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

Proposal acronym:

EU-HealthID

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 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 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.

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- 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 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 Fraunhofer 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. Fraunhofer is one of Europe's largest research and development organisations. The particular institute we would be engaging in Fraunhofer 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

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, as we understand , are using the eager approach.

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). We will achieve this through the development of our centralised database server. 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 on creating 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.