidelines for the industry that are then utilised for a formal interoperability certification programme. CHA also works to assist governments, standards bodies and providers with the appropriate adoption of this common platform.

3.5.3.4 Health Level 7 (HL7)

Health Level 7 is a non-profit organisation promoting the development of international healthcare standards. The HL7 Clinical Document Architecture (CDA) is broadly adopted around the globe. CDA is a document mark-up standard for the structure and semantics of an exchanged clinical document, encoded in XML.

3.5.3.5 IEEE Standards Organisation

IEEE is developing globally deployed eHealth related standards addressing the need to deliver integrated, globally relevant standards for the benefit of the healthcare industry and society.

3.5.3.6 European health policy, action plans and standards

To help EU Member States pool their expertise on health and to identify and share best practices, three important initiatives have been in play:

¹ www.itu.int/techwatch

² www.who.int/ehealth/publications/en/

The i2010 action plan had a particular focus on the development of eHealth strategies and defined an interoperability roadmap for greater use of technologies, new services and systems.

The Digital Agenda is part of the Europe 2020 Strategy, identifying a number of eHealth measures to be put into place or proposed over the next 2-3 years. It includes measures to use technology to address rising healthcare costs and help Member States cope with their ageing populations.

The European Health Strategy aims to provide an overarching strategic framework in the field of health and lists as strategic themes: *Fostering Good Health in an Ageing Europe, Protecting Citizens from Health Threats, and Dynamic Health Systems and New Technologies*.

The European Committee for Standardisation declares in a feasibility study that there is a considerable interest in European standardisation activities related to the provision of healthcare services. It is likely that European standards could be developed and be beneficial to the citizens, healthcare providers and governments for a growing number of issues in this very large and complicated sector.

3.5.4 Legal aspects

Medical devices and medical software are subject to strong regulation in term of security, safety and liability. In deliverable D5.2 this point will be further described.

3.5.4.1 What is a medical device?

There are two options for a realisation of the AHEAD System Product on the long run. We have the perspective to have a lifestyle version that does not need to pass medical regulations inspection. This version could be cheaper but could also not be supported e.g. by national health insurances and cannot be used to give medical valid data for emergency alerts. Therefore in the project we head for a version that is approved to be a medical device throughout Europe. The European guidelines for a medical device are regulated in [93/42/EWG](#).

3.5.4.2 . Medical device regulations

Legal rules govern the safety of medical devices as issues of patient safety as well as employee safety apply. The key European regulation in this area is the Medical Device Directive (MDD).

Directive 93/42/EEC:

Until 2010, Medical Device Directive 93/42/EEC was the key directive on regulation of medical devices.

Directive 2007/47/EEC:

This directive amends directive 93/42/EEC, and its compliance is mandatory from 21 March 2010. It provides alignment of directive 90/385/EEC with directive 93/42/EEC. Additionally the directive provides regulation of medical software, which is considered a medical device only if it is intended for diagnosis or therapy.

Table 4 Summary of healthcare systems in 15 European countries

3.5.5 Prospects for tele-monitoring services

To ensure continued delivery of quality healthcare to the citizens of Europe a change in the way healthcare is delivered and the way medical knowledge is managed and transferred to clinical practice is called for. Tele-monitoring based services may offer useful capability to open new opportunities in health and well-being management, to improve illness prevention, facilitate chronic disease management through active user participation and to enable personalisation of care that will contribute to improving the productivity of healthcare provisioning.

Self-management active aging is an area that offers exceptionally good prospects, both in clinical and social terms as well as in economical terms. The overall health status of elderly can be improved by adequate management of associated aging problems and of the associated risk factors.

To be successful, the design and implementation of tele-monitoring system architectures must go beyond the technical functionality and fulfil clinical, organisational, and user requirements.

On this basis and in line with agreed care pathways, a series of potentially exploitable AHEAD services, their drivers and inhibitors and likely entry points for the services have been identified. A service-oriented approach based on OpenAAL architecture will be assumed, with built-in rules processing so that services can be dynamically configured.

Caregivers and professionals are needed in any tele-monitoring application or service to secure correct intervention and monitoring, but a large number of routine tasks can be better left to ICT systems. Among these tasks could be included routine monitoring of physiological parameters, based on clinical significance and combined with filtering of data to facilitate event detection and handling.

A number of drivers and inhibitors have been identified, which may be medical, organisational, financial or regulatory in nature. Other motivational factors rely on users' acceptance or demography, e.g. the ageing population in Europe.

The group of healthcare commissioning bodies and healthcare providers includes national and regional healthcare authorities, care centers, emergency centers and clinics. They are prime customers for AHEAD services as part of the overall caregiver system. Other stakeholders are strategic health authorities, insurance groups and users organisations.

The main reason for the lack of successful services is rooted in lack of organisational acceptance and insufficient acceptance among healthcare commissioning bodies so that funding and appropriate reimbursement schemes are missing.

4 Discussion of Models for AHEAD

4.1 Models concerning target groups

There are several target groups that are potentially addressed by aspects of AHEAD. Primary identified are:

- People suffering from hearing impairment
- People with interest of health monitoring
- People interested in personal assistance by smartphone

These groups allow a broad market access and making AHEAD not just a medical device but also a potential life style tool. By having several classes of certifications, it is possible to address different target groups.

Especially the combination of ADA hearing tests and Bruckhoffs Hearing glasses gives an initial boost for a very specialized market. But also using ADA hearing tests as devices for tuning hearing devices to certain conditions, like HiFi Music, brings a market potential beside the health sector.

The health monitoring is already becoming something usual as Samsung, LG and Apple are starting business with monitoring devices. But the certification and functionality as medical devices is not given yet. This is where AHEAD can find its niche as professional tool.

The personal assistance by smartphone is often not so well accepted as the sound quality of the assistant is not very good outside because of noise around the user and it is not very delicate.

By using AHEAD and bone conduction from hearing glasses, this can be the breakthrough for this whole set of technology.

4.2 Models concerning stakeholder

Stakeholders are mostly health related organisations. By this, organizations like Johanniter, Samaritans or the Red Cross are interested in offering this kind of device to its clients. But for this, AHEAD has to be a certified medical device. This goes for the hearing aid, the adjustment of the hearing aid and the vital parameter sensors.

Other stakeholders, like health insurances, are to be triggered by the idea of self-management and increased compliance by this. As a result of higher compliance, better efficiency in therapy can be reached and costs are going to be reduced on a long-term perspective. This comes in handy for governments and national health systems too.

4.3 Social Business and cooperative approaches

As there are special background IPRs and further developments of existing products next to the project, that belong completely to the associated companies of AHEAD, it is not an easy-going process to have one overall business approach for all in AHEAD especially if partners are addressing different target groups in accordance to point 5.1.

Each partner has to be free to invest or withdraw his resources from a cooperative business without endangering the structure as a whole. But as a framework, the idea of a social business approach is broadly accepted as potential profits are reinvested in further developments of the system. The business form for this is not going to be an Ltd or a Joint Stock Company but maybe an association. This has to be part of Deliverable 5.2.

5 Conclusion

At this first stage of the project we are analysing four major business models in accordance with the services and products the project is going to develop. The hearing impaired aid maker could be benefited by the adding features provided by the integration of sensors into the glasses/hearing devices. The social care model will be benefited by the provision of monitoring services for supporting users in their daily activities as well in improving well-being and quality of life. All these services and products face similar drivers, barriers and threads.

The first conclusion of this report is that the financing and reimbursement schemes for health services vary greatly among the EU Member States.

The second conclusion is that, based on this fragmented picture, business models and business cases for the AHEAD platform must be tailor-made for every Member State.

The third conclusion is that very few reimbursement schemes for eHealth-based services such as telemonitoring exist.

The fourth conclusion is that several approaches for the services and for the overall system AHEAD can be fruitful.

The fifth conclusion is that a cooperative association with a social business model could provide a theoretical solution for exploitation of AHEAD as a full system.