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A Cross-Border European Biometric Enabled Health Record Identification and Data Exchange Network

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1 Scientific and/or technical quality, relevant to the topics/activities addressed by the call

1.1 Sound concept and quality of objectives

Introduction

Healthcare providers in Europe are facing incongruous challenges, which include an aging population and an increase in chronic diseases or long-term conditions of patients, while having to meet an overriding need to reduce costs and maintain high quality healthcare. These necessities fuel the demand for e-health IT innovation in general, and electronic health records (EHR) in particular is increasingly being focused on. EHR solutions have been developed within Europe for some time; however, there are still issues of privacy and data protection when it comes to realising a pan-European EHR solution. Creating an interoperable European health information architecture enabling access by patients and authorised doctors to the patient data at the point of care is a key focus for the EU. This would play a major role in enhancing patient safety by making it easier for authorised personnel to be able to get access to patient information in an emergency situation. The goal is for healthcare information on a particular patient to be accessible at any moment and no matter whether it was generated in a primary care centre, a hospital or a private physician's practice. This would make ease of access better for the healthcare professionals, however, a Pan-European EHR is also beneficial for European citizens. An example of this is when a French tourist falls ill or has an accident while on holiday in Spain; the Spanish doctor would need to easily be able to consult the electronic health record of the patient.

In Europe, however, the concept of a centralised server model of healthcare data has been poorly received due to the issues of privacy and security in such a model. A number of people from doctors, nurses, technicians and billing clerks have access to at least part of a patient's records during their hospitalisation. Recent revelations of "secure" data breaches at centralised data repositories, in financial institutions, retail industry, and government databases, have caused concern about storing electronic medical records in a central location. There is hardly any system worldwide that is completely secure especially when considering recent events with the losses of credit card records at large retails chains, or the 2006 Veterans' Administration loss[1] of its patients' records. Despite tight security on these systems, data was lost or accessed by others who should not have access.

Aside from the problem of the privacy of electronic healthcare records, there is the separate, yet equally important issue of making sure of the identity of a patient. Getting a patient's chart confused with another can be deadly if the wrong medication is given, or if a diagnosis is mixed up because the doctor is looking at the wrong information. Mistakes are being made in the healthcare system with records being mixed up and wrong medication being given to the wrong patient. There is a desperate race going on to find the best method of securing health data and preventing mistakes with consequences that range from embarrassing to deadly, while still enabling a flexible pan-European EHR system.

Biometrics is currently being introduced in various healthcare security industries across the world. Biometric devices can take unique characteristics about a person to ensure that a person is "who they say they are", and have the correct authorisation to be working with the healthcare information they are trying to access. It would make it possible for patients and healthcare professionals to feel secure that their information is being kept confidential and only being released to those who have the authorisation to see it. Biometrics technologies can potentially be a solution for the number of issues mentioned above; however, a lot of the development and growth in the area of Healthcare Biometrics are being done independently and in isolation. Hence, there is a need for a pan-European EHR solution that would make use of biometric technologies in an integrated fashion to cater for the issues of security and emergency patient identification.

Issues with European Health Service and Lack of Cross-Border Cooperation

Health policy in the European Union has a fundamental contradiction at its core. On the one hand, the EC Treaty, as the definitive statement on the scope of EU law, states explicitly that health care is the responsibility of the Member States. On the other hand, as Member State health systems involve interactions with people (e.g. staff

[1] http://www.securityfocus.com/news/11393

and patients), goods (e.g. pharmaceuticals and devices) and services (e.g. provided by health care organisations), all of which are granted freedom of movement across borders by the same Treaty. In fact, many national health activities are subject to EU law and policy. For instance, when national health systems seek to purchase medicines or medical equipment or to recruit health professionals – what would appear to be clear local health care policy choices – we see that their scope to act is now determined largely by EU legislation. Further, when the citizens of a Member State travel outside their national frontiers, they are now entitled to receive health care should they need it, and have it reimbursed by their home (national) authority. We thus have a situation where national health care systems officially fall outside EU law, but elements relating to their financing, delivery and provision are directly affected by EU law. In addition to this overarching contradiction, the EU has been required to 'contribute to the attainment of a high level of health protection' for its citizens. This is an understandable and important objective in its own right, and there is compelling evidence that access to timely and effective health care makes an important contribution to overall population health.
But, notwithstanding the EU's commitment to various important public health programmes and initiatives, it is hard for the EU policy-makers to pursue this goal of a high level of health attainment when they lack the ability to ensure that national health systems are providing effective care to their EU population as a whole, irrespective of which member state the patient is from. It is difficult for them to ensure that health systems promote a high level of health and, indeed, social cohesion, and that they comply with the single market's economic rules (particularly regarding the free movement principles) when the current health care systems are an explicit Member State competence. In this regard, EU health (care) policy can be seen to be affected by what Scharpf terms the 'constitutional asymmetry' between EU policies to promote market efficiency and those to promote social protection. That is, the EU has a strong regulatory role in respect of the former, but weak redistributive powers as requisite for the latter. This can be ascribed to the Member States' interest in developing a common market while seeking to retain social policy at the national level. More widely, this conforms to Tsoukalis' view that while welfare and solidarity remain national level prerogatives, many issues affecting the daily life and collective welfare of individuals are dependent on EU level actions. This is particularly true with regards to the example of the French tourist having an accident when on holiday in Spain.

However, in the healthcare arena, we see that the constitutional asymmetry is exacerbated by a dissonance between the Commission's policy-initiating role in respect of single market free movement concerns and the Member States' right to set their own social priorities. Wismar and colleagues have noted the 'subordinate role' of health within the broader European integration process, and others have highlighted that health policy in the EU has, in large part, evolved within the context of the economic aims of the single market programme. This has led to a situation in which the Member States have conceded the need for the EU to play a role in healthcare integration, even if only a limited one, and in specific-defined circumstances. This suggests a redefinition or, at least, a reorganisation and re-prioritisation of health at the EU level, and one that would change current policy-making dynamics with regards to an integrated European Healthcare Service.

Issues with the Health Service in Europe

The above issues make the case for needing an integrated European Health Service System where citizens can freely move across borders and still get the same level of service as they would get at their local health service. This can not be achieved without having an integrated easily accessible electronic health record system. However, there are certain issues that would make this a very difficult goal such as security and privacy, but with the introduction of biometric technology in combination with PKI these obstacles could be overcome and the goals achieved.

In this struggling economy, those in the healthcare industry have realised that the money needed to invest in biometric technology is outweighed by the consequence of fraud and the mistakes that could have been prevented if they were using the technology. Hence, the industry is growing fast, and it's changing the look of healthcare security rapidly. However, a lot of the development and growth in this area are being done independently and in isolation; and hence, not in line with the goal of achieving a pan-European biometric technology enabled EHR solution. Hence, there is a need for a pan-European EHR solution that would make use of biometric technology in an integrated fashion to cater for the issues of security and emergency patient

identification. When it comes to electronic health records (EHRs), the digital technology has major limitations. From the mechanical ability and methods for storage and transmission, to the ways they can be accessed, new and more advanced systems are becoming available every day. However, a number of limitations and issues arise from the implementation and use of EHRs. Apart from the issues of lack of standardisation, additional problems exist with security and privacy of these records as already mentioned.

Within EHR solutions, there is the ability to control content and access. One can determine who has access, and how that access is made. This provides good opportunities for controlling the sharing of the information, but it also creates roadblocks, too, when someone without access needs access to the patient records for emergency purposes. However, when biometrics technologies in combination with PKI are linked with electronic health records, more accurate and efficient medical care can be provided. This can be beneficial in many medical settings; however, it can prove invaluable in an emergency situation. For example, an unconscious individual could be identified (without requiring traditional forms of documentation) and subsequently linked to their medical records. Data can be potentially stored on a smart card, in their possession, or in a centralised database. The current EHR solutions available are not completely integrated in an innovative fashion and when trying to introduce the use of biometric technology, there is currently no solution that provides an integrated, interoperable and secure platform in order to realise the goal of a pan-European EHR system.

The Project Concept

An innovative, interoperable and integrated biometric enabled security access/exchange software platform for patient health records within the national health sectors across the European member states, which will enable patient identification within a local hospital environment; patient identification and health record access/exchange with other National and European hospital environments; and patient identification and health record access/exchange with remote/mobile healthcare professionals (e.g. ambulance service) assigned to a local hospital environment.

Project Details:

Therefore the project would involve the development of the following:

- A software based platform for the interoperability and easy exchange of data types and formats from any biometric sensor/identification system in combination with PKI and EHR system. The software platform would have various functionalities using semantics integration and exchange, which would include an alert system for dispensing medication to patients.
- A PKI security infrastructure included in the software based platform for processing data from the biometric terminals in terms of attribute management, authentication, workflow and service access control, and auditing functionality.
- A relatively low cost Biometric-enabled mobile reader system linked with a centralised digital signature (PKI root server) database network, all operating on the platform, that coordinates access of patient health records with the local database of where the patient is registered.

Technical Obstacles:

- The lack of standards for EHRs i.e. the way electronic health records are stored, transferred, displayed is different from hospital to hospital, company to company, and country to country.
- There are issues with the interoperability of biometric sensors as well as national digital signature providers and processing software as there are no “common criteria” standards that solves this.
- All healthcare biometric solutions are currently being implemented as fully integrated solutions for specific organisations.

Technological Objectives:

- Understanding the different biometric sensor hardware used in the European Union member state countries and assessing the usage of new biometric sensor technology and how future technologies would be integrated into our system.
- Centralising the European Union member states national healthcare databases.
- Develop a rule based inference system using semantics integration to standardise and clean the central database in terms of inconsistency in data, large volumes etc.
- Provide a faster trade turn around time for getting authorisation and access to patients' records but still maintaining access being given to the right person.
- Provide an automatically updated view of individual patients to all the relevant stakeholders (hospitals, GP or private doctor). For example in the situation that a patient has had an accident in another country, their private doctors are alerted when the doctor abroad accesses the patient records and updates it.
- System Integrated biometric enabled mobile reader and a software platform (fingerprint algorithm – sensor independent) that can read and is compatible with data from most biometric sensors.
- PKI Security infrastructure for the networked enterprise in terms of attribute management, authentication, workflow and service access control, and auditing functionality. There will be less than a 0.1% chance of security infringement using our system.

Benefits of:

- Save the healthcare sector time and money spent trying to access patient information by making it easier for the healthcare professional to access this information, hence improving efficiency within the sector.
- Enable European wide integration independent of biometric sensor hardware.
- Reduce the amount of deaths caused by mistaken identity and issuing of wrong prescription / medication.
- Overcomes the vulnerability of passwords and PINs and the shortcuts people use to deal with passwords.
- Increase patient and doctor trust
- Increase security of all data in transmission.

The Need to Outsource the Development of the Technology

As stated in the previous section, there is need for an innovative cross border electronic health record system for the benefits of European citizens as a whole that look to have access to the same quality of health service anywhere they are in Europe. We SME-AGs within the project have collectively identified the need and the potential business opportunity that this provides to us, and would like to be able to benefit commercially with such a solution. But we lack the research capabilities required to realise our goal, hence the need for research partners. We will use this opportunity to bring in the research support of Tomas Bata in Czech Republic and GUAS Institute in Germany and with combined effort from the industrial SME supply chain partners would be able to tackle this problem. Tomas Bata has years' experience with the research and development of innovative software solutions. Existing collaborative relations enabled the consortium to secure support from Tomas Bata. They have very good expertise in software development and electronics, which is a key area in this project. Tomas Bata also has many years of experience in language and semantic translation and would be very important to this project as this would be the basis of implementing and EU cross-border system. GUAS is one of Europe's largest research and development organisations. The particular institute we would be engaging in GUAS have significant experience in Biometrics technology and would bring their years of experience to the development of the project. With the support of our researchers and our industrial partners, we believe that we have a strong chance of realising the projects objectives and realising the benefits shown above.

1.2 Innovative character in relation to the state-of-the-art

Introduction

The solution being proposed in this project is significantly advanced over state of the art as this level of integration of data has not been done in the European healthcare sector. There are various systems that are currently being used, research projects done on national levels, technology that can be transferred to deliver our project (such as semantic integration), however, none compares to what is being proposed in this project.

Current Health Service Systems in Europe

German Electronic Health Card

The electronic health card (eGK) is still controversial. With barely six years delay, the new health card was introduced in October 2011 and simplifies many processes. But doctors and experts warn of security gaps in data security and are already talking about a so-called "transparent patients".

The practices will be charged enormously high costs by the acquisition of new readers. Therefore, KBV, KZBV, and the statutory health insurance leading professional organisation have decided that the statutory health insurance companies will pay a set fee for the new devices to the practices. Thus, there are 355 Euro for the stationary readers, 215 Euro for the installation and 280 euros available for mobile readers

In addition to the high cost of the readers, is the electronic health card for data security in the critique. In principle, it should facilitate communication between doctors because the medical file and the master data of the patient is stored on the new chip. Everyone should be aware that data that are stored on a central server will rarely be completely safe from unwanted access. For the time being, however, not all data on the card are included. Only the cut-down version was capable of consensus after years of dispute. In the long term, more data about the eGK should be made available

TOMCAT

This is a 32 bit Windows application designed around the Multi-Tier model in order to ensure speed, scalability, flexibility and reliability. TOMCAT's open architecture means it can interface to a wide variety of other systems / databases for either import or export of information. There are a number of options available for linking to other systems: SQL calls to database tables; DICOM image transfer; Flat files (ASCII, XML, HL7 etc); TCP/IP sockets; Standard software interfaces; COM/DCOM, DLL'. The system design allows users to tailor the layout of diaries, letters and management reports, plus add new fields to clinical screens for capturing additional information as required e.g. for research purposes. TOMCAT is a comprehensive, and totally scalable administrative and clinical recording and reporting tool, covering every area of the cardiac specialty - coronary care, all non-invasive tests, pacing, cath lab, cardiac surgery, cardiac rehabilitation, and all clinic appointments. As an example, TOMCAT has been running for some time in St Thomas' Hospital, London, with over 120,000 patient records and up to 100 users concurrently. It uses individual password log-on to ensure security of information and enable only relevant options to be displayed to the user with a full audit trail maintained for all clinical records. However, this is still limited to passwords and has no integration to the use of biometric access.

ProDoc

This is research on an Electronic Document System that allows users to navigate documental artefacts according to predefined process maps. In ProDoc, process models are to be considered as maps that users willingly take as a guide for their decisions and actions, rather than scripts prescribed from above. The main tenet of this research is that, by integrating documents and processes, documental practices and related work practices could better align to intended models of action. The underlying concept is the result of a long empirical research in the healthcare domain; ProDoc has been deployed as an innovative and process-oriented Electronic Patient Record. This is useful research that can be adopted in the development of our final software platform

Current Healthcare Biometric Systems

Austrian Siemens fingerprint ID project: Austria's biggest private hospital chain, the 'Barmherzige Brüder', has begun using biometric fingerprinting to control access to IT systems. With this, doctors and nurses will no longer have to remember a password to log onto the hospital information system (HIS). The 'Barmherzige Brüder' runs nine hospitals in Austria, all of which are equipped with PC interfaces that include a biometric sensor. The nine hospitals and another three nursing homes were fully equipped in 2008. The biometric solution is delivered by Siemens IT Solutions and Services. The company has integrated its ID Center software into the Citrix-based HIS, a local solution named "Patidok" provided by the Austrian company PCS. For the initial registration, users have to place both index fingers on the sensor of the mouse. After that, they simply have to tap the sensor with one of the index fingers to get access to protected data or software. Biometric sensors were installed for around 3,500 employees in the different institutions. This made it one of the first large scale biometric sensor projects in the healthcare industry of Austria. Siemens provided the algorithms for encryption and storage of fingerprint features, together with the necessary software for identity management and verification of access authorisations. The solution is available all over Europe and can be made compatible with different HIS from different companies. The software platform used here is not hardware independent even though it is compatible with other HIS, so it needs to be set up as a fully integrated solution for a particular hospital. This could create a problem when dealing with the transfer of biometric data.

Biometric identification for electronic medical records (US Department of Defense): ImageWare Systems Inc. and Vista Life Sciences formed a partnership to offer clients secure biometric identification for electronic medical records. Vista LifeSciences is the provider of automated neurocognitive assessment technology to the United States Department of Defense that has been used to create more than 400,000 neurocognitive assessments. The partnership focused on integrating ImageWare's biometric solution into Vista LifeSciences' STAT Medical Jacket, the electronic medical record used to hold all of a patient's medical history in a Web-based or mobile environment. The integration of ImageWare's biometric solution should provide added security for authorized medical professionals accessing patient records and ensure that patient medical records correspond to the correct patient. The addition of biometrics was aimed at increasing the efficiency and security of electronic medical records in a hospital, clinical and emergency environments and bringing professional medical record management to medical triage environments. Like the project in Austria, this is a fully integrated solution for a particular organisation with no flexibility for interoperability at a national level.

Patient Bedside Terminal: JAOtech has a new range of patient bedside Smart Terminals. The new Zivo, Jima and Obie terminals with screen sizes of 15", 15.4" widescreen and 17" respectively each benefit from the latest high performance, low power Intel Atom processors as well as Core Duo options for more complex multi-tasking applications. The terminals come with a number of features and a considerable reduction in weight. Constructed in anti-bacterial plastics to medical grade standard and fully sealed for easy cleaning, JAOtech bedside Smart Terminals have become the de-facto standard for the hospital bedside environment, with over 35,000 installed worldwide. The new features include upgrades such as additional USB ports, touch sensitive buttons, internal microphones and improved phone cable management. Peripheral options on all terminals include a VoIP phone, Bluetooth™, WLAN, a high resolution camera, finger print reader, as well as access control and billing support based on Smart Card, magnetic card, RFID and bar-code technology. We will be looking to incorporate a number of these features into our mobile reader devices; however, we will be aiming for a level of integration to reduce the size significantly.

Current Research in Data Exchange

Semantic Web Framework: The Semantic Web framework is built upon the current web as an infrastructure intended to describe the information in such a format that it can be interpreted by the machine, and, at the same time, to allow syntactic and semantic interoperability among the applications of the web. It follows that Semantic Web provides the opportunity to handle information located on the Internet as it offers apt technologies to overcome various obstacles arising due to the vast amount of information on the web and the variety of languages and formats in which this information is presented. Its technologies do grant certain methods for information classification and meaningful text description. A key-tool towards this aim is ontologies. Ontology is

a catalogue of the types of things that exist in a domain of interest (Sowa J., 2000). Ontologies essentially define a classification, implementing a class/sub-class hierarchy between the concepts, the vocabulary and types of arguments that can be used in the domain and a set of rules that derive new information from the existent. Our proposal is involved with understanding ontologies to describe information sources, provide commonly shared vocabularies, and enable semantic interoperability when transferring information and knowledge across borders. A number of possible languages can be used to build ontologies, including languages based on First Order Logic, Frames and Description Logics, e.g. F-Logic, OWL, etc.

Semantic Integration: XML in general, has become an enormous success and is widely accepted as a standard means for serializing (semi)structured data. However, with the advent of the Semantic Web where the data is expected to be machine readable, i.e. not just targeted at interpretation by humans, XML shows some limitations. The major limitation is that it just describes grammars. In other words, the author of an XML document has the freedom to define and use tags, attributes, and other language primitives in an arbitrary way, assigning them different semantics to describe the conceptual domain model he has in mind. Since XML does not impose rules for such a description and there are many ways how to denote semantically equivalent things, it becomes hard to reconstruct the semantic meaning from an XML document. Some documents have associated with them what is known as metadata. *Descriptive* metadata describes fields which are external to the meaning of the document (e.g. author, date, genre, etc.). *Semantic* metadata characterizes the content of the document. This second kind of metadata, when standardized, could be used in machine-processing to extract the semantics of data. With some ontology languages one can describe domain ontologies, by identifying hierarchies of concepts and relations together with axioms that can be used to derive new facts from existing ones. Ontology can thus be seen as a semantic interface for accessing heterogeneous information sources. This introduces a new, semantic-based generation of information integration architectures. Projects like On2broker and On-to-knowledge are involved in building ontology based tools for knowledge management providing architectures for semantic integration. However, both projects aim to create generalised semantic web architectures, which could then be used with specific ontologies to create semantic-based web access tools (i.e. tools which allow semantic searches, etc. to be performed on the scale of the entire World Wide Web). This project will develop more specialised and domain-specific semantic architectures which will be applicable to medical records and biometric information, and which will be used in the context of viewing, searching, aggregating and enabling interoperability of electronic health records Europe-wide.

Semantic Translation: This is the process of using semantic information to aid in the translation of data in one representation or data model to another representation or data model. Semantic translation takes advantage of semantics that associate meaning with individual data elements in one dictionary to create an equivalent meaning in a second system. An example of semantic translation is the conversion of XML data from one data model to a second data model using formal ontologies for each system such as the Web Ontology Language (OWL). This is frequently required by intelligent agents that wish to perform searches on remote computer systems that use different data models to store their data elements. The process of allowing a single user to search multiple systems with a single search request is also known as federated search. Semantic translation should be differentiated from data mapping tools that do simple one-to-one translation of data from one system to another without actually associating meaning with each data element. Semantic translation requires that data elements in the source and destination systems have "semantic mappings" to a central registry or registries of data elements. Semantic translation is very difficult if the terms in a particular data model do not have direct one-to-one mappings to data elements in a foreign data model. In that situation an alternative approach must be used to find mappings from the original data to the foreign data elements. This problem can be alleviated by centralised metadata registries that use the ISO-11179 standards such as the National Information Exchange Model (NIEM). However, while metadata registries for health information do exist, we are not aware of any such European registries, as most existing schemes are based either in the US, or in Australia. We will achieve this through the development of our centralised database server, which will host a metadata registry for this purpose. This technique would be a significant innovation for health service network applications.

Identity Management: In federation environments where different organisations work together on specified projects Identity Management is one of the most challenging topics. The secure and efficient administration of numerous personal attributes which make up digital identities is one of the key requirements in this setting. The emerging demand for sharing identity information between organisations – among other factors driven by emergency situation previously explained – results in a greater need for standardized data exchange channels. State-of-the-art identity federation therefore must rely on open standards, such as the XML-based protocols SAML or SPML, essentially connecting different Identity Management Infrastructures (IMI). At the moment different vendors are enhancing their existing IMI products in this direction, supporting SAML and SPML standards. However, there are still several security issues which remain unsolved. For example, there is a need for enforcing a strict and controlled synchronization of identity information among the different organisations user repositories and we intend to tackle this issue in this project.

Current and Past EU projects

European Quality Labelling and Certification of Electronic Health Record systems (Q-REC): Q-REC is a Specific Support Action and its main objective is to develop formal methods and to create a mechanism for the quality labelling and certification of Electronic Health Record systems in Europe, in primary- and in acute hospital care settings. The main objective of Q-REC is to create an efficient, credible and sustainable mechanism for the certification of Electronic Health Record (EHR) systems in Europe by addressing mainly:

1. *EHR Systems Quality Labelling and Certification Development, thereby:* producing a state of the art report on EHR certification schemas as already implemented in at least three European countries; performing a pan European requirements assay; proposing a profiling and classification system for EHRs to be certified; harmonising the EHR-certification procedures at a European level; drafting the certification guidelines and procedures (inc. legal); planning future pilot Implementations.
2. *Resources for EHR Interoperability, including:* the inventory of conformance criteria and guidance documents for obtaining EHR certification; an inventory and guidelines for EHR archetypes; the registration of coding schemes in Europe (as mandated by CEN/TC 251); an inventory of existing and relevant EHR standards; an inventory of XML schemas and open source components for EHRs.
3. *Benchmarking Services:* defining the formal test plans for EHR certification; preparing the business plan for EHR certification related services.

We will be looking into the results for this research and use it as a platform to aid the development of our solution.

1.3 Contribution to advancement of knowledge / technological progress

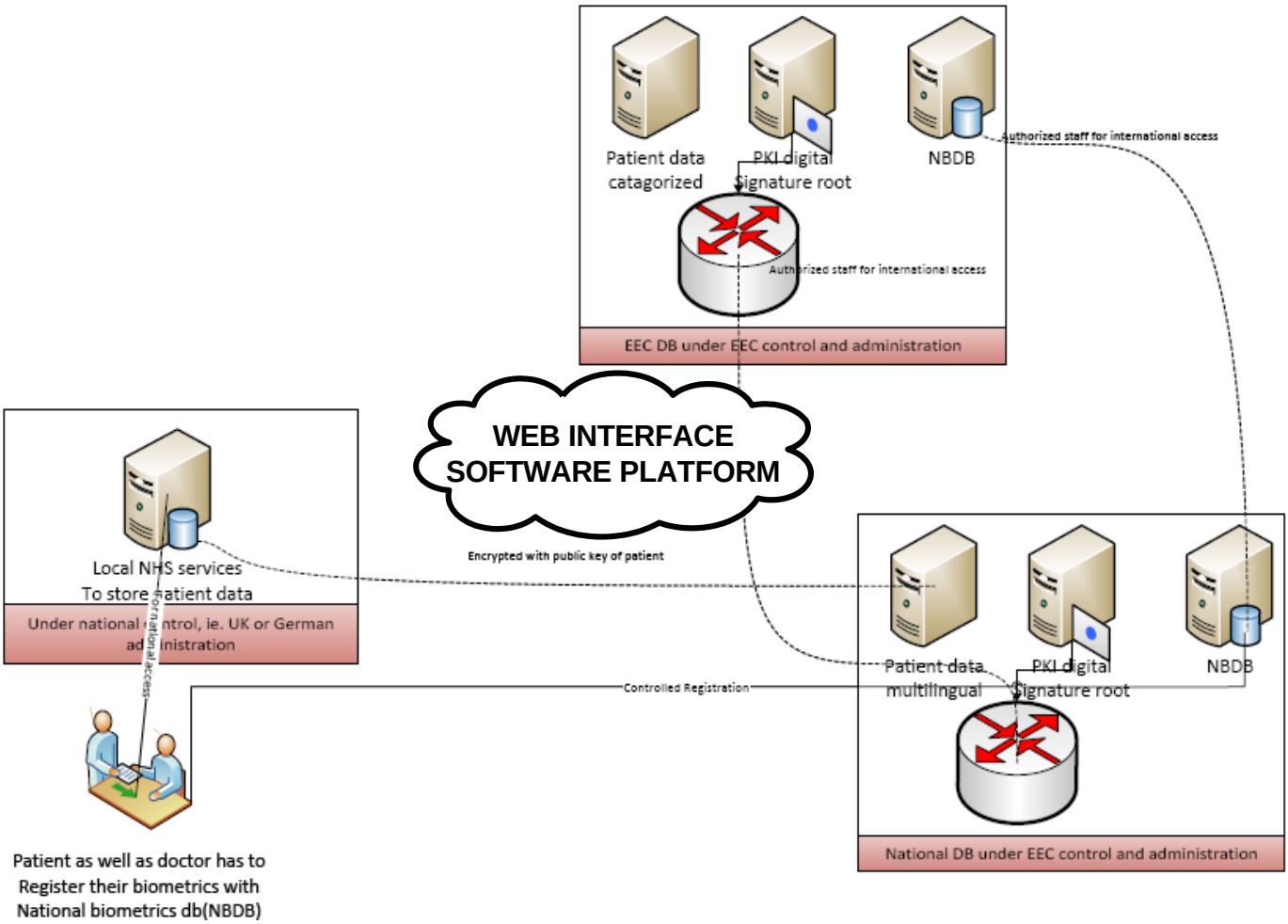
Our proposed system has significant advancements over the existing state of the art. It emphasises creation of a cross border electronic health record system with a highly automated, faster, reliable and secure communication and access architecture that will integrate distributed National Health Service databases across Europe. Integration at the scope we are proposing and the added value through accurate information availability of patients irrespective of nationality and language goes beyond any already available system. Our system will benefit citizens, healthcare professionals and the governments across the EU.

Concept Outline

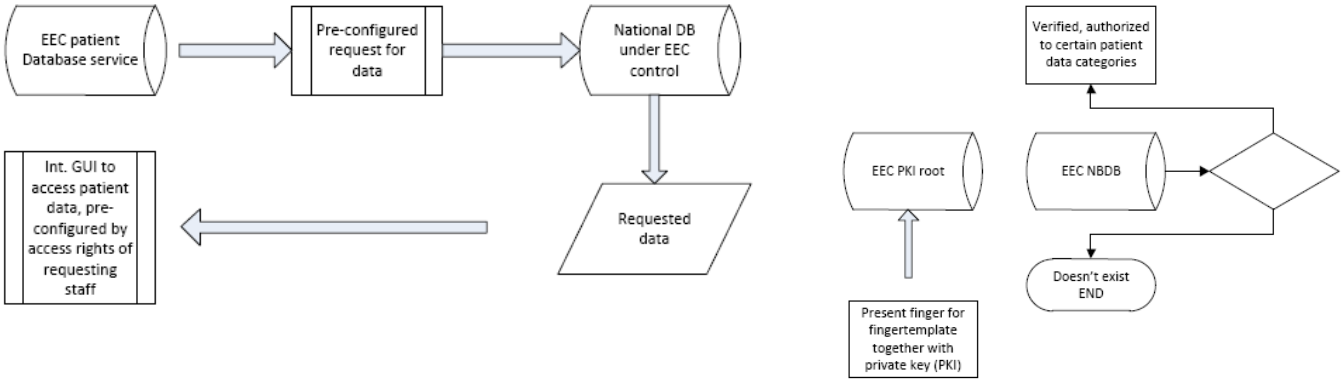
As mentioned in section 1.1, our new idea is to develop an innovative, interoperable and integrated biometric enabled security access/exchange software platform for patient health records within the national health sectors across the European member states, which will enable patient identification within a local hospital environment; patient identification and health record access/exchange with other National and European hospital environments; and patient identification and health record access/exchange with remote/mobile healthcare professionals (e.g. ambulance service) assigned to a local hospital environment. In order to achieve this development goal, there would be number of significant technological developments that need to take place. This would include:

- A Web Interface Software Platform (Web Application Tier) with a Centralised Database Server (EC Database);
- A number of Distributed Database Servers across member state borders (Local National Health Service Databases);
- A Physical Tier Interface that links with the biometric enabled mobile reader system

Below is an overview of the proposed system.



The web interface will act as an intermediary for all the different levels in the process chain for the EHR system. This interface will give the National and European healthcare professionals the appropriate access rights up to date information about any patient from any EU member state that is registered with our system. This would give an easy and less tedious process in the activities involved with trying to access patient records anywhere in the EU. A simple illustration of how we propose this would be achieved is shown below.

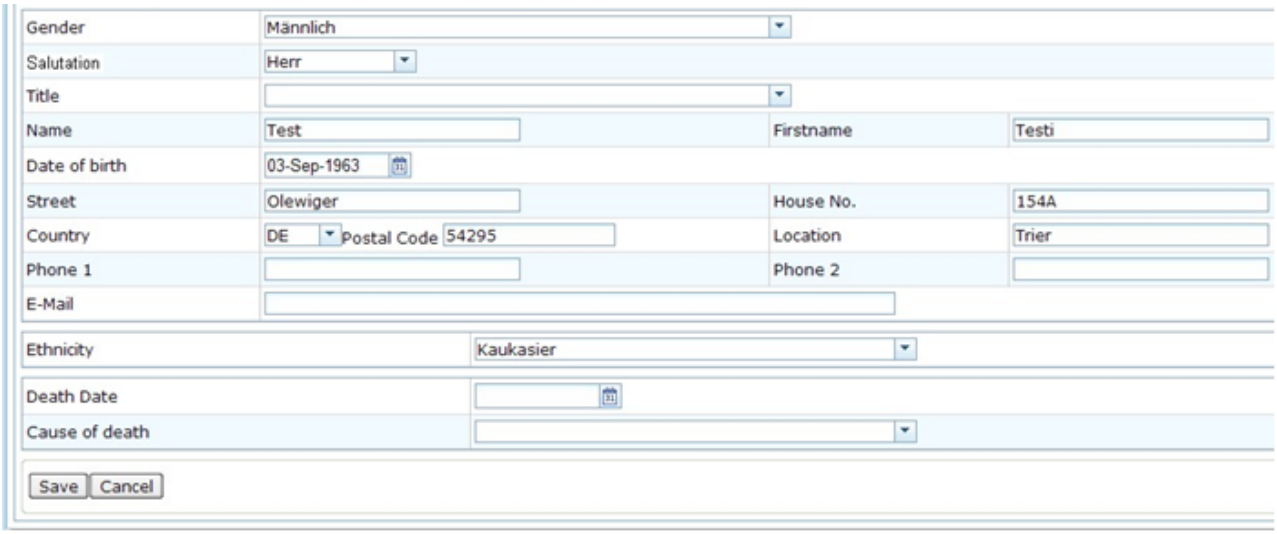


Info request by austrian emergency
Doc for info of UK patient

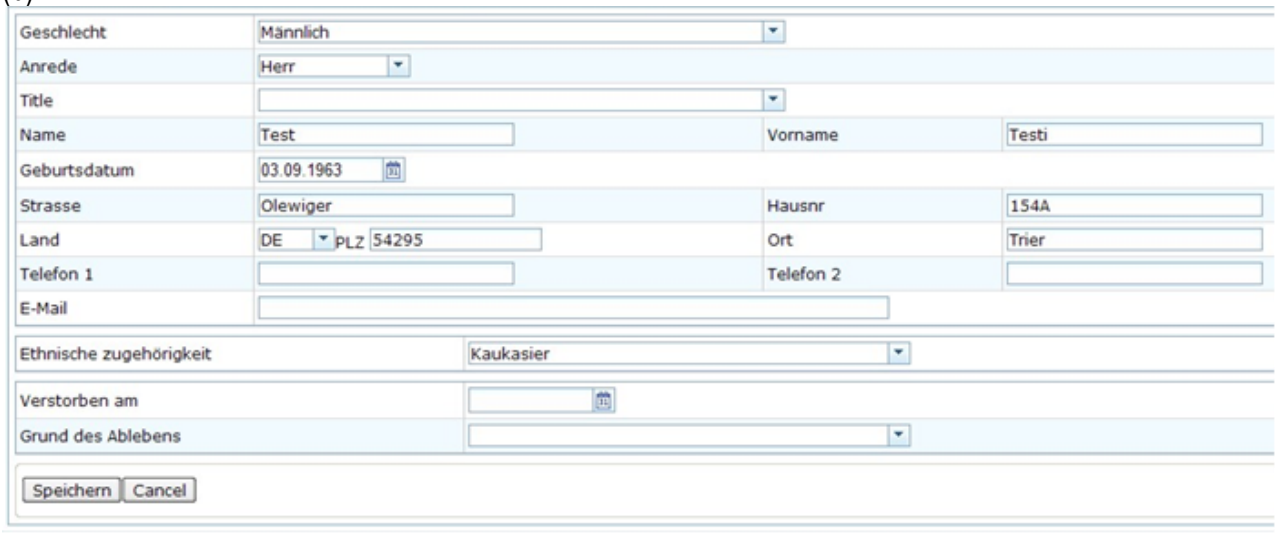
As the figure above shows, patient records and other health information remain on the national databases where they are currently stored. The central database (part of the EU-HealthID system) is only populated on request – i.e. a copy of the requested information is transferred when it is required, and deleted afterwards. This increases the security of the system and ensures that patient information is not retained after treatment is completed, fulfilling the requirements of Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (in particular Article 6(e), which states that data must be "kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed").

This is further ensured by the strong data and access security which will be built into the EU-HealthID system. Only doctors with the correct privileges will have access to, or be able to edit or amend, EHR retrieved by the system, and their privileges will relate only to information on patients they are treating. All users (i.e. doctors and system administrators) will have their respective privileges and biometric access data stored in a central European Authentication Database, which will be administered by the SNBA (which is currently the only Europe-wide biometric association).

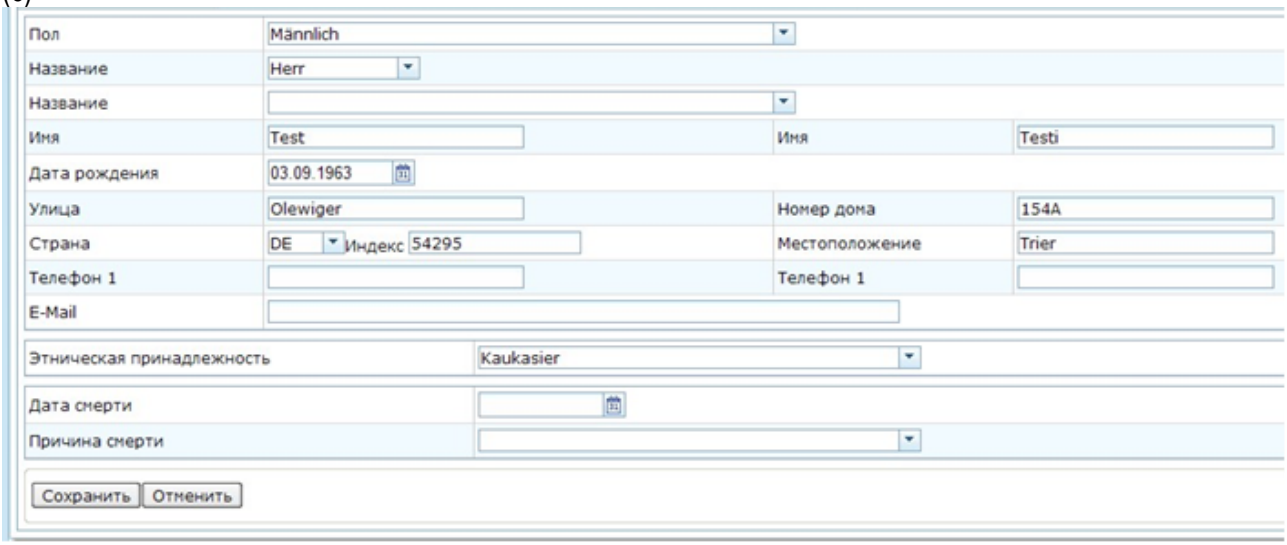
(a)



(b)

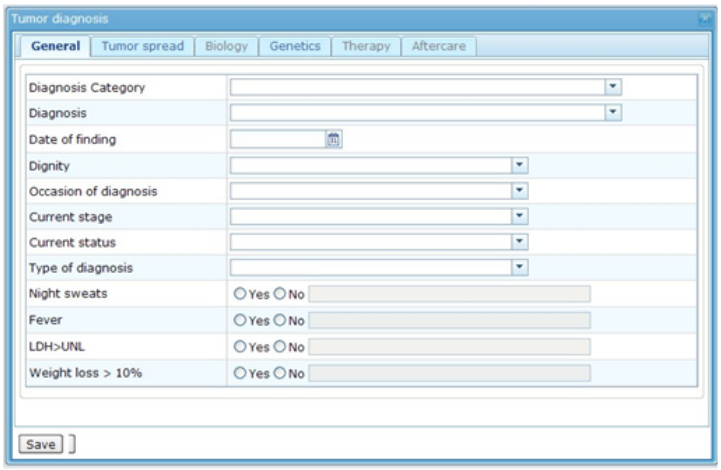


(c)

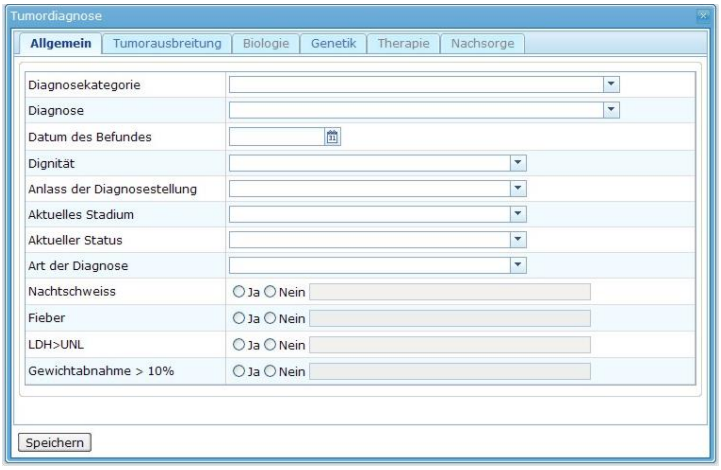


Above, and on next pages: Examples of prototype data entry GUI in (a) English, (b) German and (c) Russian

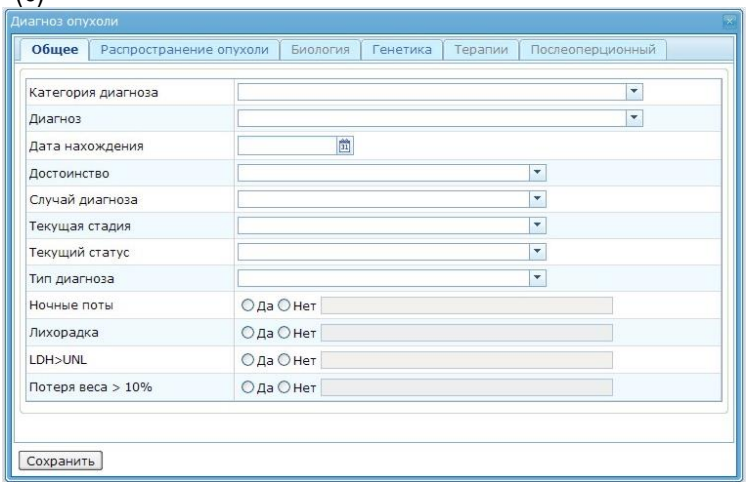
(a)


Tumor diagnosis
General
Tumor spread
Biology
Genetics
Therapy
Aftercare
Diagnosis Category
Diagnosis
Date of finding
Dignity
Occasion of diagnosis
Current stage
Current status
Type of diagnosis
Night sweats
Fever
LDH>UNL
Weight loss > 10%
Yes No
Save

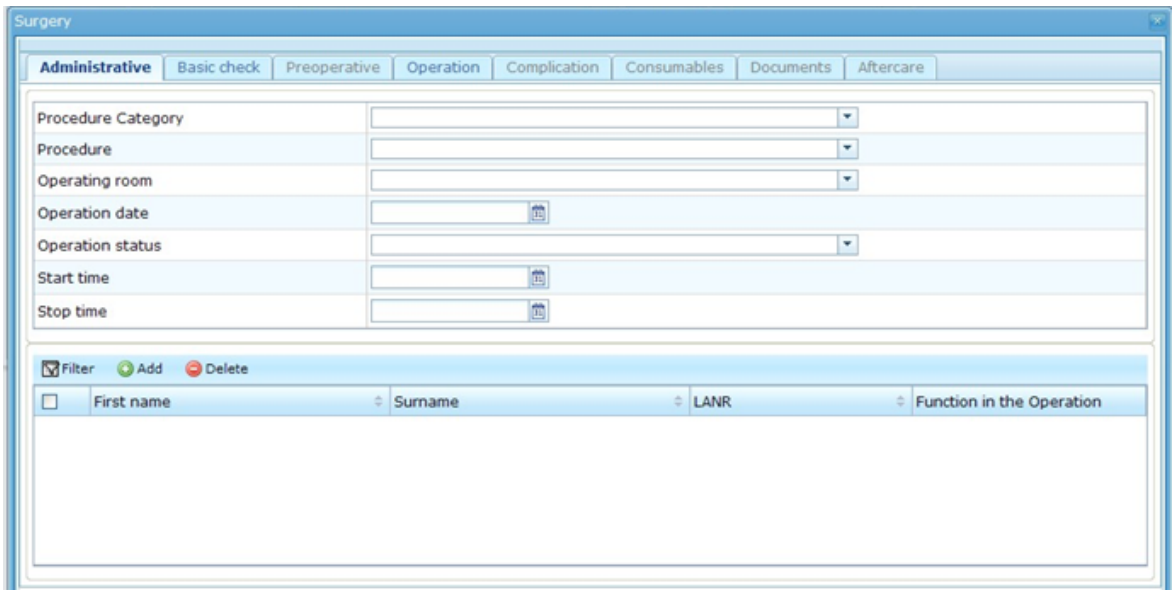
(b)


Tumordiagnose
Allgemein
Tumorausbreitung
Biologie
Genetik
Therapie
Nachsorge
Diagnosekategorie
Diagnose
Datum des Befundes
Dignität
Anlass der Diagnosestellung
Aktuelles Stadium
Aktueller Status
Art der Diagnose
Nachtschweiss
Fieber
LDH>UNL
Gewichtabnahme > 10%
Ja Nein
Speichern

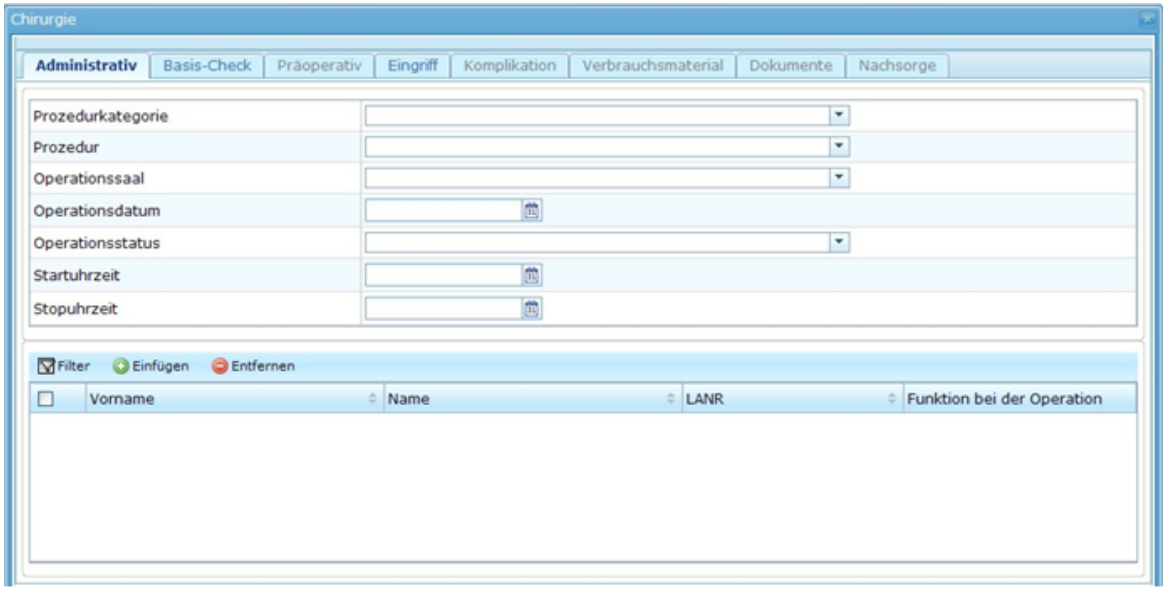
(c)


Диагноз опухоли
Общее
Распространение опухоли
Биология
Генетика
Терапии
Послеоперционный
Категория диагноза
Диагноз
Дата нахождения
Достоинство
Случай диагноза
Текущая стадия
Текущий статус
Тип диагноза
Ночные поты
Лихорадка
LDH>UNL
Потеря веса > 10%
Да Нет
Сохранить

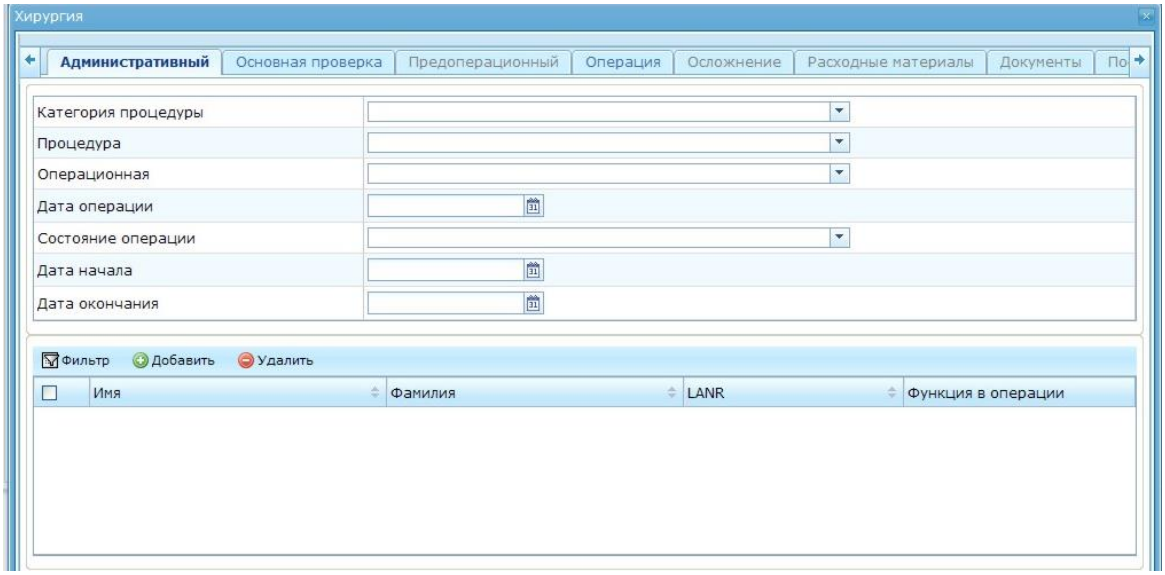
(a)

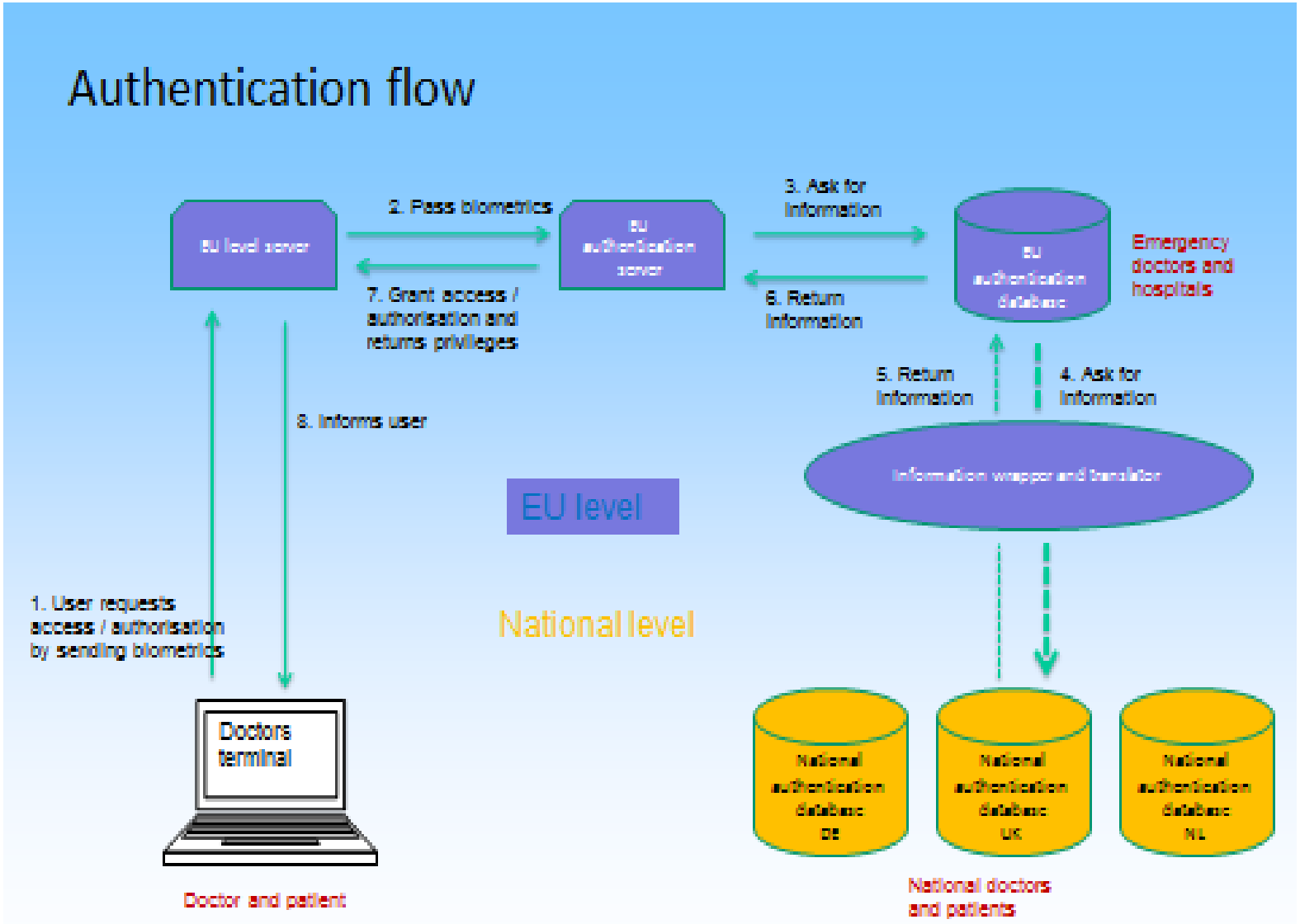

Surgery
Administrative
Basic check
Preoperative
Operation
Complication
Consumables
Documents
Aftercare
Procedure Category
Procedure
Operating room
Operation date
Operation status
Start time
Stop time
Filter
Add
Delete
First name
Surname
LANR
Function in the Operation

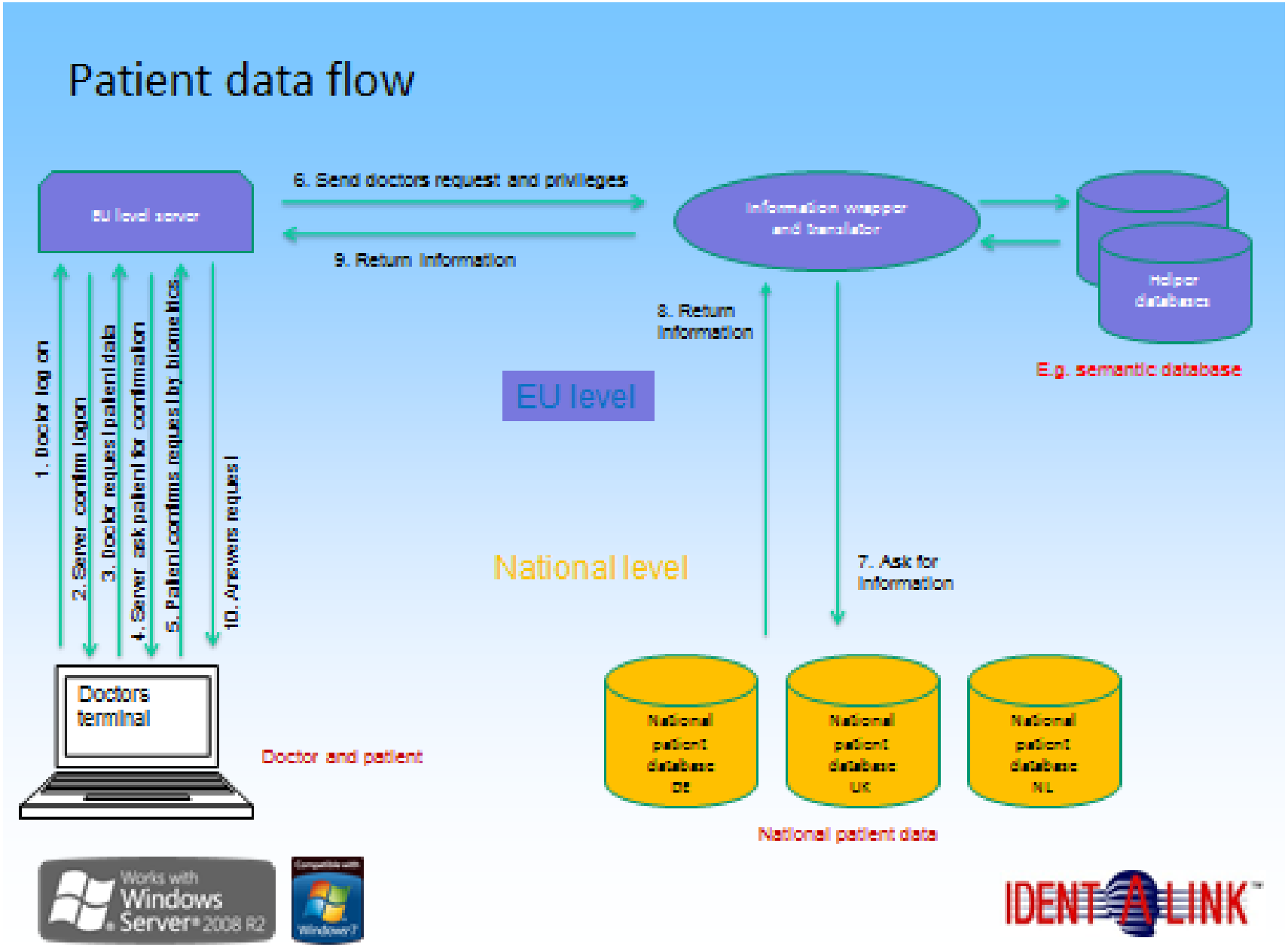
(b)


Chirurgie
Administrativ
Basis-Check
Präoperativ
Eingriff
Komplikation
Verbrauchsmaterial
Dokumente
Nachsorge
Prozedurkategorie
Prozedur
Operationssaal
Operationsdatum
Operationsstatus
Startuhrzeit
Stopuhrzeit
Filter
Einfügen
Entfernen
Vorname
Name
LANR
Funktion bei der Operation

(c)


Хирургия
Административный
Основная проверка
Предоперационный
Операция
Осложнение
Расходные материалы
Документы
Категория процедуры
Процедура
Операционная
Дата операции
Состояние операции
Дата начала
Дата окончания
Фильтр
Добавить
Удалить
Имя
Фамилия
LANR
Функция в операции





The Novelty of the Project

Our system incorporates innovations in a number of components. The two main innovations is found in the Access Control of the system and the Web Interface Software Platform (which incorporates semantics and communication). These are highlighted as follows:

Language and Communication (L&C) Agent: The development of a database neutral L&C Agent based on Service Oriented Architecture and Enterprise Service Bus technology. The open-source PEtALS Enterprise Service Bus will be adopted to manage connections between healthcare organisations thanks to a large set of already available connectors and protocols (Web Services, EDI, etc). PEtALS is compliant with the JBI (Java Business Integration, JSR 208) standard for integration technology and is based on a plug-in architecture that allows easily the adding of new components in order to take account of new connectors or communication protocols. It is a plug-in based methodology which will enable our system to be constantly improved and new biometric sensor technologies can be easily added at any time without the need for change in the main software architecture. The development of a communication tool would be primarily based on HTTP protocol; this adds greater flexibility to the solution and will allow organisations to continue using their existing solutions or easily upgrade their current systems. End-to-end encryption mechanism and SAML compliant security token propagation will be adopted to enable fully secured data exchanges. The sematic databases on EU level (see figures on page 13 and 14) will collect requested data from native (national) sources and translate into "language of request" and in official EU languages (i.e. English, French).

Intelligent Ontologies: This helps the system to make sense of the data. In a Service Oriented Architecture (SOA), the Service Model serves as the referee between the data requirements on the one hand, and the technical implementations on the other. Therefore, the Services represented in the Service Model must provide the layer of abstraction between the data representations and this would be represented in the Web Interface Software Platform. However, in today's early SOA implementations, organisations often implement static service definitions, meaning that the Web Services' interface contracts are set at design time. While Universal Description Discovery and Integration (UDDI) and Service-Oriented Management provide the means for dynamic discovery of such Services, those Services are still essentially static. Databases of all native (national) medical products (of each member state), according to Guideline 93/42/EEC, are adopted and translated on EU level and integrated into sematic databases.

Biometric Access Control Tool: This is an interface tool that has compatibility with all the biometric sensors/scanners/readers commonly used in Europe. This would be designed taking into consideration the future developments of biometric technology beyond 10 years. This would be achieved as part of our hardware integration work package where we would research and review a large number of biometric readers taking into account current research and in order to map out the Software Platform to have compatibility with as many hardware systems as possible. However, as part of our project we would be looking at the most ideal biometric technology and as the uptake of our solution grows within Europe, we would be lobbying the EC to modify the standards for biometric technology.
Following standards will initially be adhered to:
ISO/IEC 19794-2:2005/Cor 1:2009

ANSI/NBS-ICST 1-1986

System Architecture: The main purpose our architecture should serve is to provide a semantically unified interface for querying (selected) heterogeneous information sources. We do not aim at merging all possible sources together providing a cumulated view of all attributes. We argue that such an approach offers very weak semantics, where the understanding of the semantic structure of all integrated sources is effectively left up to the user who is asking the query. In possible architecture, an underlying domain model consisting of hierarchies of concepts, relations, and possibly axioms is assumed to exist. This conceptual model would be maintained centrally (at the schema level) but it is dynamically populated with instances during the query resolution. Our model corresponds to an ontology and represents a semantic integration of the integrated data sources. To

create such a model beforehand, ontology engineering tools, which are currently becoming available, could be used. The main advantage of having an underlying semantic model is that the way in which the data is structured (encoded) in the sources is transparent for the user, i.e. they can ask queries and interpret the results in terms of well-understood concepts. This is better than the traditional XML views, where queries are expressed more in terms of structure rather than semantics. We will build on this in detail at the start of the project during the Preliminary Research and Knowledge mapping work package.

1.4 Quality and effectiveness of S/T Methodology and associated work plan

For easy management, the entire work plan is divided in eight work packages, each delivering a tangible output, directly contributing to project objectives. The project will be based on **Spiral** Software Development Methodology whilst using **Agile** development process for technology development and integration. The project will start by capturing the relevant requirements for such a system from the view of all the relevant stakeholders (EU, SME-AG members, End Users, SME supply chain) and representing them in terms of System Requirement and Specification. This would be done under the Preliminary Research and Knowledge Mapping work package **WP1**. System Architecture and specifications will be done based on these requirements and research will be performed to meet these requirements by scientific and technology advancements in **WP2, 3, and 4**. The intermediate results will be integrated and tested as a prototype version of the system in **WP5**. This version will then be evaluated based on pre-defined assessment metrics and the results will be used for refining the requirements and system specification. Further development cycles will be executed to create the final system. The final version will then be assessed in a real practical scenario (test bed) in order to validate the results of the project in a real example. The use of a spiral model will allow the RTD performers to use the **Shewhart cycle** (PDCA) for **Quality improvement**. The PDCA quality control strategy consists of four stages as follows. **PLAN** is to establish the objectives of the prototype. This will be done as part of **WP1** by identifying user requirements and specifying the system architecture. **DO** is to implement the processes. This will be done in **WP2, 3, and 4** by developing the software and hardware tools and integrating them to create the prototype. **CHECK** is to monitor and evaluate the processes and results against objectives and specifications and report the outcome. In **WP5** and **WP6**, the integrated prototype will be tested and validated against the requirements and other software evaluation matrices. **ACT** is to apply actions as agile processes for necessary improvement. The results of the testing will be used to update the requirements and the architecture of the system and the entire development process will be repeated to improve the prototype (**WP1**, **WP2, WP3, WP4, & WP5**). The **WP6** will be dedicated for validation of project results by creating Test Cases for the project application scenarios especially for cross border access of electronic health records in the case of emergencies. All the management activities will be done as **WP8** and dissemination and exploitation activities in **WP7** throughout the project lifecycle.

Integration of Risk Contingency and General Risk Management

Any new technical solution carries a certain degree of risk and it is important to consider this as early as possible. A detailed risk analysis exercise was carried out in order to identify the major areas of developmental risk and possible risk contingency strategies that could be employed to minimise their impact. The results were broken down by likelihood and impact, with low-low risks ignored, high-low and low-high risks considered in design issues and high-high risks aggressively targeted for contingency. The first risk management tool used is that of milestone control points. These define discrete project stages, each reliant on the completion of a previous milestone. The project management team may use these points to decide if the required level of progress has been achieved in order to justify continuation to the next stage. If milestone requirements are not met, the management will be able to effectively implement contingency strategies without excessive adverse impact on other project stages. The need for milestones has driven the work plan design. The structure of the tasks within each work-package has also been designed to reduce task overlap. These measures ensure that, should risk triggers be activated, implementation of contingencies causes as little disruption as possible and the minimum of additional resources are used. The final milestone is different in that it is a decision point involving external review by the European Commission and as such drives the timing of the project end-point rather than the completion dates defined in the work-plan. Additional milestones may be added to meet any interim reviews by

the EC. During the project, risk will be actively managed. This will involve pre-work package risk assessments, the maintenance of a risk log and clear ownership of issues and risks throughout the project management chain. This is handled through the project management structure, using the design of the work-plan to facilitate implementation. Complete achievement of objectives will result in a new cross border biometric enabled electronic health record system with enormous European impact. However, even if some objectives are not achieved completely and contingencies have to be applied, the project will still produce an innovative system significantly beyond the state of the art.

Risk Management and Contingency Planning

Risk	*Likelihood**	*Impact**	*Mitigation*	*Contingency*
Large number of different, non-standard biometric data formats and hardware protocols make integration of all biometric formats impractical within the timeframe of the project.	L	M	Research into the available and emerging biometric information protocols and formats will be carried out during the initial stages of the project to determine whether integration is feasible in terms of financial and time budgets.	If necessary, the most widely-used formats, as well as the most promising emerging technologies, will be focussed on during the project; support for less widely-used and legacy systems will be added in post-project development.
Concerns about privacy and data security limit market acceptance.	L	H	Extensive work will be carried out during the project to ensure that the product conforms to European and national data protection legislation, and to address concerns about data security, access to data, and patient privacy.	If market acceptance is still not forthcoming, or is poor in non-European markets, further work will be carried out post-project to address stakeholder concerns.
Competing technology or product emerges during project.	L	L	Project will focus on the development of an integrated product solution, not on specific technologies.	A technology watch will be maintained to ensure that, if new or competing technologies become available during the project, they will be assessed and may be incorporated into the project if it would be possible, beneficial and cost-effective to do so.

(*) L = Low, M = Medium, H = High

Work package No[2]	Work package title	Type of activity[3]	Lead partic no.[4]	Lead partic. short name	Person-months[5]	Start month[6]	End month
1	Preliminary Research and Knowledge Mapping	RTD	7	GUAS	36.5	1	6
2	Development of Software Platform	RTD	4	PCKN	31.5	4	14
3	Language and Communication Agent	RTD	8	TBU	32	5	12
4	Hardware Integration	RTD	1	IdentAlink	35	9	18
5	System Integration and Testing	RTD	5	Secure	33.5	16	21
6	Validation of the System	DEM	2	SNBA	8.5	21	23
7	Exploitation, Dissemination and Training	OTH	2	SNBA	14.5	1	24
8	Project Management	MGT	1	IdentAlink	10	1	24
	TOTAL				201.5		

Table 1.4a: Work package list

2 Workpackage number: WP 1 – WP n.

3 Please indicate one activity per work package:
RTD = Research and technological development (including any activities to prepare for the dissemination and/or exploitation of project results, and coordination activities); DEM = Demonstration; MGT = Management of the consortium; OTHER = Other specific activities, if applicable in this call

4 Number of the participant leading the work in this work package

5 The total number of person-months allocated to each work package

6 Measured in months from the project start date (month 1)

Deliverables list

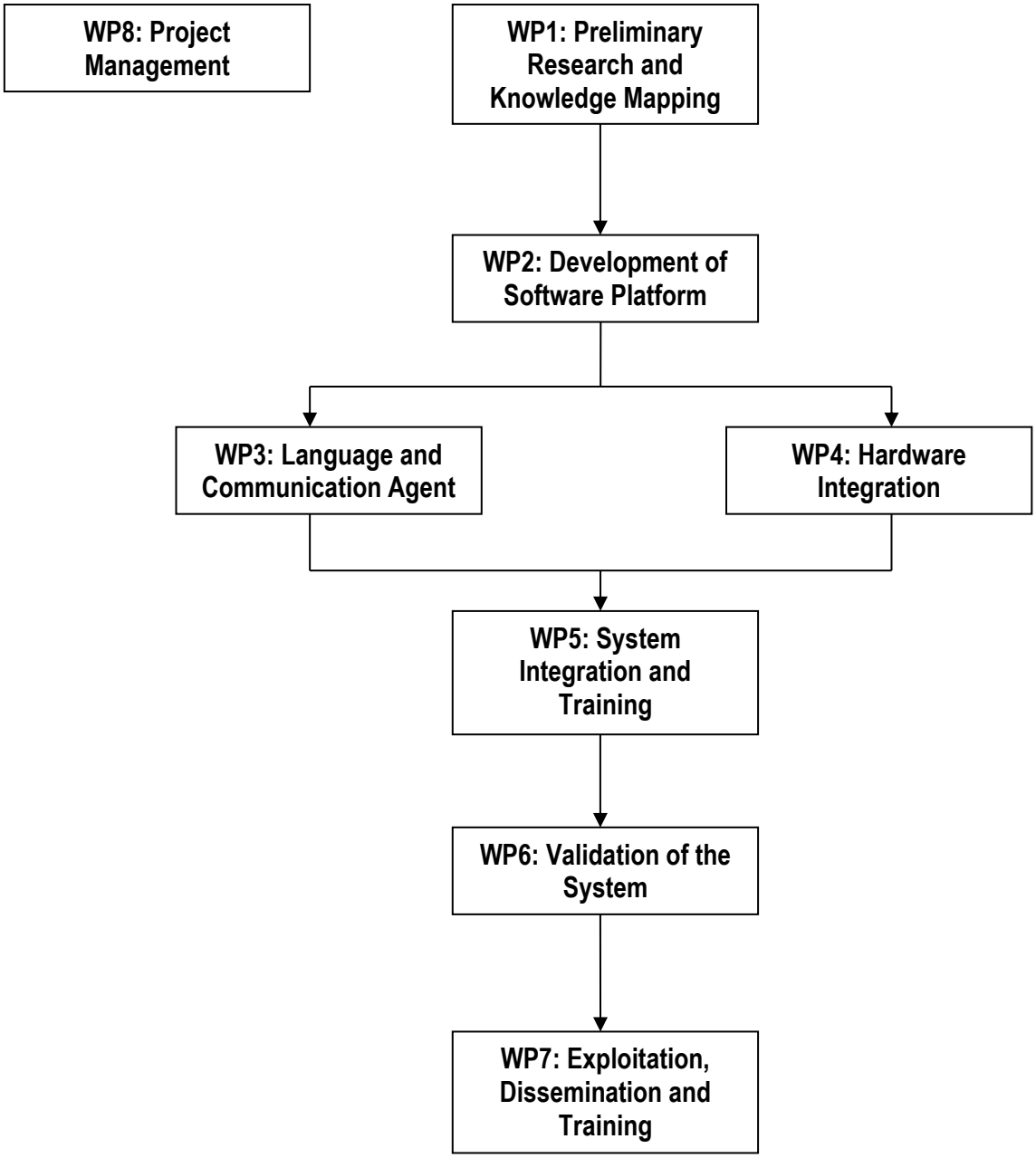
Del. no.	Deliverable name	WP no.	Nature[7]	Dissemination level[8]	Delivery date
D1.1	Working paper reviewing existing biometric technologies in the participating countries	WP1	R	PU	2
D1.2	Working paper summarizing the results of in-depth interviews and semi-structured survey with the end user communities	WP1	R	PU	2
D1.3	Working paper on the results of the research into legislative and standards issues	WP1	R	PU	4
D1.4	First draft SRD	WP1	R, O	RE	4
D2.1	Software Algorithms (software)	WP2	R	RE	6
D2.2	Centralised Database (software)	WP2	R, O	RE	9
D2.3	GUI (software)	WP2	R, O	RE	14
D3.1	L&C agent specification	WP3	R	RE	7
D3.2	L&C agent implementation	WP3	R, O	PU	8
D3.3	L&C connector specification	WP3	R	RE	9
D3.4	L&C connector implementation	WP3	R, O	PU	10
D3.5	Multi-lingual framework specification	WP3	R	RE	11
D3.6	Multi-lingual framework implementation	WP3	R, O	PU	12
D4.1	Hardware Interface Specification	WP4	R	PU	15
D4.2	Biometric Access Control Tool	WP4	R, P	RE	18
D5.1	Integration and Implementation Plan	WP5	R	PP	19
D5.2	Final Integrated System and Algorithm Evaluation Report	WP5	R, D	PU	20
D5.3	Final Testing Report	WP5	R	PU	21
D6.1	Test first pilot version	WP6	R, D	PU	22
D6.2	Analyse test results	WP6	R	PU	23
D6.3	Comparisons between objectives and trial outputs	WP6	R	PU	24
D7.1	Two papers presented at 4 conferences or major exhibitions and two publications in the form of editorials, technical papers or trade press.	WP7	O	PU	24
D7.2	Implementation strategy plan for dissemination and use in project and post project.	WP7	R	PP	12
D7.3	Project website and production of support material for transfer of the knowledge to the partners	WP7	R, O	RE	3
D7.4	Report on potentially competitive patents and a plan for patent application(s) if required with exploitation agreements between the partners.	WP7	R	PP	3
D8.1	Three monthly reports produced highlighting progress of: work delivery, deliverables achieved, milestones met.	WP8	R	RE	24
D8.2	Three monthly cost statements to be produced demonstrating spend by each partner compared with budgeted spend to date.	WP8	R, O	RE	24

7 **R** = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

8 Please indicate the dissemination level using one of the following codes:
PU = Public
PP = Restricted to other programme participants (including the Commission Services)
RE = Restricted to a group specified by the consortium (including the Commission Services)
CO = Confidential, only for members of the consortium (including the Commission Services)

Del. no.	Deliverable name	WP no.	Nature[7]	Dissemination level[8]	Delivery date
D8.3	Preparation of all minutes made available to all consortium members.	WP8	O	RE	24
D8.4	Preparation of reports for any conflict resolution matters.	WP8	R	RE	24

Table 1.4b: List of Deliverables


WP8: Project Management
WP1: Preliminary Research and Knowledge Mapping
WP2: Development of Software Platform
WP3: Language and Communication Agent
WP4: Hardware Integration
WP5: System Integration and Training
WP6: Validation of the System
WP7: Exploitation, Dissemination and Training

PERT Chart

Project	EU-HealthID
Duration	24

Work package No	Work package title	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
1	Preliminary Research and Knowledge Mapping		■	■	■	■	■	■																		
2	Development of Software Platform					■	■	■	■	■	■	■	■	■	■	■										
3	Language and Communication Agent						■	■	■	■	■	■	■	■												
4	Hardware Integration										■	■	■	■	■	■	■	■	■	■						
5	System Integration and Testing																	■	■	■	■	■	■			
6	Validation of the System																							■	■	
7	Exploitation, Dissemination and Training		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
8	Project Management		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Gantt chart

Work package number	1	Start date or event	M1
Work package title: Preliminary Research and Knowledge Mapping			
Activity type: RTD			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	0.5	0.5	0.5	0.5	17	13	3	1.5		

Objectives

- Understanding the biometric technologies in use in the participating countries
- Understanding the requirements of the end user communities
- Elaborating factors / contingencies that may affect the effectiveness of knowledge transfer / information sharing process;
- Modelling of the acquired information

Description of Work

Task 1.1 Evaluation of biometric technologies

The range of biometric hardware and software in use in Europe will be surveyed, and it will be determined which are in most common usage. These will be evaluated, with the aim of determining precise technical requirements for integration of the biometric technologies with the software platform developed in this project.

Task 1.2 Stakeholder requirements survey

Stakeholders including end-users (healthcare staff), patients, healthcare policymakers and people and organisations with responsibility for hospital purchasing will be surveyed in order to determine the requirements of the product developed in this project. Surveys and interviews will be carried out, through professional and trade organisations, patient groups, and through Torrevieja Salud, who will be a user of the final product.

Task 1.3 Legislative and standards research

In-depth research will be carried out into the national and European legislation and standards that will impact on the work carried out in following WPs. This will include regulations and standards relating to the collection and exchange of biometric data, as well as privacy, data protection and data security legislation.

Task 1.4 System requirements document (SRD)

A draft of the SRD will be drawn up, based on the information gathered in tasks 1.1, 1.2 and 1.3. This will guide the development work carried out in successive WPs.

Deliverables

D1.1: Working paper reviewing existing biometric technologies in the participating countries
D1.2: Working paper summarizing the results of in-depth interviews and semi-structured survey with the end user communities
D1.3: Working paper on the results of the research into legislative and standards issues
D1.4: First draft SRD

Table 1.4c Work Package Description

Work package number	2	Start date or event	M4
Work package title: Development of Software Platform			
Activity type: RTD			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	0.5	1	0	1	12	17	0	0		

Objectives

An innovative, interoperable & integrated biometric/PKI enabled security access software platform for patient health records within the national health sectors across the participating EU member states
Interoperability and easy exchange of data types and formats from any biometric sensors and identification systems with API capability
Collection and usage of biometric data for attribute management, authentication, workflow, service access control and auditing functionality
Building a centralised database to be used by the EU health organisations

Description of Work

Task 2.1 Algorithm implementation
Software algorithms will be developed for attribute management, authentication, workflow, service access control and auditing functionality, as well as integration of k-algorithm on national and international database in order to provide full anonymised statistics according to the EU Data Protection Directive (Directive 95/46/EC).

Task 2.2 Creation & Implementation of the Centralised Database as well as EU PKI root Server
Creation and integration of four database schemata will be involved:
1. An authorisation DB for registered GP's and emergency doctors will be created, which will be stored as a central, EU-wide database, administered by SBNA.
2. An authorisation DB for registered patients with the relevant security as it applies nationally (fingerprint, PIN, e-card, password etc.) (this will be created on a national level, and used to populate the EU-HealthID database)
3. History DB for case history of registered patients (again, these will exist on a national level, and schemata and semantic layers will be created to incorporate this data into the final system)
4. Semantic DB, including a meta-data repository for drugs and medical accessories and aids (this will be crease on an EU level, and populated using existing information from national and EU databases)

Task 2.3 Graphic User Interface Implementation
An intuitive GUI will be developed, based on state-of-the-art HCI design techniques. Fast prototyping methods, including paper prototyping (creation of a prototype GUI design on paper, allowing users to assess design features and designers to evaluate user responses to designs without the need for coding), will be used to ensure that the GUI is as easy to use as possible. The GUI will also be accessible (for users with visual impairment or other disabilities) and easily localised for use in other European countries (e.g. text easily translated into other languages).

Deliverables

D2.1: Software Algorithms (software)
D2.2: Centralised Database (software)
D2.3: GUI (software)

Table 1.4c Work Package Description

Work package number	3	Start date or event	M5
Work package title: Language and Communication Agent			
Activity type: RTD			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	0.5	0.5	0	0	10	21	0	0		

Objectives

The main aim of WP3 is to develop a database neutral Agent based on Service Oriented Architecture and Enterprise Service Bus technology.
This agent will leverage semantic technology in order to allow different EU health organizations using heterogeneous technology to communicate with each other. It uses semantic reconciliation algorithm that uses ontology's provided by partners in order to automatically generating the necessary transformation for data adaptation.

Description of Work

Task 3.1 L&C agent

The agent implements:

- A transformation engine that use semantic information in order to automatically transform data to a format that fit target partner's need. This component is the cornerstone of the interoperability feature since it allows adapting data format thanks to an Ontology matching algorithm.
- A workflow engine that implements collaborative processes that takes place between partners

Task 3.2 Building of connectors (EBM)

- This task will provide the interface with different databases and protocols. Based on JBI standards, these components will leverage those provided by PEtALS such as the generic database binding components and EDI, Web Service gateways.
- These connectors will provide necessary security and authentication mechanisms based on WS-Security.

Task 3.3 Multi-lingual

- Multi-lingual facilities will be integrated both at Ontology and user interface levels. It needs to be able to translate into at least 5 main EU languages.

Deliverables

D3.1: L&C agent specification
D3.2: L&C agent implementation
D3.3: L&C connector specification
D3.4: L&C connector implementation
D3.5: Multi-lingual framework specification
D3.6: Multi-lingual framework implementation

Table 1.4c Work Package Description

Work package number	4	Start date or event	M9
Work package title: Hardware Integration			
Activity type: RTD			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	2	1	0	0	18	14	0	0		

Objectives

The objective of this work package is to review and adapt potential biometric sensors that can be integrated with the final cross border EHR solution. The work package would also involve the development of a biometric access control tool to act as the interface with as many biometric technologies as possible.

Description of Work

Task 4.1: Hardware Interface Definition

Interfaces and platform concept or definition is necessary. For the hardware a standardised interface should be developed in order to connect different biometric sensors for customer individual application requirements for their overall solution. The interface can be designed by direct or wireless connection. For the development of all user specific application the specifications of the interface are necessary. In that case the configuration of the biometric readers can be adapted to different applications. The interface should work with a minimum of energy resources, adaptable for different reader types. Therefore the input from the partners who develop the mobile reader technologies is important for the data exchange. Also the data communication and acquisition can only be resolved by high system integration.

Task 4.2: Biometric Mobile Reader Adoption

This task involves assessing the biometric technologies that are most ideal in term of operation and compatibility for use with our final EHR solution. This task follows from task 1.1 in WP1 and would lead to the development of the access control software in order to get the best possible performance for our solution.

Task 4.3: Development of the Biometric Access Control Software Tool

Based on the outcomes of task 1.1 and 4.2, this task would involve the development of the access control software for the biometric scanners/readers that would link the readers to the web interface software platform and the national and central health service databases of patients electronic records.

Deliverables

D4.1: Hardware Interface Specification
D4.2: Biometric Access Control Tool

Table 1.4c Work Package Description

Work package number	5	Start date or event	M16
Work package title: System Integration and Testing			
Activity type: RTD			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	0.5	0.5	1	0.5	19	12	0	0		

Objectives

The objectives include: Setting up an Integration Plan that covers both implementation and configuration stages; Confirm resources to execute Implementation Plan; Confirm resources to set up integration tests, Implementation feedback, and system configuration; Update the system documentation

Description of Work

T5.1: Design of Integration and Implementation Plan

This task aims to develop a comprehensive Integration Plan that is required to effectively support the developed system based on the user requirements and specifications set out in WP1. The Integration Plan shall contain a series of activities and tasks to be executed as part of the System Integration Phase. The Integration Plan shall provide a detailed description of each major Integration task that is required for the full integration of the system.

T5.2: Implementation of System Solution

This task aims to integrate various modules developed in Work Packages 2, 3, and 4. Integration would be done in line with the integration plan developed in Task 5.1 at unit level, system level and overall system level also with external modules. Therefore the task would mainly focus on following outputs: Unit level integration outputs; System level integration outputs; and Overall system level with external modules outputs.

T5.3: System Configuration

The Implementation Plan developed in Task 5.1 will define activities to track and control changes in the software. This set of activities identifies the functional and physical attributes of software at various points in time, and performs systematic control of changes. In other words, this task is designed to control change by identifying the systems modules that are likely to change, establishing relationships among them, defining mechanisms for managing different versions of algorithm modules.

T5.4: Pre-alpha testing of individual sub-modules and overall system

This task's main objective is to identify and ensure that the developed system behaves and works properly in a given data set. The test would be based on test data, test scripts and test cases planned and developed in task T5.1. Therefore, the main aim of this task is to perform testing at the following levels:

- Sub-module integration testing- Detects defects in the interfaces and interaction between different modules.
- System testing- would test completely integrated solution used both generated and real world data sets.
- Performance testing - to ensure the efficiency of the system at worst case scenario.
- Compatibility testing - to ensure cross platform compatibility or to ensure at least minimum compatibility to run the system
- Scalability testing- to ensure the system could handle an increase in number of input data.
- Usability testing- to ensure that the system is easy to use and handle by an analyst (maybe non technical)
- Maintainability testing - to measure the degree and to ensure that user does not require too much maintenance of the system
- Security testing - to ensure the security incorporated with the system works properly
- Alpha testing- We would also perform alpha testing, which would be mainly based on the test scripts built in -house.

Deliverables

D5.1: Integration and Implementation Plan
D5.2: Final Integrated System and Algorithm Evaluation Report
D5.3: Final Testing Report

Table 1.4c Work Package Description

Work package number	6	Start date or event	M21
Work package title: Validation of the System			
Activity type: DEM			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	1.5	1	1	1	1	1	1	1		

Objectives

- Test and validate each version of the system according to user trial manuals. This will include testing by both the professional users and by the SME-AG members and SME end users.
- Analyse the feedback from the test.
- Adapt the system according to the analysis of the feedback from the experts and SME end users.
- Assess usability through expert evaluations and user tests of all versions of the system.

Description of Work

Task 6.1 First alpha test
Test of preliminary software prototype by end-users from SNBA and Torrevieja Salud. (Functionality, features, user experience and opinions). Test of preliminary system functionality. If practical and useful, the national test may each test specific features to a greater detail.

Task 6.2 First test results analysis and validation
Report of the results and validation from the SMEs trials regarding preliminary pilot version 1.

Task 6.3 Test second version
Test of second version – similar to the first test (task 6.1)

Task 6.4 Results analysis and validation
Report of the results of the tests and feedback from the SMEs regarding the second version.

Task 6.5 Usability test and assessment
Usability assessment by experts and usability test with SMEs on both versions using heuristic methods as well as conventional observation and registration methods of user behaviour.

Task 6.6 System validation
Validate the system against pre-defined criteria and publish results in a report for the benefit of those inside the consortium and for dissemination in the public domain. Validation will be carried out by SBNA and Torrevieja Salud. Where this requires processing of patients' health and biometric information, in order to test the system's performance using real data, the data will be anonymised, and all the provisions of the relevant legislation (primarily Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data) will be adhered to. Specific permission will be obtained from the individual patients involved where necessary (where such use of the data is not covered by pre-existing agreements, and where such permissions are required by national or EU law).

Deliverables

D6.1: Test first pilot version
D6.2: Analyse test results
D6.3: Comparisons between objectives and trial outputs

Table 1.4c Work Package Description

Work package number	7	Start date or event	M1
Work package title: Exploitation, Dissemination and Training			
Activity type: OTH			

Participant number	1	2	3	4	5	6	7	8		
Person months per participant	3	1.5	1.5	1.5	1	1	3	2		

Objectives

- Compile project results into a protectable form, including patent registration and develop an Exploitation Strategy to be agreed by all project partners.
- Disseminate knowledge, experience and benefits from the pilot system to expert groups, system providers, SME-AGs and SME end-users as well as user communities, industrial contact networks, trade press, regional clusters and chambers of commerce networks at conferences, workshops, exhibitions to potential user communities such as industrial contact networks and trade press, regional clusters, chambers of commerce networks,
- Demonstrate and present the concept at trade or sector specific events and/or exhibitions

Description of Work

The project partners, in particular SNBA, will play a major role in the dissemination and exploitation activities. The dissemination channels will be input to publications, promotion and demo CDs, leaflets and other printed material, web based activity, online courses and exhibitions, conferences, seminars, especially towards end-user communities and associations in the health sector.

Task 7.1 Protection of IPR

Carry out patent searches to assess the viability of a patent application. Prepare patent applications and submit through patent agent. Create a preliminary DUP at mid-term and a final version by final term. IPR ownership and exploitation agreements within the partnership and outside of the partnership in the form of potential licensee agreements will be created.

Task 7.2 Dissemination of knowledge and promotion of exploitation

Focused specifically on system implementation strategies and implications for the EU health sector. Produce publications, CDROMs, web based activity and exhibitions, especially towards end-user communities & associations.

Task 7.3 Absorption of results by proposers

The RTDPs must assure that all the knowledge and results developed in the project are transferred to the coordinator company. The researchers should be able to further transfer the results to their members and to promote the project.

Task 7.4 Establish national steering committees

Establish national steering committees that will exploit the results by setting up publicity events in the participating EU countries.

Deliverables

D7.1: Two papers presented at 4 conferences or major exhibitions and two publications in the form of editorials, technical papers or trade press.
D7.2: Implementation strategy plan for dissemination and use in project and post project.
D7.3: Project website and production of support material for transfer of the knowledge to the partners
D7.4: Report on potentially competitive patents and a plan for patent application(s) if required with exploitation agreements between the partners.

Table 1.4c Work Package Description

Work package number		8	Start date or event	M1					
Work package title: Project Management									
Activity type: MGT									
Participant number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**		
Person months per participant	3	1	1	1	1	1	1	1		

Objectives

- To coordinate all project activity and act as the administrative interface with the Commission. To manage time, resources and facilities allocation to optimise the application of resource and establish exploitation mechanisms.
- Effective coordination of knowledge and innovation-related activities. On-time and correct cost claims. Effective consortium management of these other aspects.
- Effective two way communication between consortium and EC. Organisation of project meetings. To co-ordinate the Gender Equality Ethical and Societal Aspects of the Project.

Description of Work

Task 8.1 Coordination of knowledge management and IRA
Preliminary version of Plan for Dissemination and Use (PDU) to be issued at mid-term. Definition of IPR ownership by mid-term. Development of the Consortium Agreement. Dissemination Strategy in place mid-term, confirmed by draft PDU.

Task 8.2 Collation of cost statements and audit certificates
All partners will have to arrange cost statements and the provision of audit certificates under new framework programme guidelines. Project Coordinator will collate the cost claim before submission to the EC.

Task 8.3 Coordination of legal, contractual, and financial aspects
Updating and revision of various consortium documents. For example, Consortium Agreement and PDU. Coordination of payments and distribution of funding.

Task 8.4 Communications between the Consortium and the EC
Organisation of Project Meetings, Dissemination of EC communications to the consortium. Handling queries and enquiries from the EC regarding consortium and project. Liaison with EC project officer and point of contact with EC for all project enquiries from partners. Arrangement of project meetings and presentations.

Task 8.5 Coordination of gender equality, ethical and societal aspects of the project
Assessment of potential impact of the technology on society aspects. Promotion of new technology to citizens of the EU. Generation of feedback questionnaire to end-users to assess impact on any ethical or social aspects.

Deliverables

D8.1: Three monthly reports produced highlighting progress of: work delivery, deliverables achieved, milestones met.
D8.2: Three monthly cost statements to be produced demonstrating spend by each partner compared with budgeted spend to date.
D8.3: Preparation of all minutes made available to all consortium members.
D8.4: Preparation of reports for any conflict resolution matters.

Table 1.4c Work Package Description

Participant no & short name	Part.1 IdentAlink	Part.2 PCKN	Part.3 Secure	Part.4 SMATOS	Part.5 GUAS	Part.6 TBU	Part. 7 SNBA	Part. 8 TS	Total SME-AG	Total RTDP	Total OTHER	Total all Partners
Research & innovation activities - total	4	3.5	1.5	2	76	77	3	1.5	1.5	153	12	198
WP1	0.5	0.5	0.5	0.5	17	13	3	0	0	34.5	3	46
WP2	0.5	1	0	1	12	17	0	0	0	29	2.5	40.5
WP3	0.5	0.5	0	0	10	21	0	0	0	31	0	33
WP4	2	1	0	0	18	14	0	0	0	32	3	41
WP5	0.5	0.5	1	0.5	19	12	0	0	0	31	3.5	37.5
Demonstration activities-total	1.5	1	1	1	1	1	1	1	1	3	3.5	8.5
WP6	1.5	1	1	1	1	1	1	1	1	3	3.5	8.5
Other activities – total	3	1.5	1.5	1.5	1	1	3	2	2	7	7	24
WP7	3	1.5	1.5	1.5	1	1	3	2	2	7	7	24
Management activities – total	3	1	1	1	1	1	1	1	1	4	7	13.5
WP8	3	1	1	1	1	1	1	1	1	4	7	13.5
TOTAL ACTIVITIES	11.5	7	5	5.5	79	80	8	5.5	5.5	159	29.5	244

Table 1.4d Summary of Staff Effort

Milestone Number	Milestone name	Work package(s) involved	Expected date	Means of verification
1	System Design and Specification	WP2	Month 6	Achievement of successful reports shown through deliverables D2.1
2	Centralised Database and PKI System	WP2	Month 12	Achievement of successful reports shown through deliverables D2.4
3	Language and Communication Agent	WP3	Month 12	Achievement of successful reports shown through deliverables D3.6
4	Integrated Hardware Design	WP4	Month 18	Achievement of successful reports shown through deliverables D4.1, D4.2
5	Completion of Integration and Testing	WP5	Month 21	Achievement of successful reports shown through deliverables D5.3
6	System Validation	WP6	Month 23	Achievement of successful reports shown through deliverables D6.2
7	Proof of Project Completion	WP7, WP8	Month 24	Success of Project Final Review

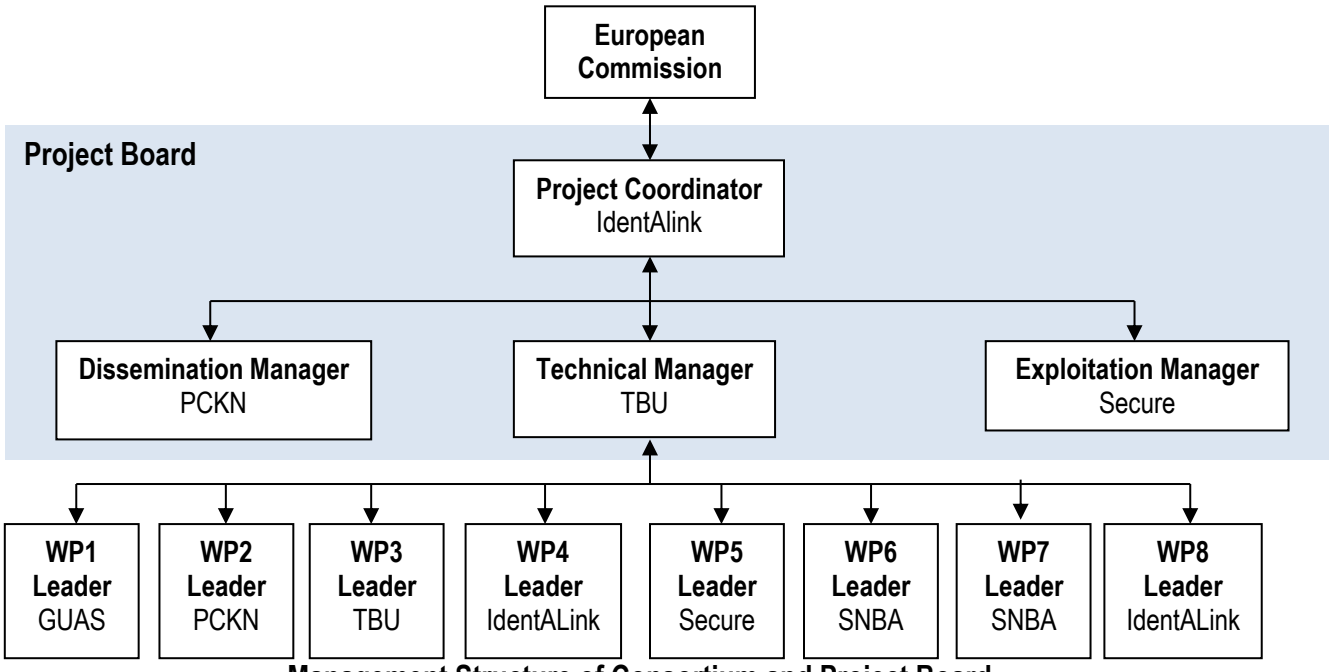
Table 1.4e List of milestones

2 Implementation

2.1 Quality of the consortium as a whole

2.1.1 Description of project management structure and procedures

The management of the EU-HealthID project will take up a structure defined by the Project Board. A Project Board will be put together to establish a clear and defined mode as required by every organisation structure. This structure will allow each partner in the consortium to work together efficiently with clearly defined positions of responsibility and allocation of those positions. These positions have been allocated to the partner most suited through their role in the development work, their skills, knowledge and their experience. The Project board structure and its inter-relationship with the EC and the consortium members are shown below:



Management Structure of Consortium and Project Board

The fundamental criteria for making decisions on the project relative to progress per partner per deliverable will be as stated in the detailed Work Plan in section 1.4, which described the assignment of WP leaders along with clear WP milestone deliverables. The groupings of deliverables have been timed strategically to coincide with milestone points in the project along with specific meetings of the Project Board to enable major Yes/No decisions to be made. Arrangements for representation, delegation and voting rights are defined below along with clear informal and formal reporting structures into the Project Board.

Specific Management Roles

Project Board: The project board has overall responsibility for the successful delivery of EU-HealthID. The project board will be chaired by the Project Coordinator who will have responsibility for the day-to-day responsibility of the project. However, the Project Coordinator will have assistance from other managers and be able to delegate coordination work to the board's other authorised representatives. The Project Board's main duties during the project are:

- Authorisation of the release of deliverables
- Ratifying of risk contingencies for each project stage
- Approval of work package commencement

- Monitoring of milestones (stop/go decision points) and approval for commencement of next project stage
- Resolution of any administrative or contractual issues within the partnership and EC
- Ultimate escalation point for project issues

The project board has the power to appoint new managers to each of the managerial positions described below, should this become necessary. It also has the power, through consultation with the European Commission, to approve partner changes if required. The Project Board comprises a representative from each of the partner organisations. The decision-making procedures for the project board are described later in this section.

Project Coordinator: The Project Coordinator and Project Administrator are the authorised representatives of the Project Board. They are responsible for the day-to-day running of the project and for ensuring that it is completed on time, on budget and to the required quality standards. They are also responsible for ensuring that any result is capable of meeting both the specified technical and business aims of the project. The Project Coordinator is the main point of contact for communication with the European Commission and is responsible for keeping the project board fully informed, but will be assisted by the Project Administrator in executing some of their duties. ***The Project Coordinator appointed by the consortium for EU-HealthID is Elmar Hilgers, of IdentAlink***. (His expertise is illustrated in section 2.1.2).

The project coordinators responsibilities include the following:

- Collation of all deliverables and milestone reports;
- The overall legal, contractual, ethical, financial and administrative management of the consortium;
- Preparing, updating and managing the consortium agreement between the participants;
- Resolution of any administrative or contractual issues within the partnership and with the Commission;
- Organisation of Project Board, project technical management and exploitation board meetings;
- Overseeing the promotion of gender equality in the project;
- Collation of all the cost statements;
- Ensuring prompt payments of financial contributions;
- Preparing for and facilitating audits by EC staff;
- Coordinating payments and the distribution of money;
- Co-ordination at consortium level of participant contractual obligations and collective responsibilities;
- Communications between the consortium and the consortium and the EC.

Due to the scale of EU-HealthID, it would be unreasonable to expect a single person to take on all project management responsibilities. Therefore, some tasks will be delegated to 3 other management roles (Technical, Dissemination & Exploitation) as shown below.

Technical Manager: The Technical Manager is responsible for ensuring that technical issues raised by the work package leaders do not adversely impact the project as a whole. They must therefore have a clear grasp of the way all the work packages interact and the technical consequences of any issues. In order to achieve this global vision, the technical manager and their organisation will not be solely responsible for delivering an individual work package. The technical manager will be responsible for performing technical risk management for the project. As such, they will draw up the risk assessments for each work package and ensure that, when the task leaders escalate issues, the correct triggers are activated and suitable contingencies employed. Where relevant, the technical manager may choose to escalate issues to the Project Board via the Project Coordinator. ***For EU-HealthID, the Technical Manager will be Elmar Hilgers from PCKN.*** He has extensive expertise in running and coordinating developmental projects in addition to his considerable technical expertise (His expertise is illustrated in section 2.1.2).

Dissemination Manager: The Dissemination Manager will be responsible for ensuring that dissemination activities are carried out appropriately and in a timely fashion to ensure maximum dissemination of the project without exposing commercially valuable knowledge by liaising with the Exploitation Manager. The Dissemination Manager would be tasked with initiating all the activities involved in informing the relevant technical and commercial

communities about the progress the project is making during the lifetime of the project, and in the case on project end, the results. ***For EU-HealthID, the Dissemination Manager role will be held by Babak Goudarzi Pour from SNBA.***

Exploitation Manager: The Exploitation Manager is tasked with developing detailed exploitation plans for the project and maintaining and updating these plans throughout the project in response to technical developments and consortium issues to ensure optimal exploitation at project close. He will be responsible for protecting any foreground IPR created during the project and have had a suitable subcontract budget assigned as shown in section 2.2. They will also be responsible for locating sources of future funding to ensure a smooth transition from project development to production and commercial exploitation. He will ensure potential customers; suppliers and licensees are identified and targeted. ***For EU-HealthID, the Exploitation Manager role will be held by Stefan Muller, of Secure***.

Work Package Leaders: Work package Leaders will ensure that the technical work defined in the work programme is completed in a timely fashion, within budget and achieves the work package objectives and the resultant deliverables. They will be responsible for handling small issues but, where an issue will have an impact outside of their work package will escalate issues to the appropriate manager (usually the Technical Manager) and implement any contingencies as advised. The Work package Leaders have been nominated as follows:

WP1 – Preliminary Research and Knowledge Mapping (GUAS)
WP2 – Development of Software Platform (PCKN)
WP3 – Language and Communication Agent (TBU)
WP4 – Hardware Integration (IdentAlink)
WP5 – System Integration and Testing (Secure)
WP6 – Validation of the System (SNBA)
WP7 – Exploitation, Dissemination and Training (SNBA)
WP8 – Project Management (IdentAlink)

Communication Strategy

EU-HealthID will use communication models for both scheduled and unscheduled communication. Scheduled communication will cover reports, deliverables and other planned documents. Unscheduled communication will cover the raising of issues and the implementation of any consequent actions.

Scheduled Reporting: In order to keep the amount of time spent on project administration to a minimum, a simple reporting structure will be used. This will certify maximum effort on task delivery whilst ensuring transparency of task progress.

Every Month the task leaders will prepare a **Monthly Progress Report** for the work package leaders. The task leader is a nominal position responsible for monitoring and reporting progress. The progress report will detail the currently active tasks and the progress made, as well as a record of any issues and envisaged problems or delays. These reports will be no longer than 1 page and will use a pre-defined template format.

Every 3 Months the Work package Leader will use the progress reports to assemble a **Technical Progress Report.** This will detail the planned vs. actual work, raised issues and resultant actions, implemented risk strategies and their impact and plans for the next reporting period. This will have no maximum length but will also use a pre-defined format. This document will be passed to the Project Board in order to facilitate progress monitoring.

Every 6 Months the project board will issue a short **Management Report** to the European Commission and partners detailing the project progress for the last reporting period, in line with the consortium's contractual obligations.

At Each Milestone the Project Coordinator will present a **Milestone Report** to the Project Board. This will be a short document summarising the planned vs. actual achievements of the previous project stage. It will also summarise any major issues and the risk strategies implemented and describe the risk management strategy for the next stage. This document will be assembled from the Technical Progress Reports and will be used by the Project Board to approve the next project stage.

Unscheduled Reporting: Each management position will maintain an issue log. As issues arise, these will be recorded in the logs and dealt with by assigning an action (recorded in each partner's action list). If appropriate, work package leaders will escalate issues to an appropriate manager. This will usually be the Technical Manager. The Project Coordinator will also be made aware of any escalated issues. Should an issue be considered serious enough, it will then be escalated to the Project Board for a consortium decision on resolution. Resultant actions will filter down to the appropriate project partners in the same fashion. Software tools will be employed to integrate the issue logs and action lists to ensure all information is bought to the attention of the relevant managerial positions.

Meetings and General Communication: During EU-HealthID, we will use a number of scheduled meetings to monitor progress and agree plans for the next stage. The project board will meet as follows:

Meeting Title	Purpose	Month
Kick-Off Meeting	Formally open project, approve first 6-month work plan (WP1)	0 (kick-off)
6-Month Meeting	Manage Milestone 1 (approve/contingency), approve work for next stage (WP2, WP3, WP4), approve issuing of 6-month Management Report	6
Mid-Term Meeting	Manage Milestone 2, 3 (approve/contingency) Review progress on WP2, WP3, WP4 report to European Commission at Mid-Term Review, approve 12-month Management Report, approve work for next stage (WP3, WP4, WP5)	12
18-Month Meeting	Manage Milestone 4 (approve/contingency), approve issuing of 18-month Management Report, approve work for next stage (WP5 and WP6)	18
Final Project Meeting	Manage Milestone 5, 6 (approve/contingency), report to European Commission through Final Review, formally close project, approve issuing of final project report, approve final PUDF, agree post-project implementation plans	24

Scheduled Project Board Meetings

In addition to the Project Board meetings shown above, there will be a number of technical meetings and working group meetings arranged on an ad-hoc basis. These will normally be 3-monthly to enable review of the Technical Progress Reports. These meetings will be chaired by the Technical Manager and will be attended by all partners actively involved in current technical development. At all meetings, minutes will be taken and circulated to all project partners. Meeting locations will vary depending on the need to access technical equipment and to minimise travel costs. Other ad-hoc progress meetings will make use of teleconferencing and video conferencing where possible. As described earlier, each management level will be responsible for maintaining an Issue Log. Each project partner will have their own action list detailing both planned and contingency actions. The Project Coordinator is responsible for maintaining the **Project File.** This will be an electronic filing system containing all partner contributions, communications, issue and risk logs and action lists.

Decision-Making Procedures

Ultimate decision-making responsibility lies with the Project Board. Each SME or SME-AG member of the Project Board is entitled to one vote and majority voting will prevail. The RTD Performers and Other partners will not be permitted to vote but will be present on the board in an advisory capacity. Where a majority decision cannot be reached, external arbitration may be used, either through consultation with the European Commission or a third party arbitrator. Because the Project Board cannot decide on every issue raised, decision-making is delegated down the management chain and issue escalation is used to ensure that decisions are made at the correct level. Decision-making can be summarised as follows:

Management Level	Decision Scope	Escalate to:
Work package Leader	Task-level or work package-level technology/planning decisions where impact is contained within work package and planned contingencies exist	Technical Manager/ Project Coordinator
Technical Manager	Project-level technical issues where planned contingencies exist, task/WP-level technology issues where impact is contained within work package	Project Coordinator
Dissemination/Exploitation Manager	Dissemination/exploitation issues where planned contingencies exist	Project Coordinator
Project Coordinator	Project-level financial/planning issues where planned contingencies exist, any other issues where impact is within project tolerances	Project Board

Project Management Decision-Making

Risk & Contingency Management

EU-HealthID is an ambitious project with a large budget and a multinational partnership. It consequently carries a high level of risk that will need managing effectively. As shown in section 1.4, a provisional risk assessment has been carried out. Before each stage of the project commences the appropriate manager will complete a full risk assessment. This will follow the process of identification, evaluation (ranking in terms of likelihood and impact) and response planning. Prevention or reduction plans can be put in place or the risk can be accepted and tolerated. Alternatively, a contingency plan could be put into place and a contingency trigger assigned. The impact of this risk will then be assessed and contingency resources planned. Once the risk assessment is complete, it will be included in the Milestones Report and approved by the Project Board. Whenever a major change to the project occurs, risk assessment will be revisited to ensure no new risks are evident and that existing risks have not changed. The management of risk will be facilitated through the Risk Log. This will detail the identified risks, their likelihood and impact, contingency plans, the risk owner and the contingency trigger. Once a risk contingency has been activated it will record the details of this and the outcome for the project. The Project Coordinator maintains the risk log.

Management of Knowledge

EU-HealthID intends to develop an innovative cross-border electronic health record system, in order to benefit the SME-AG and SME members of the project and inadvertently Europe as a whole. As such, all Intellectual Property Rights will lie with the SME-AG and SME partners. The RTD Performers ***will not share in the foreground IPR, nor will any agreement entered into be allowed to restrict future exploitation of the IPR***.

The consortium will implement the long-term exploitation strategy, as laid out in the project ***Exploitation Plan***. This strategy will cover how the partners will expand exploitation to meet demand in Europe and capture markets in the rest of the world, how licensing will be structured and how the consortium will benefit from revenue coming in by licensing. The Exploitation Plan will also detail sources of post-project funding and how such funding can be effectively used to enable commercial prototype development and post-project dissemination and marketing. The ownership of the Exploitation Plan lies with the ***Exploitation manager***, ***Stefan Muller of Secure***, as described earlier in this section. He will be responsible for liaising with the Project Board throughout the execution of EU-HealthID to ensure that the correct IPR protection is applied for and a credible plan for early implementation is developed. An initial budget for protecting foreground IPR has been included in the cost breakdown for EU-HealthID.

2.1.2 Description of the consortium

Individual Partners

No.	Name	Ref	Type	Country	

1	IdentAlink Limited	IdentAlink	SME	United Kingdom	

Organisation Description: IdentAlink was founded in 2000 to develop and provide a practical and efficient identity management solution for public and private sector entities based on biometrics and PKI. IdentAlink's special expertise in software development, biometrics, PKI, encryption and network architecture has been used to produce BioPassport Enterprise Server for this purpose. IdentAlink provides greatly increased security for both physical access control and all aspects of IT. IdentAlink has designed and built a comprehensive identity management solution including biometrics, public key infrastructure, digital signature, high level encryption, and many other features. This solution is designed to give an enterprise a reliable, easy to install and operate system for physical access control and IT security together with significant cost savings. IdentAlink's server software, BioPassport Enterprise Server, is multi-modal, platform independent and can be installed on existing IT systems (Windows, Linux, Novell, Unix) without the need for additional hardware other than biometric sensors. It becomes an embedded part of an enterprise's IT infrastructure. It is hardware independent and can work with any finger sensor, web cam, iris or other sensing device. The client modules have been ported onto DSPs for use in physical access applications.

Role in the Project: Due to the experience of IdentAlink in Biometric Security technologies, and as they were the initiators of the proposal concept, they will lead the project as coordinators with support from the other partners in key roles within the consortium. Also, due to their experience with biometric security technology, they have been given the role of work package leader for work package 4 (Hardware Integration) along with being work package leaders for work package 8 (Project Management).

Key Personnel: ***Peter Caroe*** is a major shareholder and director of IdentAlink Limited. He is a Fellow in the Royal Institute of Chartered Surveyors with education background from Mons Officer Cadet School and Royal Agricultural College (Cirencester). His experience is as follows: Short Service Commission 11th Hussars (PAO) 1965 – 68; Royal Agricultural College Diploma in Estate Management 1969 – 71; Joined Knight Frank 1971; Appointed Principal, Knight Frank 1981; Chairman, Knight Frank Africa 1983; Retired after 36 years with Knight Frank 2007; Joined IdentAlink Ltd 2007. ***Elmar Hilgers*** is the co-founder of IdentAlink Ltd. His education background includes: MBA – computer science , University of Bedford 1987 – 89; SAP Education Center, Walldorf Germany in periods 1994 – 98; cert. Data Protection Commisioner 2006; cert. Medical product consultant IT 2007. His experience is as follows: American Forces – General Manager PX, Hahn Airbase, Germany 1974 – 78; Sperry Univac - Security Manager software encryption, Wichita, Kansas USA 1978 – 82; KHS Cable TV GmbH – Managing Director, Ludwigshafen, Germany 1982 – 85; Eismann Int. GmbH – European Logistic Coordinator (Multinational Frozen Food HomeService) 1986 – 96; Consultant Licensing Dept. Microsoft, Reno, Nevada 1994 – 1996; Member of Policy Making Group, GCHQ Cheltenham, United Kingdom 'Common Criteria EU for digital signature' 1999 – 2001. His professional memberships include: "CAST" Forum Fraunhofer Gesellschaft, Darmstadt; Silicon Trust, Siemens AG; SeSAM BB network, Berlin/Brandenburg; GDD – Organisation for Data protection and Data Security e.V.; MITL – IT and media and region Trier; EBU (European biometric forum); Global member of ISOC ***Malcolm Douglas McMillan*** is the chairman of Secure MedData SA. His education background includes: BS Maths St Lawerence University, New York; Massachusetts Institute of Technology, BS 1962; MBA Wharton School of Finance, University of Penn. 1964. His professional experience is as follows: White Weld & Co, New York 1966 – 72; Credit Suisse White Weld Limited, London 1972; MD, Sumitomo White Weld Ltd, London 1973 – 75; MD, Sumitomo Finance International 1976 – 79; Executive Director, Chase Manhattan Ltd, London 1980 – 82; McMillan & Associates 1982 – 99.

No.	Name	Ref	Type	Country
2	Swedish National Biometric Association	SNBA	SME-AG	Sweden

Organisation Description: Sweden established Scandanavia's first biometric association, the Swedish National Biometric Association (SNBA) in July 2004. The initiative to form Swedish National Biometric Association (non-profit organisation) on July 1, 2004 was taken by the municipality of Karlskrona, Karlskrona Innovation Center, Optimum Biometric Labs AB and Blekinge Institute of Technology. Their mission is to develop into the Swedish focal point for biometrics. One of the main purposes of the SNBA was to allow a meeting place for knowledge exchange relating to Biometrics. The association's purpose is: to strengthen the national knowledge of biometrics and create a meeting place for the exchange of biometric knowledge, news, development and commercial applications. The association contributes to diminish the distance between the biometric industry and their end user. It also works towards the arrival and usage of international standards. SNBA creates a meeting place that is open for companies, organisations and private persons. The board was elected on the annual general meeting held 1st of July 2004. Swedish National Biometric Association is governed by its statutes, which was established on the constituent meeting.

Role in the Project: Firstly, SNBA would be taking up the role of Dissemination Manager. With the commercial experience from among their member organisms and the experience in the area of biometrics and its applications, they are well placed to take up this role. Secondly, SNBA would be given the role of work package leaders of work package 6 (Validation of the System) and work package 7 (Exploitation, Dissemination and Training). Since they have the relevant industry experience, they would see to it that we arrive with a feasible and validated solution.

Key Personnel: ***Babak Goudarzi Pour*** has served as the Chairman of the Swedish National Biometric Association, SNBA, since its inception in 2004. He also works as Swedish technical expert in the international standardization work ISO/IEC/JTC 1/SC 37 and its expert groups WG2 and WG5 with specialization on Biometric-technical interface and Biometric-testing and reporting. He has frequently chaired industry panels in Brussels coordinated by the European Commission/Joint Research Center (JRC) and European Biometric Forum (EBF). Babak's breakthrough started in 2003 when he was invited to guest lecture at the Biometrics Identification seminar held by Dr. James L Wayman at the UCLA. He presented his multiple-award-winning work “Facial Recognition Biometrics, applying new concepts in performance improvement and quality assessment” for representatives of FBI, DoD and DHS. Babak holds a M.Sc. and B.Sc. in Electrical Engineering with emphasis on Signal Processing and Telecommunications from Blekinge Institute of Technology. ***Robert Rydell*** has extensive experience in business development as well as process and product development, project management and change management. He has 18 years’ experience in consultancy work. During the past 3 years he has worked extensively with biometric and general business development in the Nordic region. Prior to that Rob focused on project portfolio management solutions, product development and project management. His combined knowledge of technical and commercial aspects from a management perspective allows him to give strategic advice on how to achieve business objectives while ensuring that IT and business work most effectively together.

No.	Name	Ref	Type	Country
3	SMATOS UG & Co.	SMATOS	SME	Germany

Organisation Description: Future-oriented software solutions for oncology clinical centres and test centres are the core business of SMATOS UG (limited) & Co. KG. This spin-off has set itself the goal of developing a comprehensive ICT system, with the various disciplines linked across sectors, which provides data aggregation and data management tools to facilitate evidence-based medicine in oncology centres. With a Study Management module allows SMATOS optimal performance of clinical studies and improved data quality.

Role in the Project: SMATOS will provide their expertise in medical data management and in the usage of ICT systems for providing data to support clinical trials and evidence-based medicine. This will support the development of use cases and stakeholder requirements in the first stage of the project (WP1), and for testing (WP6); they will also be involved in the development (WP2) and integration (WP5) of the software product.

Key Personnel: ***Dr. Ali-Reza Waladkhani*** is the founder and CEO of SMATOS. After graduating from the University of Hohenheim with a BSc in Nutrition Science, he obtained his PhD in Experimental Science from the Medizinische Klinik Tübingen and the University of Hohenheim, Germany, in 1996. He has extensive experience of medical data handling and the organisation and conducting of clinical trials: since 1999, he has acted as research co-ordinator at the Klinikum Mutterhaus der Borromäerinnen; since 2009, he has been coordinator for documentation and responsible for preparing of tumour patients' data for benchmarking; and since 2010 has been the head of the certified centre for oncology and haematology at the Klinikum. During his career, he has obtained qualifications in Corporate Management (a course including marketing, finance, investment and business English); in Network Administration and Object Oriented Program Development (a course including NT-, Novell-, Lotus-, UNIX-administration and programming in C++, Delphi, VB, VBA, Java); and Total Quality Management (obtained from Kaiserslautern University, Germany, in 2002).

No.	Name	Ref	Type	Country	
4	PC Klinik & Netzwerksicherheit GmbH	PCKN	SME	Germany	

Organisation Description: PCKN was established by Elmar Hilgers, a full-time professional with 24 years of IT experience. They advise on all aspects of the software development and architecture and provide maintenance and care and the operation of existing IT systems and develop customized solutions. They assist businesses, municipalities and small and medium-sized companies with applications that support their business processes and that integrate fully into their systems. Such applications provide savings that pay for themselves quickly. The focus is on securing Microsoft networks by biometric technologies such as specially developed BioSECID / BioPassport server software based on their own fingerprint recognition algorithm and licensed IRIS. The product portfolio is being expanded by its own modules for time attendance and access control. They employ only skilled developers in Java, .Net, C and C++.

Role in the Project: PCKN are going to play a very important role in the EU-HealthID project. Firstly, PCKN would take up the role as Technical Manager. They have the relevant experience when it comes to database solutions and their staff members have experience with dealing with biometric security solutions. They would take charge in determining the technical direction of the overall project giving instructions to the research partners on relevant tasks. They would also specifically be in charge (work package leader) of work package 2 (Development of Software Platform).

Key Personnel: ***Elmar Hilgers*** is the owner and founder of PC Klinik & Netzwerksicherheit. His education background includes: MBA – computer science , University of Bedford 1987 – 89; SAP Education Center, Walldorf Germany in periods 1994 – 98; cert. Data Protection Commisioner 2006; cert. Medical product consultant IT 2007. His experience is as follows: American Forces – General Manager PX, Hahn Airbase, Germany 1974 – 78; Sperry Univac - Security Manager software encryption, Wichita, Kansas USA 1978 – 82; KHS Cable TV GmbH – Managing Director, Ludwigshafen, Germany 1982 – 85; Eismann Int. GmbH – European Logistic Coordinator (Multinational Frozen Food HomeService) 1986 – 96; Consultant Licensing Dept. Microsoft, Reno, Nevada 1994 – 1996; Member of Policy Making Group, GCHQ Cheltenham, United Kingdom 'Common Criteria EU for digital signature' 1999 – 2001. His professional memberships include: "CAST" Forum Fraunhofer Gesellschaft, Darmstadt; Silicon Trust, Siemens AG; SeSAM BB network, Berlin/Brandenburg; GDD – Organisation for Data protection and Data Security e.V.; MITT – media and it region Trier; EBU (European biometric forum); Global member of ISOC. ***Volker Biermann*** is a senior software developer at PC Klinik & Netzwerksicherheit. His education background includes: "Universität-Gesamthochschule Paderborn", Germany diploma as chemical engineer 1984 – 1990; Sun Microsystems, Germany JAVA programming 2000; Sun Microsystems, Germany JAVA programming (database) 2000; "TÜV-Akademie", Germany further education for IT specialists 2002 – 2003; "Berufsfortbildungswerk (bfw)", Germany training for trader 2006 – 2007. His professional experience includes: "Staatl Gewerbearzt des Landes NRW", Germany as chemical engineer 1991; "BITservice Rhein/Ruhr GmbH", Germany as system advisor 1993; "Evas Service", Germany (owner) programmer and computer trainer 1993 – 1995; "C.O.S", Germany as database developer 1986 – 96; "Moog GmbH", Germany as database developer and computer support 1996 -1998; "Übungsfirma der DAA", Germany, as computer trainer 1997; "Groupe Perry", Luxembourg as database administrator and application developer 1998; "Anite Systems", Luxembourg as database analyst and JAVA programmer 1998 – 2000; "Ge Systems", Luxembourg as JAVA developer and specialist on statistical confidentiality 2001 – 2002; "Ge Systems", Luxembourg as JAVA developer and specialist on statistical confidentiality 2003.

No.	Name	Ref	Type	Country	SECURE MedDATA SA
5	Secure MedData SA	Secure	SME	Luxemburg	

Organisation Description: Secure MedData SA is a company based in Luxemburg devoted to highest standards, coupled with real cost savings in Medical Transcription, for Health Professionals and Healthcare Organisations. They have a highly experienced team built over the years of Healthcare, Business, Management and IT experience. They require in depth experience and training in Medical Transcription, IT and Education before individuals can become an employee of their team. Equally stringent requirements are in place for all Personnel fulfilling clients' needs. Their mission is simply to provide the highest level of service, support, accuracy, and cost savings to the healthcare industry. To accomplish their mission, they are leading the medical transcription industry in shifting to the new paradigm of transforming Medical Reports into Electronic Medical Records through their proprietary in-house systems.

Role in the Project: Firstly, Secure MedData SA would be taking up the role of Exploitation Manager. With their commercial experience in the field of providing medical data solutions, they are well placed to take up this role. Secondly, Secure MedData SA would be given the role of work package leaders of work package 5 (System Integration and Testing). Since they have the relevant industry experience, they would see to it that we arrive with a feasible and viable solution.

Key Personnel: ***Stefan Muller*** is a System Integration Engineer at Secure MedData. He has worked in this position since 2007. His previous experience is as follows: apprenticeship as motorcar mechanic at Autohaus Ziefer, Daimler-Chrysler authorized workshop at Simmern 1995 – 1998; motorcar mechanic at development company 1998 – 2000; employee responsible for monitoring the cash transport above a computer operated GPS-System at the Deutschen Bundesbank headquarter Mainz 2000 – 2003; worked in Geodis Logistics in Mainz Hechtsheim responsible for receipt of goods and product testing as well as transport charging- and discharging 2003 – 2004; SIXT car rental agency at airport Hahn 2004 – 2005; Europcar car rental agency at airport Hahn. 2005 – 2007. ***Udo Klink*** is a senior software developer at Secure MedData SA. His education background includes: Gymnasium, Wittlich Germany – university-entrance diploma 1984; Dionysos Wine agency – apprenticeship as a clerk 1986 – 1988; Further education EDV-administrator 1988;Studies (with Diploma): business administration with a major in business information technology 1991 – 1997; Web-application-developer 2001 – 2002. His professional experience is as follows: SuKi Limited Company – Service employee 1988 – 1991; GWI Research Limited Company – Software developer 1997 – 2000; AEins IT Limited Company – Software developer 2003 – 2005.

No.	Name	Ref	Type	Country	
6	Gelsenkirchen University of Applied Sciences	GUAS	RTD	Germany	Fachhochschule Gelsenkirchen

Organisation Description: The Institute for Internet-Security is an innovative, independent and scientific facility of the Gelsenkirchen University of Applied Sciences (Fachhochschule Gelsenkirchen). Besides research and development it is a creative service provider with a focus on Internet Security. One of its overall tasks is to push forward research and development in terms of Internet Security and to improve the statutory framework of Internet Security. Since the official opening in May 2005 the young and creative research team turned the Institute into one of the most considerable competencies for Internet Security with about 50 employees. The aim of the Institute for Internet-Security is to make the Internet a more trustworthy and secure place. Main research is conducted in the area of Internet Early Warning, Trusted Computing and Identity Management, Situation Awareness Systems, Internet exploration and e-mail Security. The Institute for Internet Security has participated in several research and development projects. Main tasks in these projects were as well located in the field of architecture design as well as software development and testing. The Institute also participated in projects regarding Identity Management, at last with a study for the German Federal Armed Forces (Deutsche Bundeswehr).

Role in the Project: The Institute for Internet Security within GUAS is a highly rated research institute with a lot of technical experience in European framework projects. So they would bring that experience to contribute to the smooth running of the EU-HeathID project in Germany and Europe. The main role for GUAS is to provide research support to the SMEs in the area of Biometric Security and Access Control. However due to their research background they would be given the role of WP1 leader (Preliminary Research and Knowledge Mapping).

Key Personnel: ***Prof. Dr. (TU NN) Norbert Pohlmann*** is Professor in the Computer Science Department for distribute systems and information security and director of the Institute for Internet Security at the University of Applied Sciences Gelsenkirchen. From 1988 till 1999 he was managing director of the IT security system house KryptoKom in Aachen. After merging with Utimaco Safeware AG, he was a member of the Utimaco Safeware management board till 2003. In addition to that he is chairman of the board of the TeleTrusT association and member of the Permanent Stakeholders' Group of the ENISA (European Network and Information Security Agency). Norbert Pohlmann is one of the initiators of the „Information Security Solutions Europe“ (ISSE) and the chairman of the ISSE program committee of the ISSE conference. Numerous publications (265 articles and 13 books), lectures and seminars on the subject of information security testify to his expertise and commitment to this subject. He also published articles regarding PKIs (Public-Key-Infrastructures) and biometric methods (e.g. “Integration of biometric appliances high security infrastructures” and “Biometrics and IT Security”). ***Dominique Petersen*** received his B.Sc. in computer science at the Gelsenkirchen University of Applied Sciences. In his thesis he developed an update and control system for the Internet Analysis System. This system has a distributed architecture and the cryptography used based on Public Key Infrastructures. Dominique Petersen is the project manager for the research area of Internet Early Warning Systems at the Institute for Internet Security. In this role he has successfully accomplished many projects dealing with early warning, software design and development, information security and authorization methods.

No.	Name	Ref	Type	Country	
7	Tomas Bata University	TBU	RTD	Czech Republic	Tomas Bata University

Organisation Description: Tomas Bata University in Zlín (TBU) is a dynamically growing higher education institution comprised of six faculties offering students the possibility of studying humanities, natural sciences, technology and art. It is one of the most prominent centers of research in the Czech Republic and, in many respects, also abroad. With about 13,000 students, TBU ranks among medium-sized Czech universities. TBU follows the forty-year tradition of the Faculty of Technology, which was founded in Zlín in 1969 and since then has educated hundreds of highly-qualified professionals. The University is named after the originator of the shoe industry in Zlín and a world-famous entrepreneur Tomáš Baťa (1876 – 1932). Renowned R&D expertise in Applied Informatics and advanced artificial intelligence, TBU is a top rated educational and research institution. The university is aiming to be a top research institute in Europe and currently doubled its R&D spent and its efforts in forming new alliances with the Czech and European Industries. Since the forming of the new Informatics department, research students are producing award cutting edge research and the department is widely recognized in ICT projects.

Role in the Project: TBU is also a highly rated research institute within their University with considerable technical experience in European framework projects. They too would bring that experience to contribute to the smooth running of the EU-HealthID project. The main role for TBU is to provide research support to the SMEs in the area of Semantic Integration and Translation. Due to their research background and expertise in this area, they would be given the role of WP3 leader (Language and Communication Agent) and be primarily responsible for developing this tool.

Key Personnel: ***Prof Ivan Zelinka*** joined Tomas Bata University Zlin since 1997. He currently works as the Vice Dean for Science and International Relations Faculty. Through his career, he has been awarded several awards and medals of excellence. He has published a number of journal papers in the fields of Artificial Intelligence and Theoretical informatics. He is currently working at the Tomas Bata University in Zlin (TBU), Faculty of Applied Informatics and has been for 11 years. In his education background, he has attended Technical university in Brno (1995 - MSc.), TBU in Zlin (2001 - Ph.D.) and again at Technical university in Brno (2004 - assoc. prof.). Before his academic career, he has worked as a TELECOM technician, computer specialist (HW+SW) and computer and LAN supervisor in a commercial bank. During his career at TBU he has been invited for lectures at 7 universities in different EU countries. Currently, he is the head of the Department of Applied Informatics and in total he has been supervisor of more than 20 MSc. and 17 BSc. diploma theses. He was awarded by Siemens for his Ph.D. thesis, as well as by journal Software news for his book about artificial intelligence. Ivan Zelinka is a member of British Computer Society, expert team of company Day Spring Global Multinational Inc., division Knowledge Management & Mining division, a few international programme committees of various conferences and three international journals (Associate Editor of MSE, Hindawi, Editorial Council of Security Revue, Editorial board - Journal of Computer Science, Riga, Latvia).

No.	Name	Ref	Type	Country	

8	Torrevieja Salud UTE	TS	LE	Spain	HOSPITAL DE TORREVIEJA DEPARTAMENTO DE SALUD TORREVIEJA

Organisation Description: Torrevieja Hospital, with four awards, is the most successful in the region, with awards for the areas of trauma, surgery, digestive, respiratory and hospital management. These are the TOP 20 prestigious awards, granted by IASIST based on comparative treatment data of 163 participating schools (126 public and 37 private). After review of the indicators analysed by the consultant, the Hospital of Torrevieja is positioned as the Best National Hospital under the category "large general hospitals," getting this award for the fourth time in its history and competing with 33 hospitals in the same category throughout Spain.

The hospital's software development group has developed a number of tools and applications to support the hospital's activities, one of which is Florence. Florence is a set of applications and their structural data that support the relationship between the patient and their doctor. This includes clinical history, radiology information system (RIS) and departmental applications within the hospital. It also features management tools – utilities which make use of the data generated by the clinical systems – with very different user types and clearances to healthcare ones, as well as decision support, billing and cost management systems.

Role in the Project: Torrevieja Salud will represent the end-user in this project, and their expertise and experience of both the use and the creation of hospital ICT systems will be employed in deriving the legislative and stakeholder requirements, understanding the requirements of the various relevant standards, and drawing up the system specification (WP1); they will also be involved in validation of the final product (WP6), and the dissemination of the project results to other potential end-users (WP7).

Consortium as a whole

In order to deliver the project objectives a suitable range of expertise has been comprised in the partners that make up the consortium in order to deliver a good and robust partnership to take the results of the project forward. The consortium has the skills to successfully develop the EU-HealthID concept during and beyond the duration of the project. The consortium has been established as a group of Researcher, SME partners and SME-AGs able to implement and validate all the aspects needed for the completion of the project, adequately and quickly bringing the EU-HealthID system to the market place, as well as a future end-user (Torrevieja Salud) who will ensure that that project meets user requirements and provide expertise for testing and validation of the end product. The partners provide a balanced match of technological skills and industrial objectives. Each having a specific role to play in the completion of the work and the exploitation of its results, and they form the basis for a partnership for product support and marketing after the project has been completed.

Our partners were selected to provide the required skills i.e. Semantic Integration, Semantic Translation, Intelligent Software Development/Integration, Biometric Technology Implementation and in the Healthcare Industry. They have come together to provide a balanced match of technological skills, and industrial objectives related to the prospective outputs of the Research and Development Project, with each having a specific role to play in the completion of the work and the exploitation of its results.
The researchers necessary for the success of this project are GUAS (Germany), and Tomas Bata University (Czech Republic). TBU has for many years been involved in the research and development of distributed and intelligent systems, shaping them to the demands of problems in engineering, bioinformatics, and healthcare, through a number of European funded collaborative projects. GUAS (especially Prof. Norbert Pohlmann) have many years' experience with the research and development of Biometric Technology and innovative sensor technology. GUAS have been involved with delivering state of art solutions for a number of industries including security, medical and more. They have significant experience in application specific research and will help us realise the final prototype. The combined experience of the partners will be very beneficial to the overall success of the EU-HealthID project.

The researchers still need direction from market present companies, hence the need for SME partners in the project. The SME partners would give technical assistance to the researcher with respect to the direction to which the overall project would take. That is why the SME partners have been given significant roles in the set-up of the Project Board. IdentAlink, who are the initiators of this project concept operate as leading solution providers to the Biometric Security application market, providing state of the art solutions in biometrics, public key infrastructure, digital signature and high level encryption. As such, they are the project coordinators and would be driving the success of the project in order to introduce a new biometric enabled cross-border EHR system to the market. As part of the partnership, PCKN and Secure would provide dedicated hardware support and software support in Germany and Luxemberg that would be able to implement the algorithms developed in the project as modules for our EU-HealthID solution. Due to the complexity of the project, we opted in using 2 different support houses dedicated to different modules of the final system. They all have experience in complex development projects and would be able to make significant contributions to the project. SNBA and Torrevieja Salud are here to lead the direction of the project and to provide consultation work on the industry needs and also help validate the end product and disseminate the project results.

We are confident that with this group of partners in our consortium we have all the skill required to achieve the objectives set out in section 1 of this proposal. Hence, we will be able to deliver a project that has significant benefit to the healthcare services in Europe and potentially worldwide.

2.2 Appropriate allocation and justification of the resources to be committed

Travel and Subsistence

All partners have budgeted travel at €1000 per person per trip. Within management, each partner has made provision for a few consortium meetings. The Project Coordinator, SME-AG and SME partners have budgeted for additional management trips. Travel budgets for RTD activities are in line with project effort.

Consumables and Computing

The following budget has been allocated to the SME and RTD partners for consumables and computing:

TBU (RTD) **Total budget: € 100,000**

1 VmWare Server
1 license Sybase Enterprise Application Server
1 license Oracle weblogic Application Server
1 license Oracle DB
1 license Paradox DB
1 license DB2
1 license Dbase Plus
1 license various exotic DBs
1 license SUN application Server
1 license Netweaver (SAP)
2 licenses SQL Server 2008
9 licenses Visual Studio 2008

GUAS (RTD) **Total budget: € 100,000**

5 Modular Server with 4 modules
(PKI root server, authentification server, development server, terminal server)
1VmWare server
1 license IBM websphere
2 licenses SQL Server 2008
9 licenses Visual Studio 2008
18 SmartCard Reader
22 Fingerprint sensors

IdentAlink (SME) **Total budget: € 15,000**

1 VmWare server
1 Hardware firewall
4 workstations Win7
4 MS Office 2010 licenses
1 license SQL Server 2008

PCKN (SME) **Total budget: € 60,000**

1 VmWare server
InstallShield Professional
MSDN Pro membership
1 Hardware firewall
8 workstations Win7
8 MS Office 2010 licenses
1 license SQL Server 2008

SecureData (SME) **Total budget: € 15,000**

1 VmWare server
1 Hardware firewall
3 workstations Win7
3 MS Office 2010 licenses
1 license SQL Server 2008

SATOS (SME) **Total budget: € 15,000**

1 VmWare server
1 Hardware firewall
3 workstations Win7
3 MS Office 2010 licenses
1 license SQL Server 2008

Other Costs

€30000 has been allocated to the coordinator for the purposes of outline IP protection. Each partner receiving more than €375000 in grant has to pay for audit certificates, which comes out of their management budget. We have also provisioned some extra cost for subcontracting for the duration of the project.

Integration of Resources

It is vital that the EU-HealthID project provides the right people using the right equipment for the right length of time at the right price. As can be seen from the partner descriptions in section 2.2, we have brought together significant Commercial, University and R&D resources. We have access to all the materials and equipment required to make this project a success. The project duration is ambitious but we believe a focused, targeted project such as this will have more chance of success and, longer term, commercial potential and have scaled our resources accordingly. Also, we have within the consortium leading SMEs that have the capability to take a significant role in the exploitation and ensure the results get to market within the shortest possible time. Lastly we believe the budget represents value for money, with a compact, complimentary consortium providing focused input for a specific set of measurable objectives. This ensures that there will be minimal waste from overlapping or superfluous effort.

We have produced the cost calculations in a bottom up manner, carefully considering and planning the effort from the respective partners. Detailed discussions were undertaken to consider the major elements, work packages and tasks. This led to the creation of a PERT diagram to show the project flow and the creation of a Gantt chart detailing the project timings and the inter-dependencies of the elements and work packages. This enabled us to work out the manpower and resources we felt were needed to complete those including materials, consumables, subcontracting cost, travel expenses, and potential patent applications. By applying the relevant partner's respective rates and estimates on materials and subcontracts done by the partners in the past, a figure for the project was arrived at. The estimated proposal budget for the EU-HealthID project is shown in the table on the following page.

Participant No.	Participant Short Name	Country	Cost Model	Number of Person Months	Personnel Costs	Travel & Subs	Consumables	Other Costs	Protection of Knowledge	TOTAL DIRECT COSTS -	Indirect Costs - Overhead	RTD Subcontract	Subcontract	Total Estimated Eligible Costs	Number of Person Months	Personnel Costs	Travel & Subs	Other	Indirect Costs - Overhead	RTD Subcontract	Subcontract	TOTAL Estimated Eligible Cost
1	IdentAlink	UK	Special Transition Flat	[redacted]																		
[redacted]																						

PARTNERS [redacted]																	TOTALS	
[redacted] No.	Participant Short Name	Country	Cost Model	Number of Person Months	Personnel Costs	Travel & Subs	Other	Indirect Costs - Overhead	Subcontract - Including AUDIT CERT	TOTAL Estimated Eligible Cost Incl. Subcon	Number of Person Months	Personnel Costs	Travel & Subs	Other	Indirect Costs - Overhead	Subcontract	TOTAL Estimated Eligible Cost Incl. Subcon Audit [redacted]	[redacted]	[redacted] Estimated Eligible Cost for Whole Project
[redacted]																		
[redacted]																		147360
[redacted]																		70876
[redacted]																		

Budget Table

Table 2.2 Indicative breakdown of the offer from the RTD performers to the SME participants

Name of RTD Performer	Number of Person/Month	Personnel Cost	Durable Equipment	Consumables	Computing	Overhead Costs	Other Costs	Total by RTD	Project Results (No **)	Work Package No (***)
[redacted]		185,948.00		€ [redacted] 15,000.00	€ [redacted] 10,000.00	€ [redacted] 141,692.36	€ [redacted] 20,000.00	€ [redacted] 372,640.36		[redacted]
[redacted]		132,820.00		€ [redacted] 15,000.00	€ [redacted] 10,000.00	€ [redacted] 101,208.83	€ [redacted] 26,000.00	€ [redacted] 285,028.83		[redacted]
[redacted]		192,589.00		€ [redacted] 20,000.00	€ [redacted] 20,000.00	€ [redacted] 146,752.81	€ [redacted] 98,000.00	€ [redacted] 477,341.81		[redacted]
[redacted]		135,000.00		€ [redacted] 15,000.00	€ [redacted] 10,000.00	€ [redacted] 121,500.00	€ [redacted] 16,000.00	€ [redacted] 297,500.00		[redacted]
[redacted]		150,000.00		€ [redacted] 20,000.00	€ [redacted] 20,000.00	€ [redacted] 135,000.00	€ [redacted] 80,000.00	€ [redacted] 405,000.00		[redacted]
[redacted]		105,000.00		€ [redacted] 15,000.00	€ [redacted] 10,000.00	€ [redacted] 94,500.00	€ [redacted] 19,000.00	€ [redacted] 243,500.00	3	1, 4, 5
	155.00	€ 901,357.00	€ -	€ 100,000.00	€ 80,000.00	€ 740,654.00	€ 259,000.00	€ 2,081,011.00		

(*) This Total is equal to the figure estimated in Form A3.1
(**) Same numbering as in table 3.2.2

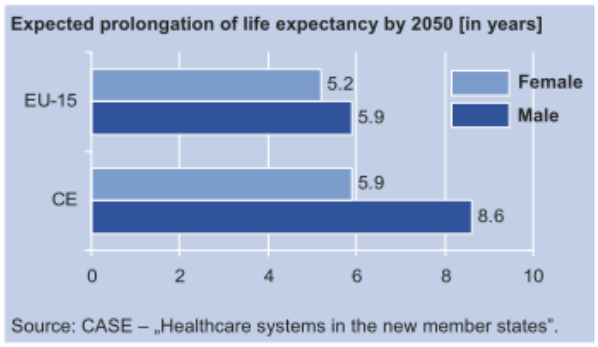
3 Impact. The potential impact through the development, dissemination and use of project results

3.1 Contribution, at the European (and/or international level) to the expected impacts listed in the work programme under the relevant activity

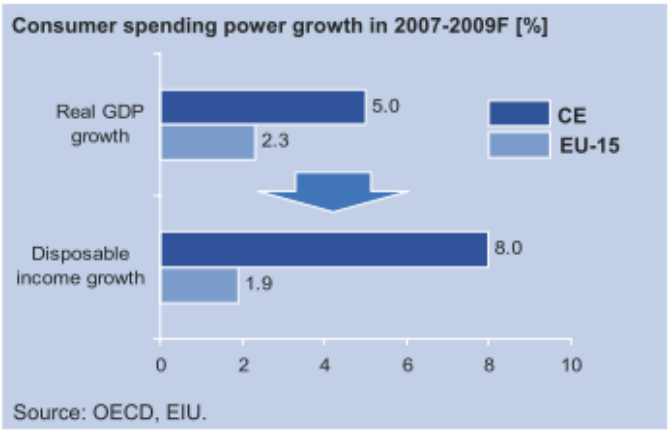
European Health Service Sector Overview

A strong interest and intense market activity in Europe's healthcare sector have been observed recently, as a result of the following drivers:

- Changes in demographics and economic growth – the increasingly aging population and growing consumer spending power. Healthcare expenditures in the European region will grow by 1.2-2.0% of the GDP as a result of changing demographics alone.
- A shift from public to private provision of healthcare services –poor quality of public healthcare contrasting with the excellent service level of private healthcare induce an increasing number of affluent consumers to switch to private service.
- Greater consumer awareness – medical advancement and better educated consumers drive the demand for an increased number and more specialized range of treatments and services.



The healthcare expenditures in the CE region will grow by 1.2 -2.0% of the GDP as a result of changing demographics alone.



Healthcare expenditures in Central Europe as a percentage of GDP are lower than those of EU-15 by one third, i.e. 6% vs. 9.4% respectively (2006), which indicates a high growth potential in the mid-term.

In USD terms, healthcare spending per capita in the Central Europe region accounts for just 32% of the EU-15 average. As the share of public funds in total healthcare expenditures is significant (ca. 75% in the EU, on average), the key to high future growth of the private healthcare sector in Central Europe is an efficient public private partnership system, with private healthcare providers being reimbursed for the services offered from the public national health insurance funds and the private sector having better access to the public sector information.

The analysis of consumer (patient) needs in the healthcare sector results in the identification of a number of key success factors for private outpatient healthcare providers:

- Competitive prices for corporate clients.
- Location – a network of ambulatories (geographical coverage) and good locations in large cities.
- Speed of service – with focus on queues management.
- High quality – reception service, organizational culture, level of equipment and infrastructure.
- Product offering – various packages, both for corporate and individual clients, own hospitals / cooperation with public hospitals in order to provide full service offering.
- Enrolment potential and expansion of client base in order to reach a sufficient scale of activity.

- In the long run, medical cost control systems will become increasingly important, as in the developed markets (such as the US), where the MCR (Medical Cost Ratio – direct medical costs divided by premium revenues) often amounts to over 80%. It can be reduced by efficient hospital/ambulatory utilization and control over physician costs.

However, the public healthcare system is unable to meet the consumer (patient) needs, which results in a supply shortage and a gap that is currently filled with private healthcare services. The development of that sector depends on a number of issues, including:

- Social opposition, which blocks or slows down the reforms.
- Public healthcare lacks sufficient financing. One of the solutions could be public hospitals starting to offer private commercial services.
- Patients and healthcare personnel are accustomed to higher standard for making informal payments - changing that perception is a long-term process.
- Tax incentives (e.g. tax relief for patients) would encourage the use of services provided by insurance companies.
- Availability of skilled physicians (which in Central Europe is lower than the EU average).

Consequently, there are a number of challenges that healthcare providers in the region are facing:

- The dependence on regulatory environment / state policy is very high, creating a major risk to business stability.
- There is a large market potential, if the informal payments, constituting substantial amounts on the regional scale, are transferred to private subscriptions and health insurance.
- Developing a large customer base for efficient product pricing and organizational culture of high service quality will take a few years. So far, it has been developed only by the top private healthcare providers in Central Europe.
- Revenues from other sources (beside own subscriptions) should not be underestimated. For instance, in 2006 in Poland, out-of-pocket fees for services, service for health insurance and contracts with the National Health Fund constituted up to 50% of total revenues.
- On the one hand, the inefficiency of public systems fuels growth of private healthcare, but, on the other hand, the development of public-private partnerships and public healthcare providers starting to offer commercial services may capture some of the current revenues of private healthcare providers.

Impact on the industrial competitiveness across the European Union

European Economy: A trans-national approach was necessary when building the consortium for this project, in order to be able to involve SMEs with the best complementarities in the value chain. We believe that the trans-national approach is not only necessary, also very positive in terms of the commercial exploitation of the EU-HealthID system. The mix of companies from different geographic regions across Europe, allows the consortium to create a business network of international contacts at a pan-European level, **facilitating** the international exploitation of the system. For each of the SMEs participating in this project, it would otherwise be difficult to have access to a European market. The commercial operations of most of them have been limited to their country boundaries; only few had activities in neighbour countries.

The opportunity to work as members of a consortium in the development of the EU-HealthID system, allows them to face a business expansion by being able to initiate commercial transactions at a pan- European level. As the market demand for the EU-HealthID system grows in the years following its market entry, the current capabilities of the participant SMEs might not be enough to cover the whole demand and new jobs will be therefore created. The SMEs will not only need to increase their labour force, also the demand of supplies will increase and new equipment will need to be acquired. This will have a subsequent impact on other companies in the value chain, not participant in this project, as are suppliers of the equipment and consumables.

The participant SMEs may prefer to limit the growth of their companies and implement different business strategies to cope with a growing demand. As the participant SMEs are the owners of the Intellectual Property generated in the project, they can use a licensing model to work with other European organisations in the implementation of the system, and contributing to a distribution of the benefits generated by this project among an increasing number of European companies.

European Knowledge Economy

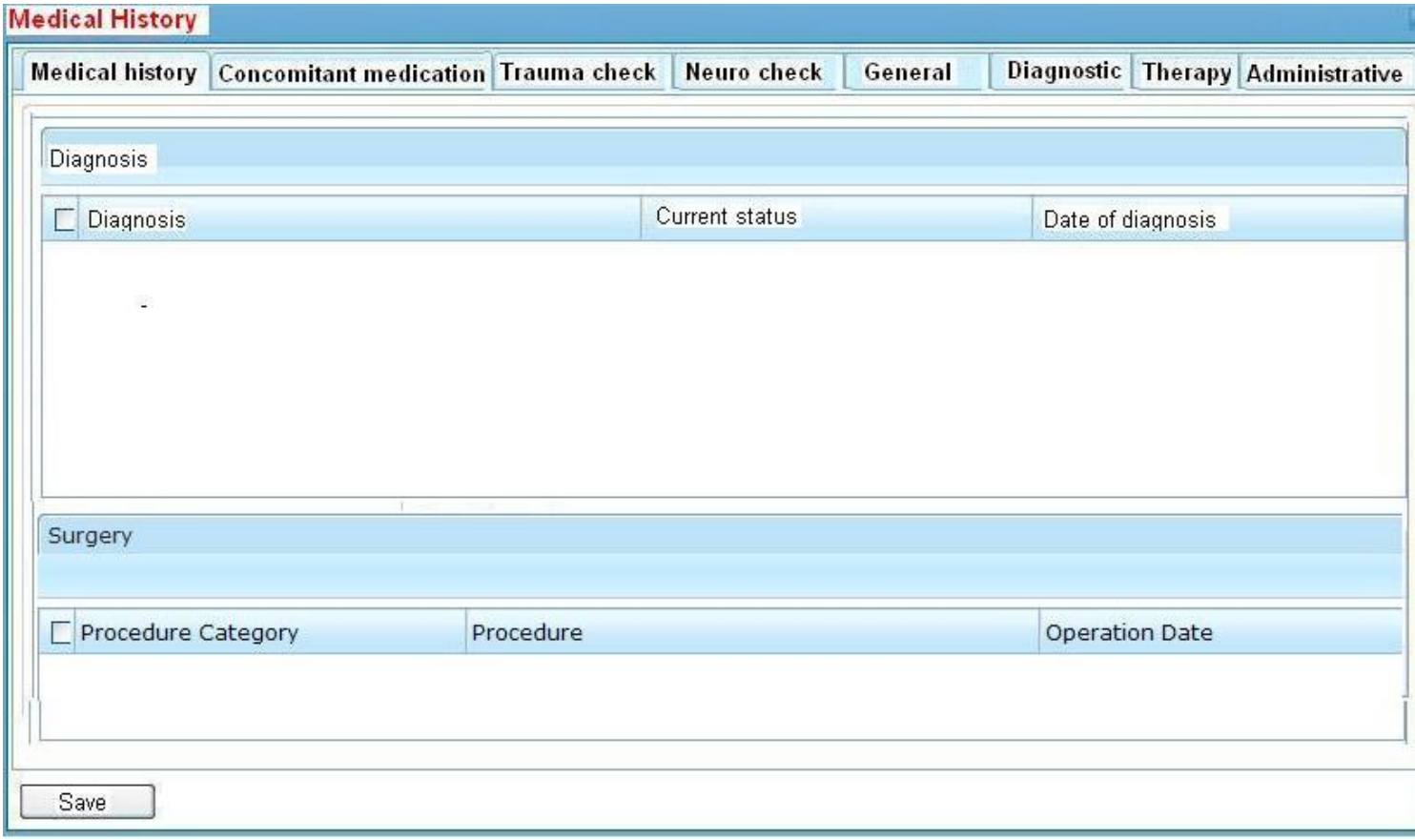
Our project consortium was concerned about the possibility that research projects similar to the one we propose, had been undertaken in the past or were currently under progress, since that would risk the novelty of our system and thus the effectiveness of the effort and resources that the SME proposers will devote to this project. We have dedicated great efforts to make sure the project we propose here has never been addressed before. We have used Cordis tool for searching projects funded under previous Framework Programmes and we have found that no project has been carried out aiming to develop a biometric enabled cross border electronic health record system.

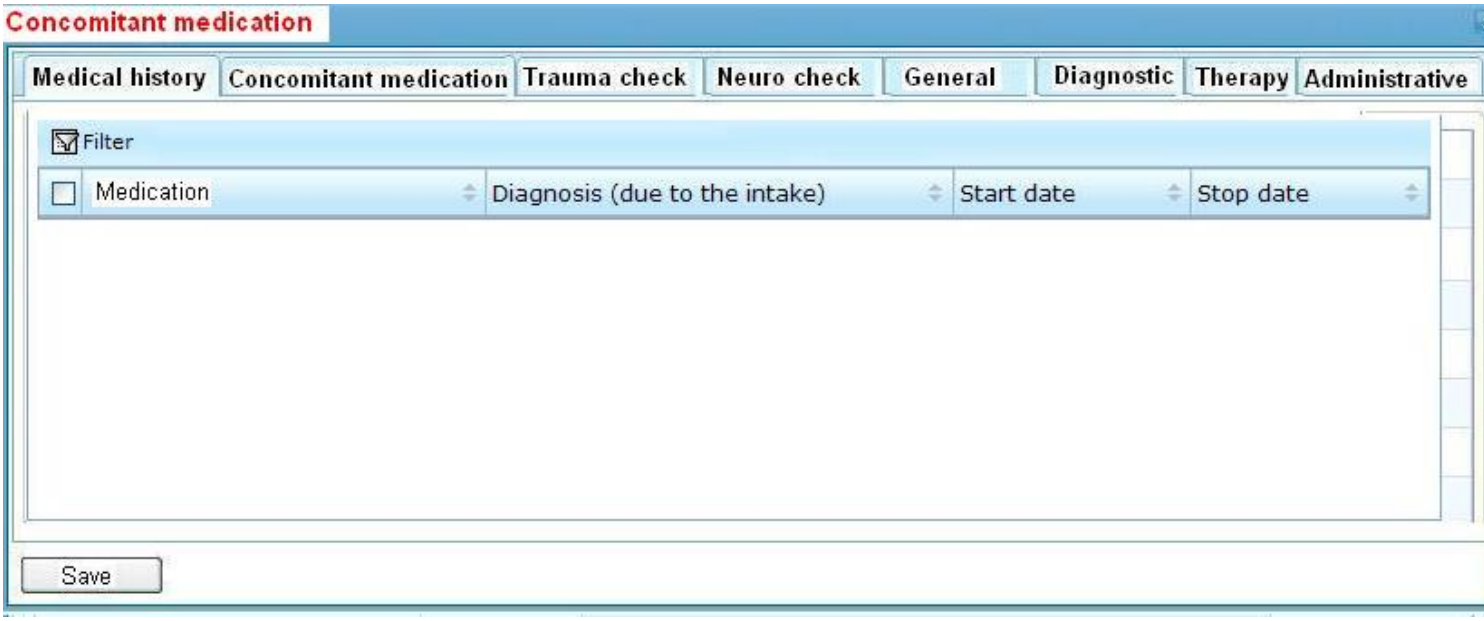
We have also searched for projects that aimed to develop biometric devices for detecting access control in various application areas. Although a number of projects have been funded that relate to the development of biometric enabled technologies, for a huge variety of applications, we have not found a project that aimed to develop a solution for our target area and definitely not in a cross-border fashion.

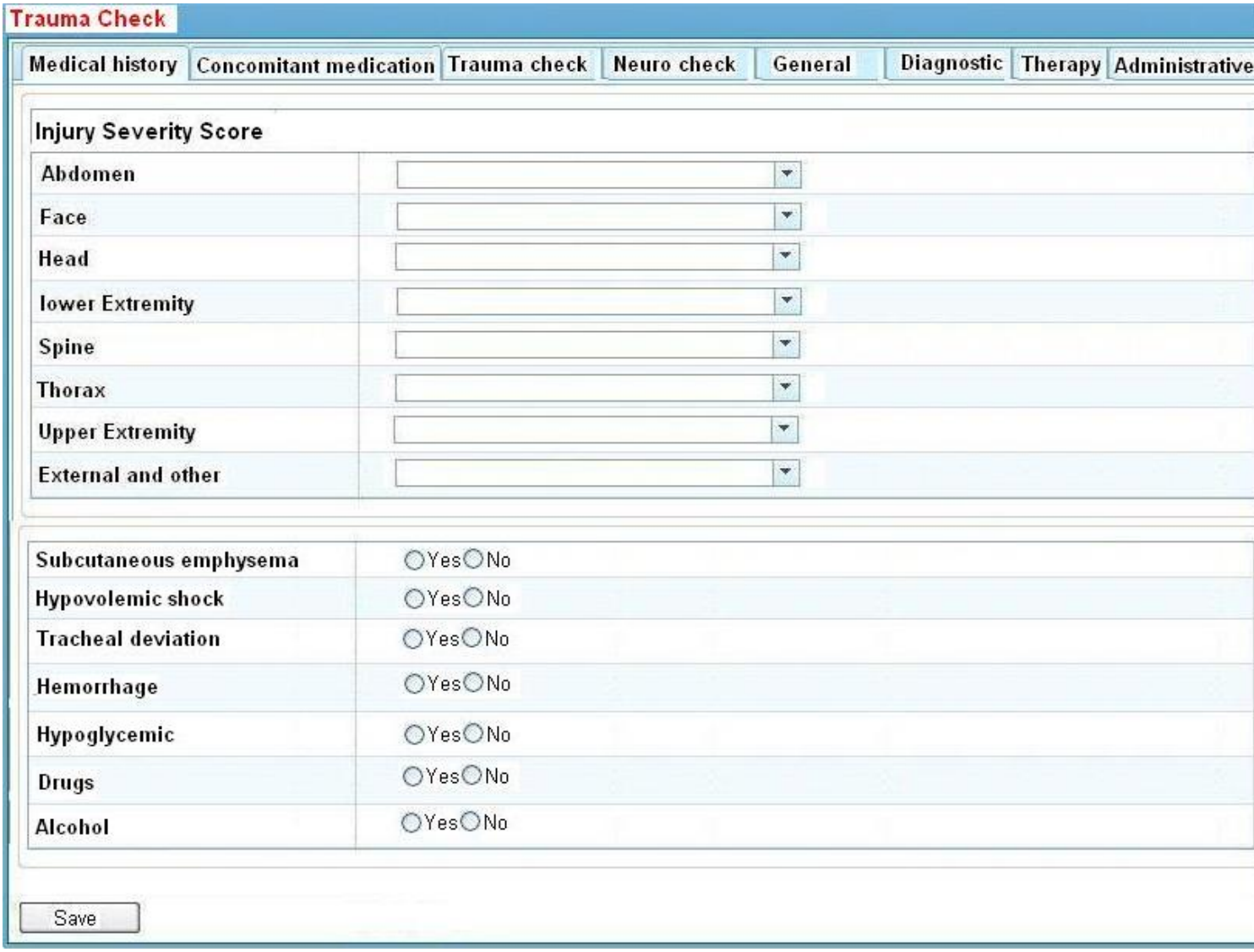
In order to establish if the research topic proposed in our project is in line with the European research priorities for the 7th Framework Programme, we have studied the 10 thematic areas in which the Cooperation programme is divided. **Our project is relevant to two thematic areas**: Health and Information and Communication Technologies. In particular, our project perfectly fits under the sub-programme *"Optimising the delivery of health care to European citizens"* in Heath and the sub-programme for the ICT calls that encourages the development of "innovative scientific technology, based on natural and artificial cognition, in conjunction with new systems design and engineering principles and implementations for devices which are robust and versatile enough to deal with the real world and to behave in a user-friendly and intuitive way with people in everyday situations". Therefore, we feel very confident that by funding this proposal the EC would not be duplicating efforts. This project contributes to the European knowledge economy and is in line with the European research priorities.

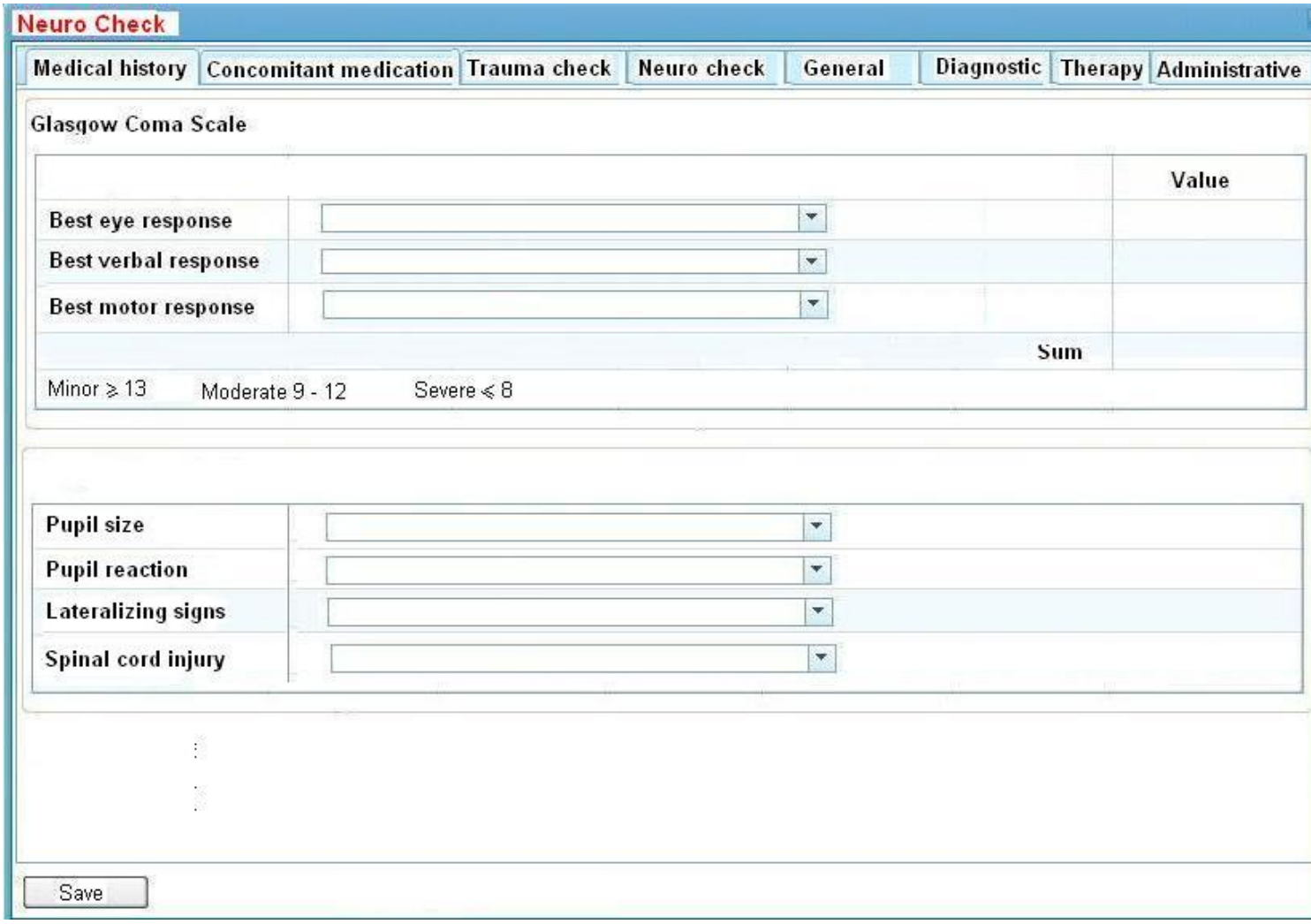
Program features which provide detailed patient and treatment data in a – til now – not known fashion. This forms part of the EU-HealthID project's groundbreaking and innovative technology. Some sample screenshots of the to be implemented GUI /database features:

Ie. After an accident the physician can use following forms to document therapy and diagnostic in case of an emergency. Further he can find medical history and concomitant medications which patient are actually using or has used in the past!!!


Medical History
Medical history
Concomitant medication
Trauma check
Neuro check
General
Diagnostic
Therapy
Administrative
Diagnosis
Diagnosis
Current status
Date of diagnosis
Surgery
Procedure Category
Procedure
Operation Date
Save


Concomitant medication
Medical history
Concomitant medication
Trauma check
Neuro check
General
Diagnostic
Therapy
Administrative
Filter
Medication
Diagnosis (due to the intake)
Start date
Stop date
Save


Trauma Check
Medical history
Concomitant medication
Trauma check
Neuro check
General
Diagnostic
Therapy
Administrative
Injury Severity Score
Abdomen
Face
Head
lower Extremity
Spine
Thorax
Upper Extremity
External and other
Subcutaneous emphysema
Hypovolemic shock
Tracheal deviation
Hemorrhage
Hypoglycemic
Drugs
Alcohol
Yes No
Save



Economic impact and market acceptance

The market acceptance achievable by the EU-HealthID system will depend on the benefit that the hospitals and patients perceive that the system is generating. The system has a major social impact related to the wellbeing of the patients that cannot be translated into economical terms; however the project also has a direct economic impact related to the time being saved by the nurses and healthcare professionals. As we have seen in the section 1, nowadays the cost to the European healthcare services relating to the time spent by healthcare professionals in terms of verifying a patient's record and also the cost of getting it wrong is very high.

The current process of verifying a patient's records has also an economic impact on hospitals related to labour cost. Nurses and care givers need to spend a significant part of their time on this duty. In average, a healthcare profession will need to perform this activity over 12 times daily. If we consider a labour cost for nurses equal to €15 per hour + 30% benefits, and that the total staff time to perform this activity is 5 minutes, the annual labour cost of searching a patients record once a day is ~ €7.000. That is considering only one healthcare professional is used for the activity, many times two are required to perform the same activity. This value is showing a great cost effectiveness and savings our system can provide. By reducing the time healthcare professionals need to spend in verifying patient records, they will be able to spend more time in the rest of their duties, being able to deliver more added-value healthcare service.

Therefore, the economic return of the project to the EU in year 5 after project finalisation (year 3 after market entrance) will be the addition of the direct impact related to the sales of the EU-HealthID system and services, and the indirect economic impact related to the savings to European hospitals and to the redirection of hospital funds (reduction of labour time spent in verifying patients' records).

Time to market

This project aims to develop and validate an alpha version of the EU-HealthID system at a pre-commercial stage. Once the project has finalised and have a validated system in preclinical trials is available, the EU-HealthID system needs to enter into a phase of clinical trials (in accordance with Article 17 of the Council Directive 93/42/EEC on medical applications, certification can only take place following medical trials). This period is estimated to take around 18 months, after which the products and services gets validation to enter the European market. As explained in the project work plan, the consortium has taken into account the need of getting *future funding* from commercial sources such as banks, venture capitalists, business angels in order to carry out post R&D commercialisation activities such as the full trials. During the course of the project the consortium will create a detailed business plan and develop an attractive and compelling investment case to present to both investment institutions and individuals (business angels).

The consortium has already identified a private equity funding Acquisition Company to help identify and secure future investors to help fund the exploitation of the results of the project. This specialist organisation will become a sub-contractor to the project and provide links into venture capital and business angel community through EBAN, the European Business Angel Network. We feel confident this link will help us secure the required funding to undertake the commercialisation of the EU-HealthID system. Furthermore, the Consortium will actively approach future exploitation funding programs and sources. Project partners will research on various programs offered by their regional and national development agencies.

During the trial period, the enterprises in the consortium will prepare for scaling up the implementation of the EU-HealthID system prototype. The SMEs will work in the development of robust implementation capabilities and the coordination of their service offerings in order to secure they can achieve industrial realisation of an EU-HealthID integrated system at the required quality and price.

Once the system gets validation, industry implementation of the commercial EU-HealthID system will start and marketing strategies will be put into action, so that the service providers can generate an initial demand for the EU-HealthID system that is expected to reach the European market approximately 24 months after project finalisation.

Societal Impact

In the following we will show that the EU-HealthID project is in line with the societal objectives of the EC:

<u>*Contribution to quality of life and health objectives*</u>: A main societal contribution of the EU-HealthID project is the improvement in the quality of life of patients in hospitals and of the European citizens in general. The EU-HealthID system will overcome the risks involved in getting a patient's medications wrong and also not being able to access in time a patients' medical history in a case of an emergency. In addition, nurses and healthcare professionals will save the time that they spent before in the periodical checking of patients, being able to spend that time in other duties that contribute to improve the provided healthcare services. The EU-HealthID project will have a major impact on the aging society of the EU27, improving their autonomy and quality of life. Dependant on our rate of penetration in the market, we can say that by 2016 this project will provide a real improvement on their quality of life to hundreds of thousands of people each year.

<u>*Contribution to working conditions objectives*</u>: As the population ages, the age of carers are going to be increasing (with the registration of new nurses and healthcare professional reducing), and so will the impact of this problem. According to a study carried out in US, within 10 years 40% of working registered nurses will be 50 years or older. As those retire, the supply of working nurses is projected to be 20% below requirements by the year 2020. For these reasons, hospitals are in a situation where need to reduce the nurses and healthcare professionals workload to

make sure their tasks are focused in services that can significantly contribute to the quality of the health care service they offer. Our EU-HealthID system will significantly reduce the time nurses need to spend in verifying patients medical records and therefore contribute to the quality of the health care services they deliver, and to their quality of life in their work sites.
As before, considering our rate of penetration in the market, we can say that by 2016 this project will have a significant social impact by providing a real improvement on their work conditions to more than 100,000 nurses and healthcare professionals annually.

Contribution to gender equality: Discussed in section 5 "Consideration of gender aspects".

Impact on Policies
The members of the consortium are aware of the importance of the industrial standards established by the EC, as a regulatory mechanism that eliminates trade barriers and increase consumer's confidence. EC directives regulate the industrial standards for a whole cohort of products and services with similar functions and characteristics. These directives need to be dynamic and kept updated to the new technological advancements. To this aim, EC technical committees evaluate the need for new standards accordingly to the proliferation of new technologies in a similar area. The Directive 98/48/EC, a revised version of Directive 98/34/EC, rules the process by which standards are allowed to evolve and dictates the mechanism for the development of new directives on which standards are based. The European Commission encourages the development of new standards as a mechanism to facilitate European entrepreneurs more easily gain market entry by launching standardized products.
The EU-HealthID project aims to contribute to industrial standards. The EU-HealthID system is subject to the regulations laid out in Council Directive 93/42/EEC, concerning medical applications. The routes to compliance depend on the classification of the product. To gain CE marking, the manufacturer has to produce a technical file, including product test results to relevant standards. Once the application has been accepted for an audit by a Notified Body in the EC, the application can then be put forward for simultaneous FDA approval. Therefore, wherever possible, the consortium will submit new knowledge to the Commission, which may contribute to the development of new standards. Nevertheless, the consortium has as a priority the protection of the Intellectual Property on the new technologies developed in the EU-HealthID project. Since the development of new standards requires disclosure of new technologies, we will be assisted by a law firm specialized in the protection of intellectual property rights, to make sure we do not risk the patentability of our results. In summary, the EU-HealthID technology is unique but would gain CE marking via compliance with the Council Directive 93/42/EEC. Our ambition is that the EU-HealthID project contributes as well to the development and implementation of viable, improved regulations protecting the health and safety of hospital employees.

Need for a Trans-National Approach
The proposed project demonstrates a trans-national European approach bringing together leading researchers from Germany and the Czech Republic, SME companies from Germany, Luxemburg and UK, a Biometrics Association from Sweden. Each partner cooperating in this project will use the same collaborative system and database information. Supporting and administrative actions will improve pan-European cooperation through the possibility of establishing steering groups, user forums etc. The users will also have the possibilities to enter into joint agreements if required. EU-HealthID is an ambitious project that requires complimentary expertise from a number of different organisations. As the EU-HealthID concept developed, it became clear that getting a good combination of organisations from countries across Europe that have similar interests in terms of the implementation of biometric technology and healthcare services would hence have an interest in the success of the project. Also, these would have the skills and expertise available to enable the realisation of the application. In order to realise the EU-HealthID electronic patient record system, a number of complementary skill sets were required. Tomas Bata has years' experience with the research and development of innovative software solutions. Existing collaborative relations enabled the consortium to secure support from Tomas Bata. They have very good expertise in software development and electronics, which is a key area in this project. Tomas Bata also has many years of experience in language and

semantic translation and would be very important to this project as this would be the basis of implementing and EU cross-border system. GUAS is one of Europe's most eminent research and development organisations. The particular institute we would be engaging in GUAS and especially Prof. Norbert Pohlmann have significant experience in Biometrics technology and would bring their years of experience to the development of this project. Europe-wide collaboration is also the key in order to ensure effective dissemination and exploitation. The rest of the partnership has the combined experience and geographical spread to provide the level of industry drive that a project such as this needs. The problems that EU-HealthID addresses are of international importance, meaning that any solution needs to be approached in a trans-national fashion to achieve the greatest benefit. By having a committed presence in some of our target countries (Germany, UK, Luxemburg, Czech Republic), we can achieve a much greater initial market dissemination of the results, increasing the chances of the technology becoming accepted by the relevant industries. This not only benefits the consortium but also has a greater impact on "global demand", one of EU-HealthID main aims.

Benefit of the Trans-national approach of the EU-HealthID project

The combination of expertise from enterprises and research centres from different European countries is necessary for this project. The project coordinator, IdentAlink, was unable to locate partners within a single company, the pan-European level of this project is essential to the success in the development of the new system for a cross-border electronic health record system. Only by bringing together the relevant expertise, independent of their nationality, will we have chances to develop a competitive product and service with success in bringing it to the market. This project will give a chance to the participant SMEs to enhance their network of international contacts, working with enterprises and research centres they never had a chance to meet before, and having access to a common network of contacts. Most of the SME participants have never before worked in collaboration with a research centre, and they probably would not even have considered this possibility without the support of schemes such as the European Framework Programme. This project will give the participant SMEs an insight into how the activities of an R&D centre can be supplementary to the activities of an SME, how much value the collaboration with expert researchers can add to an innovative SME and to take mutual benefit of their respective expertise. By participating in a trans-national project, SMEs will have a great opportunity to learn about other European markets where they had never operated before; they will be able to compare technology and business practises, generating a diffusion of best practises that will contribute to increase the pan-European competitiveness and cohesion. Our project brings together companies from different geographical regions, facilitating the dissemination of results at a pan-European level and the technologies take up.

3.2 Appropriateness of measures envisaged for the dissemination and/or exploitation of project results, and management of intellectual property

3.2.1 Project results and IPR

EU-HealthID is a highly innovative concept with a number of Intellectual Property components, namely:

- Biometric/PKI Access Control Tool
- Language and Communication Agent
- Web Interface Software Platform

The list above is the main and obvious protectable components of the overall proposal, but as the project progresses coupled with the extensive IP search (as mentioned in Deliverable 7.4) carried out at an early stage and at certain interval through the course of the project, we will identify other key intellectual property. Our primary means of protection will be through the use of European and global intellectual property protection. We will look to protect a number of areas of the EU-HealthID technologies as early as possible in the project (as soon as results are achieved) as commercialising under unprotected conditions will not offer us the optimal level of exploitation post project. We expect to draw up a plan for the preliminary protection of results after successful completion of the key Milestones, as this will provide proof of concept of the enabling technologies.

The partnership will develop an agreed Exploitation Strategy for the management of knowledge and all intellectual property. The main innovations in the project will be evaluated for protection by means of patents, copyrights or any other methods. It has been agreed by the consortium that all the partners (except the RTDs) will have some benefit from any new IPR directly arising from work related to and stemming from the Project. Full recognition will be given to any existing prior art (IPR), especially where that is owned by a Consortium member. Secure, in their role as the Exploitation Manager, will ensure that any such relevant pre-existing IPR needed for the project is given maximum visibility to all members from the beginning and throughout the duration of the Project. They will also ensure IdentAlink (the coordinator) would be responsible to hold the IP, but that the commercially potential rights are given to the various participants. IdentAlink would retain all IPR except any new jointly developed IPR that may be independent of the existing IdentAlink IPR and unique to this specific project. Following the project funding model, efforts will be made to give exploitable rights to the SME members. All agreements will be properly implemented using professional IPR Agents so that the IPR is protected for the members. By the second post project year, to comply with the Commission's policies, we expect to sell or license our new solution system to other potential third party users across the European Union.

We have also devised a clear ownership model, and will make use of a distributed model to ensure every industrial partner gets a beneficial sharing of the results of the project. This will involve the sharing of multiple results from the project. Each SME can then sub-licence their share of the results to European SMEs in the supply chain. Within the consortium, partners will be given royalty-free access to the results for certain parts of the system relevant for their operations. They will also receive preferential rights for the services they would provide to the project. As mentioned, each SME partner will retain any developed results and we will enter into joint agreements to ensure all results can be exploited fairly. These will be laid out in a Consortium Agreement (CA), as shown by deliverable D8.4. The CA will also ensure that any IP developed during this product is retained for the benefit of the European companies involved.

EU-HealthID is a research for SME Associations scheme to benefit the SME-AG partner of the project, as well as the SME partners. As such, all Intellectual Property Rights will lie with the SME and SME-AG partners. The RTD Performers **will** not share in the foreground IPR, nor will any agreement (i.e. Consortium Agreement) entered into be allowed to restrict future exploitation of the IPR. Also, the Background owned by the RTD performers or the SME partners which are found necessary for the implementation of the project will be granted royalty free to all partners

for the whole duration of the project. That is, after the end of the project, the RTD performers will grant royalty free access (for an agreed time period) to background needed to use the foreground. IdentAlink will be given distribution and exploitation right as agreed by the consortium. As Exploitation Manager, they will be in charge of the exploitation strategy, and would be responsible for the exploitation of the foreground and the derivation of the exploitation benefits for the SME partners within the consortium.

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Installed EUHealth DB	1	0	0	0	0	**1**
€	[redacted]					[redacted]
Installed systems (national)	1	2	4	7	10	**24**
€	[redacted]					[redacted]
Installed systems (hospitals)	2	6	28	60	120	**216**
€	[redacted]					[redacted]
Installed systems (GPs)	15	10	520	1200	2300	**4045**
€	[redacted]					[redacted]
Registered digital signatures	[redacted]					
	[redacted]					[redacted]
Total	**€** [redacted]					[redacted]

Table 3.2.1a: Predicted sales and total revenue in the first 5 years post-commercialisation

Post-project, SNBA will set up, install and administer the central European EU-HealthID database; they will charge a per-user fee of €0.36 for use of this database, as well as a one-off installation fee of [redacted] which will form the mainstay of their revenue post-project. IdentAlink, as well as owning the main IPR, will sell the EU-HealthID to hospitals, GP surgeries and national health services, with user support and training services provided by PCKN. IdentAlink will also offer the system to resellers – SecureData and SMATOS will act as the first resellers.

		After 5 years		
Partner	**Post-project Role**	**Revenue**	**Post-project development costs**	**Profit**
(1) IdentAlink	Vendor (to end-users and resellers)	€ [redacted]	[redacted]	[redacted]
(2) PCKN	User support, training, etc.	€ [redacted]	[redacted]	[redacted]
(3) Secure	Reseller	€ [redacted]	[redacted]	[redacted]
(4) SMATOS	Reseller	€ [redacted]	[redacted]	[redacted]
(7) SNBA	Database administrator	€ [redacted]	[redacted]	[redacted]

Table 3.2.1b: Predicted economic benefit to SME and SME-AG partners (total for 5 years post-commercialisation)

3.2.2 Dissemination and Use

Exploitation (Route to Market)

A number of our industrial partners will be assisting the realisation of the EU-HealthID development into market: IdentAlink will extend their existing services in the biometric technology market, on the basis of results achieved in the project. PCKN intends to contribute their extensive knowledge in software development to build the EU-HealthID system based on IdentAlink's initial software platform and this will allow for new application area which the company can use to market themselves as having expertise in. This project will help Secure in Luxemburg to achieve its mission of developing new intelligent solutions in various new markets and this can be used to improve their market and added value service being offered. The SMEs intend to implement the project results into their respective range of services for its member companies supporting them in their efforts to get access to new business opportunities on an international level. In general, the exploitation of the EU-HealthID will occur in phases, covering post-project

development and trials, initial exploitation, European expansion and global expansion. These stages are detailed below:

Post-Project Development and Trials (Year 1)
During this period, the consortium partners will look to move from a post-project alpha version to an exploitable full trialled framework with saleable services. This will require significant investment, potentially from outside sources in the form of venture capitals or loans, as identified during the project by the Exploitation Manager (SecureData). This is the highest risk period of the exploitation, as no revenue is being generated. During this period we will seek to establish a trademark and ensure that our innovations are fully protected. We will carry out an extensive testing and validation programme during this phase to ensure that the EU-HealthID framework can operate for various European Union national countries' protocol.

Initial Exploitation (Year 2-3)
Our Initial Exploitation phase will concentrate on establishing awareness and a market presence in each of our target countries, with initial focus on the countries of our participating partners; this will be carried out primarily through the national steering committees established in task 7.4 (see page 29). These are Czech Republic, UK, Germany, and Luxemburg. These countries have been selected as they are potential markets for the EU-HealthID technology (being EU members) and we have the presence of our partners to make easy dissemination. However, the scope of the EU-HealthID project spans the whole of Europe (even globally) and we will be aiming to reach all these markets. In order to gain a market presence, we will need not only a market penetration route but also an implementation, testing and training route. We will achieve this through a licensing scheme, whereby a potential licensee is trained in the technology and granted an approved solution provider status. A number of our partners look to benefit significantly from the license fee generated from the EU-HealthID technology. Also, partners like IdentAlink will be in a good position to act as training facilitators as they look to sell a number of their software packages to healthcare consultants looking to offer the EU-HealthID services.

European Expansion (Year 3-5)
The main activity during this period will be to consolidate the markets in the target countries and use the results from the initial exploitation period (over the previous 2 years) to penetrate key new markets. Precise targeting of new markets will largely depend on the direction that healthcare policies and EU regulations take in these countries and the European Union in general. During this period, we expect demand to ramp up significantly as we build a portfolio of successful implementation and application usage. As a result, we expect to license some aspects of maintenance and service provider rights as well as approving further solution providers. Based on our projections, we see a particular need for licensed EU-HealthID solution providers in all the European Union member states and associate members in order to ensure a fully European presence and implementation of the system.

Global Expansion (Year 5-8)
Also, there is a potential for EU-HealthID in international markets, particularly in the US and Asia. This will also stand to benefit the European Union in terms of allowing European citizens to feel safe and secure outside the European Union. There is also a need in countries like Australia and any country advanced in their healthcare service being provided. Once we have sufficient European penetration, we will be in a position to exploit the technology abroad. We believe there would be a growth in demand of the EU-HealthID framework, hence we predict this period to be very productive. It is highly likely that markets will have evolved significantly in this period, through government policy, grants and other technologies. As such, we will monitor the market situation throughout the project and will collate our findings in the project's Plan for Use and Dissemination of the Foreground.

Training and Dissemination

The research partners will disseminate the scientific achievements in biometric/PKI access control, semantic integration, semantic translation and distributed databases through the publication of research papers, and will present consortium approved papers on the potential applications of the solution system at suitable conferences and seminars (for more detail see deliverable D7.1 on page 29). International conferences will be targeted for specific thematic areas (biometric technology and healthcare services etc.) to ensure widespread knowledge across the world. All the consortium members will attend and present, whenever possible, at appropriate scientific conferences and seminars to publicise the project innovations. The technology will be available for post R&D best practice dissemination through the use of the project's case studies, and the system will be implemented and tested through the appropriate government channels, which will be a valuable asset for the post-project exploitation and dissemination in building a network of licensees.

Through the help from the European Commission, some healthcare institutes would be encouraged to use the system for free on a trial basis with limited licence and thus validate the technology developed. All partners will play an active role in technology transfer and dissemination, promoting the technology development to possible research advancements, and through networks of industrial contacts. The initial exploitation would be done through the SME we have present in the consortium. The SME partners intend to implement the project results and the associated range of services in the European Commission recommended healthcare institutes for its patients, giving the other participating institutes access to records on a European level in case of an emergency. From the success stories in this initial period, we will be able to attract a wider share of the market and realise our targets. The detailed exploitation plan has already been highlighted in this section.

All partners will play an active role in technology transfer and dissemination, promoting the technology development to possible research advancements, and through networks of industrial contacts. Materials will be produced demonstrating case study scenarios including CD ROM design guides and process validation scenarios. Where possible, links will be established with existing EC funded projects and relevant Thematic Networks involving Biometric/PKI Access technology and healthcare services etc. This will be carried out primarily by SBNA, as the European biometrics association. The industrial partners will be encouraged to participate at various scientific and commercial events to network the results and help demonstrate the technology to end users in a variety of national sectors, as well as the placement of advertorials and technical articles in journals and publications connected with the technology used in the project. Dissemination will take place through a series of defined routes, each corresponding to a different stage in the post-project exploitation (described previously). Ultimately, we need to disseminate the developments of EU-HealthID to the customer base of the National Health Services in the European Union countries, namely the European citizens. This project will aim to produce a market-ready framework (with future developments considered), which is why it is important to ensure that public awareness is raised in advance of commercialisation. We will achieve this through articles in the Science and Innovation sections of the popular press. We will also submit articles to popular science and technology magazines. We will also take the opportunity to raise public awareness about the need for the EU-HealthID technology in general. Initially, there will be a need to disseminate the scientific advances of EU-HealthID. This will be through papers published in international journals and presented at conferences. There are a number of already published papers regarding the theoretical design and performance of cross border integrated systems and the same exploitation routes will prove particularly relevant.

Some relevant journals and conferences, at which the scientific and technical results of the project will be demonstrated through white papers, journal articles, presentations and posters, are given on the following page:

Journals	**Conferences / Exhibitions**
Biometrics (International Biometric Society)	Biometrics Conference and Exhibition (Elsevier / Planet Biometrics)

International Journal of Biometrics (InderScience Pulbishers)	International Biometric Conference (International Biometric Society)
Journal of Biomedical Informatics (Elsevier)	International Conference on Health Informatics (INSTICC)
BMC Medical Informatics and Decision Making (BioMed Central)	Annual Data Protection in the Healthcare Conference
Health Informatics Journal (SAGE Publications)	

At the same time as disseminating the scientific results of the project, the top-level practical results need to reach the wider industrial community in our initial market sectors. This will also be achieved through specific industry publications across the healthcare industry in both the private and public sectors in Europe. These publications will tend to be national and so we will target magazines in our partnership's countries and our target countries. At this stage, the project website will be developed into a more overt dissemination tool, designed to arouse interest in the technology and encourage expressions of interest. It will feature graphical demonstrations of the technology, facts and figures on effectiveness and an itinerary for trade fairs where information will be presented. As dissemination continues, it will be expanded to include product reviews and user case studies. An important dissemination route will be through the European Commission. The value of a joint research project such as EU-HealthID comes not just from the technology developed but also from promoting further collaborative R&D. We will therefore provide the EC with progress updates suitable for use in promoting R&D for European companies and will share experience with other programme members and potential members whenever possible. We will make use of government support to encourage consumers to purchase resulting packages and whilst EU-HealthID is attractive without subsidy; government support would help us achieve rapid market penetration. Therefore, we will disseminate information about the project to local institutes via their local government. We see EU-HealthID as a cross-border electronic health record platform for the wider Europe. We also see EU-HealthID with scope beyond Europe and the developed world. We will review other potential countries to disseminate EU-HealthID as a means of providing higher quality, efficient and cost effective healthcare services to patients and healthcare professionals within these regions irrespective of language and procedure barriers. The dissemination plans for EU-HealthID will be defined in the 'Plan for Use and Dissemination of the Foreground' to be developed during the project, as shown by D7.3.

Table 3.2.2 Project [redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	€ [redacted] 6.88	€ [redacted] 01.44
[redacted]	[redacted]	€ [redacted] 251,129.56	[redacted] 3.65	€ [redacted] 757,364.54
[redacted]	[redacted]	€ [redacted] 136,130.89	€ [redacted] 142,209.77	€ [redacted] 410,547.90
[redacted]	[redacted]	€ [redacted] 80,142.76	€ [redacted] 83,721.51	[redacted]
[redacted]	[redacted]	€ [redacted]	[redacted]	[redacted]

[redacted]

4 Ethical Issues

	YES	PAGE
Informed Consent		
• Does the proposal involve children?		
• Does the proposal involve patients or persons not able to give consent?		
• Does the proposal involve adult healthy volunteers?		
• Does the proposal involve Human Genetic Material?		
• Does the proposal involve Human biological samples?		
• Does the proposal involve Human data collection?		
Research on Human embryo/foetus		
• Does the proposal involve Human Embryos?		
• Does the proposal involve Human Foetal Tissue / Cells?		
• Does the proposal involve Human Embryonic Stem Cells?		
Privacy		
• Does the proposal involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)	X	p.28
• Does the proposal involve tracking the location or observation of people?		
Research on Animals		
• Does the proposal involve research on animals?		
• Are those animals transgenic small laboratory animals?		
• Are those animals transgenic farm animals?		
• Are those animals cloning farm animals?		
• Are those animals non-human primates?		
Research Involving Developing Countries		
• Use of local resources (genetic, animal, plant etc)		
• Benefit to local community (capacity building ie access to healthcare, education etc)		
Dual Use		
• Research having potential military / terrorist application		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

5 Consideration of Gender Aspects

There is no gender issue associated with the subject of this proposal. However, in accordance to Articles 2 & 3 of the Treaty of Amsterdam (1997) and other EU policy directives (COM (96) 67 final) and reports (EUR 20022) the Programme Team is committed to incorporating the principles of gender mainstreaming throughout the various elements of the programme. To this end, every effort will be made to ensure that the work programmes and related activities contribute to the promotion of gender equality wherever possible, and steps will be taken to ensure that none of the activities within the programme contribute to gender inequality or aggravates existing gender inequality. The following objectives underpin the gender action plan:

- Ensuring that women and men have equal opportunities to participate in the various parts of the programme.
- In addressing diversity, the work programmes will take account of the different situational needs and interests of women and men.
- The work programmes will contribute to reducing inequalities between women and men.

With regard to promoting the active participation of women scientists in the programme:

- Active measures will be taken to ensure that women scientists are well represented in the partners' organisations and that women scientists lead elements of the programme.
- Steering Committees and Advisory Panels established to support individual work programmes will reflect the needs of the particular programme but will target a minimum of 40% membership of women.
- Opportunities for mobility within the programme will take account of the different needs of women and men in order to enhance participation by women scientists.