

TENDER RESPONSE DOCUMENT

MINI-COMPETITION

ICT INTEGRATED SERVICES FRAMEWORK

LOT 4 INFORMATION ARCHITECTURE

**PROVISION OF SPECIALIST STANDARDS SERVICES
FOR THE HSE**

HSE Tender Reference: Project 2550

**This document should be read in conjunction with the Invitation to Tender and
Competition Rules Document**

Candidates may expand reply cells as necessary.

1) STANDARD TENDERER INFORMATION

1.1 Tenderer Details

Company Details			
Name	Address		Website Address
Electronic Record Services B.V.	Ditlaar 7, NL-1066 EE, Amsterdam, The Netherlands		www.e-recordservices.eu
How long the Tenderer traded under this name?		Since 21-11-2007	
Tender Submission Contact			
Name	Telephone		Email
Mr. R.M. Schippers	+31623961239 or +31206761052		r.schippers@e-recordservices.eu
VAT Number		NL818661744B01	
Withholding Tax Number		NL818661744B01	
Company Registration No.	Date of Registration		Country of Registration
34286812	21-11-2007		The Netherlands
Parent Company		Not applicable	
Other Subsidiary Companies		Not applicable	
Company Status			
Sole Trader	<input type="checkbox"/>	Partnership	<input type="checkbox"/>
Private Company	<input checked="" type="checkbox"/>	Public Company	<input type="checkbox"/>
		Consortium	<input type="checkbox"/>
		Other	<input type="checkbox"/>
Auditor Name & Address		DRV Accountants & Adviseurs Hoofdweg 52 NL-3067 GH Rotterdam The Netherlands	
Banking Institution & Address		ABNAMRO Bank N.V. Leidseplein 29 NL-1017 PS Amsterdam The Netherlands	
Tax Clearance Certificate Number		40040842-00001M	
Tax Clearance Expiry Date		20/8/2013	

1.2 Insurance

Please provide details of your current insurance cover. The HSE's standard insurance requirements are set out below. HSE may alter its standard insurance requirements where appropriate to the relevant Tender requirements or Contract. Where applicable, details will be set out in the Tender Documents. Please state your willingness to increase insurance levels to the HSE requirements if successful – Yes/No.

Insurance Type	HSE Standard Requirement	Levels held by Tenderer
Product Liability	€ 6.5m	€ 2.000.000

Tender Response Document - Open Procedure

Professional Liability	€ 6.5m	€ 2.000.000
Public Liability	€ 6.5m	€ 2.500.000
Employers Liability	€ 12.7m	€ 2.500.000
Name of Insurer	Liberty Mutual Insurance Europe Limited	

Note: Please submit Tenderer's Current Insurance Certificate as an Addendum.

1.3 Consortium

If the Tender is from a consortium, the Tender should clearly state which entities are proposed to be members of the consortium, which are to be sub-contractors and how each firm would be jointly and severally liable to HSE for the fulfilment of the terms of the contract:

Entity Name	Description of Roles of each member	Liability

Note: It is essential that where the capacity of an entity is relied upon to support the Tender, evidence of that support is provided in each relevant section of this Tender Response Document.

1.4 Conflicts of Interest

Tenderers must declare any current or previous work undertaken, or any relationship that may be reasonably perceived to potentially conflict with the scope of the Contract and proposals for dealing with same:

Response:
Electronic Record Services B.V. declares there is any current or previous work undertaken, or any relationship that may be reasonably perceived to potentially conflict with the scope of this contract and proposals for dealing with same.

Note: The above statement will not automatically preclude a Tenderer from signing the Tenderer Declaration. A Tender will not be excluded unless the above statement is deemed by HSE to be material to the Contract.

2) AWARD CRITERIA (SPECIFICATION RESPONSE SECTION)

2.1 Proposed Methodology

Tenderers are required to demonstrate how their Tender fulfils this criterion.

Part-1 Determination of the Information Model

1.1- The establishment of a suitable standards based Information Architecture Reference Model (IA-RM)

ERS will deliver a document describing a holistic, standards based, overarching, Information Architecture model that takes into consideration: syntactical and semantic interoperability, future proof and standards assured National EHR.

Semantic Interoperability in health care is a feature of IT-systems and common services that supports on one hand healthcare providers to document the care provided, re-use the data for reporting and research, but on the other hand allow them to co-operate in the delivery of

healthcare.

Most IT-systems were designed many years ago to support the delivery of healthcare. Increasingly there is a demand for interoperable IT-systems. National or Regional EHR projects endeavor to establish a set of services that support semantic interoperability: an Infostructure.

Such National/regional Infostructure must be based on Requirements and Use Cases as those are also the foundation for standards development. The use of standards play a key role in HSE requirements and specifications ERS is responding to. At a generic level the Infostructure must be able to create a neutral standards based data bus that existing and IT-systems yet to be designed can make use of, including a National EHR.

The Information Architecture Reference Model (IA-RM) is a high level conceptual description of this overarching infostructure that must enable semantic interoperability as described.

It will show the orthogonal layers, each based on existing standards, that all together will allow semantic interoperability supporting individual healthcare providers, co-operating ones, and reporting, research and auditing ones. The IA-RM will take in consideration existing and planned business activities.

The proposed AI-AM gives consideration to the 'Standards Based' foundational requirements for semantic and syntactical interoperability of Health ICT Systems across a TRUST based structure. The proposed AI-AM defines the necessary foundational components required for assured Data Collections and a future 'standards assured' National EHR.

It is obvious that any National/Regional Infostructure will have several kinds of stakeholders, that all must be (come) part of the community that use this facilitator of semantic interoperability:

- | | |
|-----------------|---|
| (i) ICT: | <ul style="list-style-type: none"> The ICT Senior Management Team The ICT PMO The ICT Planning Team ICT Corporate Information Facility Team |
| (ii) Business: | <ul style="list-style-type: none"> Department of Health (ICT & CMO) Corporate Planning & Corporate Performance (x2 teams) Health Intelligence Team Public Health (x2 teams) Special Delivery Unit & CMIO Health Information & Quality Authority National Standards Authority of Ireland HSE Procurement |
| (iii) Clinical: | <ul style="list-style-type: none"> Clinical Programme Director Clinical Leads |

ERS expects HSE to invite representatives of those stakeholders for consultation sessions in a central location and make available workshop facilities. The same is applicable for the consultation of other partner agencies having agreed to provide comments and guidance to ERS and HISA. These include NSAI, HIQA and Academia. In total 20 consultation sessions are expected to be needed lasting on average 2.5 hours each.

Generic Use Cases and existing requirements (as used for standards development and published in named projects like NHS, Canada Infoway and Singapore) will be used to

evaluate with the representatives of the stakeholders on completeness and mapped to existing open (CEN/ISO) standards. These standards will be listed and evaluated in a holistic way taking into account all requirements listed in this tender, but also taking into account the Irish/European eHealth roadmap and the need to work towards a business case for all stakeholders, ICT (eHealth application development), Clinical (clinical and population research) and Business (effective and transparent delivery of high quality healthcare) to create a sustainable Infostructure. So the resulting outcome, and not the starting point, is the choice for the more technical (artifact expression) standard(s) to use that are part of the European Interoperability Framework Base-Standards (HL7CDA and EN13606) and other international open standards.

Using the selected standards a proposal for a conceptual high level model will be described, discussed and fine-tuned with the stakeholders in order to build a common ground, understanding, acceptance and support from the start. The in depth knowledge of ERS of the Use Cases and Requirements that founded existing relevant standards for the IA-RM will make it possible to provide sufficient context information to stakeholders to give guidance in the endorsement process. In this way a Top-down and Bottom-up approach is secured. The proposed IA-RM can be used a referential tool to define, explain and provide oversight for data requirements and structures with key stakeholders before final endorsement. The proposed IA-RM will reflect ERS' in depth knowledge about partial examples of this model exist within Healthcare ICT, for example high level expressions of the NHS Logical Record Architecture, as well as the Canadian Infoway and Singapore Information Architecture Models. Further the proposed IA-RM will reflect recent experiences in the delivery of eHealth infrastructures in the Madrid and Valencia region's in Spain with up to 6 Million EHR records each.

Steps: (Month 1-2)

- ERS will perform desktop research on Use Cases and requirements for an IA-RM.
- ERS will produce a first draft document on the Uses Cases and requirements and how they can be mapped to a selection of relevant open standards; meaning relevant for the IA-RM.
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

1.2- The provision of a standards based subject area model (SAM)

ERS deliver a document describing a standards based subject area data model (SAM).

The IA-RM will indicate how the various domains in healthcare can flexibly express their local requirements/needs for data documentation and exchange or re-use. To that end and in order to create semantic interoperability they must be able to use common and shared artefacts that all together will be the Subject Area Model (SAM). Standards selected in the IA-RM will indicate how these SAM's will be constructed and what tools will support the creation, quality assurance and publication of these.

A generic Subject Area Data Model will be proposed by ERS, and discussed and fine-tuned with stakeholders. This generic SAM will become the basis for the development of data sets specialised for a clinical domain. The generic SAM can be used in combination with the

European Interoperability Framework base standards HL7CDA and EN13606 for content development in for instance IHE profiles. The generic SAM makes the use of a new generation of artefact modeling tooling possible that via question/decisions trees gives guidance when modeling. A major quality and efficiency gain in the production of SAM's across National/European wide initiatives.

Steps:

- ERS produces a draft document, based on the IA-RM document, on a Subject Area Model (SAM).
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

1.3- The determination of which technical systems should participate in the subject area model (SAM)

ERS will deliver a document describing the validation of the proposed model proving that core systems and their interfaces can be integrated.

When the IA-RM and SAM's are in place existing core IT-systems need to be able to use the artefacts produce that enable semantic interoperability between them.

ERS has available a validated questionnaire to assess Hospital/GP/Pharmacy/Registries related core IT systems capabilities to participate in the subject area model (SAM), without unviable demands being placed on these systems and their interfaces. This questionnaire can be used by vendors and/or organisation's ICT departments for a self-assessment.

Core IT-systems will have to be indicated by HSE. Vendors and/or users of those core systems must be willing to participate when validating the proposed model. Willing means that within 5 working days on request of ERS/HSE for the provision of interfaces, supported messages and supportive materials, to those vendors and/or healthcare providing organisations, these materials will be provided. At a technical/syntactical level validation will be performed using data-types. The semantic validation is described in Parts 2 and 3 of the tender response.

When successful it shows that at a technical level a neutral standards based SAM supporting data bus is possible.

Steps: (Month 1-2)

- HSE will define the list of 'core systems' that need to be evaluated; maximum 2 systems for 2 domains (Medication and Laboratory).
- ERS will use the validated questionnaires as received to validate the proposed model and investigates the viability of possible integration.
- Stakeholder groups' .tives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

1.4- Recommendation of a Governance Framework and Tooling for

Model maintenance and expansion

ERS will provide a document describing a recommendation of a Governance Framework and Tooling for Model maintenance and expansion.

ERS' experiences from European projects like Q-REC, experiences in EU Supported Initiatives like EN13606 Association and EuroRec, and thesis work that builds on those experiences will be used for the provision of the recommendation of a Governance Framework. Next to this NHS NpflT will be consulted under the MoU with HSE. Canada Infoway and Singapore MOHH will be consulted when deemed necessary by HSE and/or ERS.

The semantic interoperability artefacts (SAM's), as described, will need to be created, tested, maintained and published using tools.

Existing potential tool-sets will be evaluated based on existing published requirements in literature, by EU supported Initiatives websites, deliverables of former and on-going European Research projects and experiences in eHealth infrastructures like the one in Madrid.

The results will be discussed and fine-tuned with stakeholders.

Steps: (Month 1-2)

- ERS will produce a draft document for a Governance Framework and Tooling for Model Maintenance and expansion.
- 2 Stakeholder groups' representatives (those responsible for the data architecture and business users) will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

1.5- A catalogue with the Standards and associated sub-sections for the Model

ERS will provide a documented list of the data standards applicable in part or entirety to the model, along with a brief explanatory script or blueprint to provide appropriate guidance to the user in a readily understood manner. Where possible, any relationships with other standards already recommended in parallel work streams will be noted. This will result in a catalogue with the Standards and associated sub-sections for the Model.

Steps: (Month 1-2)

- ERS will produce a draft document on Standards used plus guidance on their use
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 1, maximally 2 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

Part 2 Data Dictionary

2.1- The determination of a Standards Based Data Dictionary including the specification of meta data structure, data classes,

entities and attributes.

ERS will provide a specification of a Standards Based structure for the HSE's Master Data Dictionary, including provisions for integrity of meaning, relationships to other data, origin, usage, and format. Content for the data dictionary will include both clinical and related data items. When commissioned the data dictionary will have associations with data sets and other reference sources including terminologies and classifications. The data dictionary will be based upon a commercial, open source, or alternative national platform and will be architected upon a 'standards based' structure.

The IA-RM will define the high level architecture for an infostructure.

One of the layers will produce the library with SAM's.

These SAM's will be based on one generic pattern that can be specialised for use in a defined domain. These patterns will be conformant to a standard such as *CEN/ISO 13940 System of Concepts for Continuity of Care* in order to be able to align organisational and health processes between co-operating healthcare providers or their organisations.

Each produced artefact can be considered to define all relevant data elements around one topic including its complete context needed for semantic interoperability. These artefacts will be able to support semantic interoperability because the maximal context can be documented, when needed.

Each artefact in the end will carry in all of its nodes all relevant bindings to coding systems, ontologies, value sets, code-sets and local thesauri.

Each node in the artefact, is one Data Element. All together these artefacts will constitute the HSE's Master Data Dictionary, after quality assurance.

It is proposed that the *ISO/IEC CD 11179 Information Technology -- Metadata Registries (MDR) - Framework Ed 3* will be used for the HSE Data Dictionary. Tooling that supports this ISO 11179 specification will be used.

On one hand the collection of artefacts (for instance 13606 archetypes or HL7 CDA) can be considered to be a form of a Data Dictionary. On the other hand the ISO 11179 is a suitable standard for any Data Dictionary with registered data elements and their bindings to coding systems plus relationships. It provides a neutral way for vendors to be exposed to the data sets as required.

Steps: (Month 1-3)

- ERS will deploy the ISO/IEC 11179 conformant Data Dictionary service.
- Stakeholder groups' representatives will be selected by HSE.
- ERS will demonstrate, explain, the deployed Data Dictionary service in minimally 2, maximally 3 sessions, with the stakeholder groups.
- ERS will describe how Nodes in semantic interoperability artefacts populate the data elements in the HSE Data Dictionary
- ERS will send a pre-final version of a report about the demonstrations to HSE for acceptance.

2.2- Validation (Proof-of-Concept) of the Data Dictionary

ERS will demonstrate the standards based structure and functionality of the Data Dictionary. A

number of clinical datasets will be made available for this purpose and if successful the prototype may be formalised by HSE and applied for full stakeholder usage. The proposed dataset(s) will contain no more than one hundred items.

HSE will propose two data sets (not more than 100 data points) to be converted into semantic interoperability artefacts that will populate the HSE Data Dictionary.

ERS suggests strongly to start with Medication and Lab results, since this type of information is available in most systems in a structured way and can be re-used easily as low hanging fruit.

The Validation of the Data Dictionary will be done by demonstration of the standards based structure and functionality of the Data Dictionary. A number of clinical datasets can be made available for this purpose.

Steps: (Month 1-3)

- ERS will establish the two data sets to be used in the Validation of the Data Dictionary.
- ERS will convert into two artefact libraries with bindings to relevant coding systems.
- ERS will populate the HSE Data Dictionary.
- ERS will demonstrate the artefacts produced, data elements and their relationships in minimally 2, maximally 3 sessions, with the stakeholder groups as selected by HSE.
- ERS will send the pre-final Validation Document to HSE for acceptance.

2.3- Recommendation of a Governance Framework and Tooling for Dictionary maintenance and expansion

ERS will produce a recommendation of a Governance Framework for the Dictionary maintenance and expansion will be produced. Suitable arrangements for assuring the integrity and quality of the dictionary will be determined using standards. When commissioned the data dictionary will have associations with data sets (both clinical and business) along with other reference sources including terminologies and classifications. Appropriate tooling and proven standards based governance model needs to be identified designed, and presented in a manner that will address this requirement.

Based on ERS' experiences in Q-Rec and other EU projects and EuroRec, literature research and responses obtained from for example NHS NpflIT, Canada Infoway and Singapore MOHH plus ongoing PhD level research, a Governance Framework will be proposed.

The defining document will be discussed, and fine-tuned with the 3 defined coherent stakeholder groups, that need to be invited by HSE.

Standard based and/or supporting Tooling will be needed for:

- The production of standards based artefacts.
- The assurance of the integrity and quality of the Data Dictionary.
- Tools to define and publish reference sources: terminologies, classifications, code-sets, value sets.
- The Data Dictionary maintenance and publication.

Based on the decisions taken due to work executed in Part 1 the relevant tools will be analysed with respect to functionality, extendibility and conformance to standards; a set of tools will be proposed.

At the technical level (artefacts and Data Dictionary) the tools will secure conformance to the

IA-RM, SAM patterns, and the standards they are based upon.

Steps: (Month 1-3)

- ERS will produce a recommendation on a Governance Framework and Tooling for a Data Dictionary, its maintenance and expansion, as a first draft document
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

2.4- A catalogue with the Standards and associated sub-sections for the Dictionary

ERS will provide a list of the data standards applicable in part or entirety to the data dictionary, along with a brief explanatory script or blueprint to provide appropriate guidance to the user in a readily understood manner. Where possible, any relationships with other standards already recommended in parallel work streams will also be noted.

A document will be produced that lists the relevant standards used to define the HSE Data Dictionary, plus a description of how the standard is to be used as informative guidance.

Steps: (Month 1-3)

- ERS will produce a first draft document about the standards used.
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

Part-3 Terminology Assurance

3.1- Provision of a blueprint for the deployment, management and maintenance of the terminology service

ERS will execute the objective of this deliverable is to determine the necessary foundational components and structure for the deployment, management and maintenance of the terminology service. Although the core focus of this requirement relates to SNOMED CT, the design will be able to accommodate additional terminologies such as LOINC, ICD-10 etc.

Inside semantic interoperability artefacts and therefore the HSE Data Dictionary codes for nodes in these artefacts and code-sets for data fields will be needed.

Terminological services will be created, maintained, published and governed.

ERS will perform desktop research what terminological services and coding systems minimally are needed as external resource. Possible coding systems and classifications that need to be accommodated are: SNOMED CT, ICD-10, LOINC, and possibly a drugs data base. This desk top research is further used to determine the necessary foundational components and structure for the deployment, management and maintenance of the terminology service.

Results from the CEN Concurrent Use project (harmonisation of CEN/ISO EHRCOM, ContSys

and HISA standards via intersections in the generic SAM modeling patterns) will propose generic solutions for linking with external resources as described.

ERS will investigate existing tools to create code- and value-sets such as the tools published by IHTSDO and those conformant to the HL7 CTS specification and (open source) products based on it. One of the important requirements to investigate is if and how those tools can be foundational components and contribute to a structure for the deployment, management and maintenance of the terminology service.

Steps: (Month 1-3)

- ERS will perform desktop research.
- ERS will produce a first draft document on: tooling, deployment, management and maintenance of terminological services.
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

3.2- Validation of the proposed model through the binding of SNOMED CT concepts to a specified clinical data set

ERS will research the confirmation of suitability (or otherwise) of SNOMED CT as an adoptable terminology for use within HSE core systems. The process requires the binding of a number of clinical data set elements (100 elements approx) to the SNOMED CT terminology. The process and output of this effort will be reviewed by HSE and stakeholders for scalability and deployment within HSE systems and stakeholder settings. It will also be reviewed by HIQA and NSAI for quality control and Governance Assurance including guideline development. Ideally, the terminology validation will be based upon the dataset associated with validation of the Data Dictionary in Part-2 above.

The ERS proposed data sets for medication and lab results as defined will be adorned with the appropriate codes from terminologies and classifications. In this ideal situation, the terminology validation will be based upon the dataset associated with validation of the Data Dictionary in Part-2 above.

To a large degree the quality of the codes will be dependent on the quality assurance process of the issuing organisations. The way in which the codes are used inside the artefacts needs human review.

The process and expertise needed to attach bindings to terminologies and classifications plus the Governance will be documented for evaluations.

ERS will make use of the possibility of working together with NHS NpflIT under the MoU with HSE.

To confirm the suitability (or otherwise) of SNOMED CT as an adoptable terminology for use within HSE core systems a number of clinical data set elements (100 elements approx) to the SNOMED CT terminology will be bound.

In collaboration with HSE ERS will support, via documented processes describing the implementation of the bindings, that the process and output of this effort can be reviewed for

scalability and deployment within HSE systems and stakeholder settings. Via this support of ERS outcomes can also be reviewed by HIQA and NSAI for quality control and Governance Assurance including guideline development.

Steps: (Month 1-3)

- ERS will produce a draft document on the Governance of terminological services.
- ERS will produce a draft document on the correct deployment of the applied (SNOMED) codes.
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

3.3- A catalogue with the Standards and linkages associated with its operation and maintenance

ERS will provide a list of the standards applicable in part or entirety to the terminology service, along with a brief explanatory script or blueprint to provide appropriate guidance to the user in a readily understood manner. Where possible, any relationships with other standards already recommended in parallel work streams will be noted. This will result in a catalogue with the Standards and associated sub-sections for the Model.

Steps: (Month 1-3)

- ERS will produce a draft document on Standards used plus guidance on their use
- Stakeholder groups' representatives will be selected by HSE.
- In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- A pre-final version of the document is sent to HSE.

Part 4: Support Process and Services

4.1 What standards based toolsets and support structure are required and available to manage the collective practical outputs and relationships of the information components listed above

ERS will provide a brief outline of the appropriate quality toolsets and support system by which the current and future use of the IA-RM, DD, and Terminology Services can be effectively directed and managed in a controlled and integrated manner. ERS will consider and include any internal or external specialist skill sets and service arrangements.

In order to address the requirements of part 4.1 the work as performed under Parts 1, 2 and 3 will be used as input to provide an outline of the appropriate quality toolsets and support systems that serve the HSE infostructure.

Attention will be paid to the skill-sets needed to maintain, publish, govern and use the HSE Infostructure for semantic interoperability.

ERS will take into account work on skill-sets from the relevant Irish (HISI) organisation.

Steps: (Month 1-3)

- Work performed in Parts 1, 2, and 3 will be used as input for desktop research by ERS.
- ERS will consult relevant international eHealth initiatives about relevant experiences with regards to appropriate quality toolsets and support systems to validate the desktop research.
- ERS will seek advice from relevant Irish organisations on the inclusion of any internal or external specialist skill-sets and service arrangements.
- ERS will produce a first draft document that can serve as an outline of the toolset in the HSE Infostructure and required specialist skill sets.
- Stakeholder Groups' representatives will be selected by HSE.
- In minimally 1, maximally 2 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

4.2 A brief comparison of the products that best meet this need including commercial and open source toolsets

HSE ICT runs a mixed IT environment, and wishes to make a decision based on informed choice as to what toolset(s) are best for these emerging system needs. ERS will do a brief comparison including proven and well established products with reasonable functionality. The brief comparison will include commercial and open source products, and if deemed appropriate any in-house bespoke toolsets available from 3rd parties or potential collaborative agencies.

In order to address the requirements of part 4.2 the work as performed under Parts 1, 2 and 3 and Part 4.1 will be used.

As much as possible tools evaluation will be based on requirements, standards used, functionalities and (non-) or commercial availability.

Steps: (Month1-3)

- ERS will use relevant parts of Parts 1, 2 and 3 as input for desktop research
- ERS will consult relevant international eHealth initiatives using the outline produced under Part 4.1.
- ERS will produce a first draft document for discussion with stakeholder groups
- Stakeholder Groups' representatives will be selected by HSE.
- In 1 session, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

4.3 The recommendation of an established toolset and management approach to facilitate integrated governance of the data model, data dictionary and terminology service

The recommendation of an established toolset and management approach to facilitate integrated governance of the data model, data dictionary and terminology service is the natural last stage in Part 4 in which work as performed in Parts 1, 2 and 3 and Part 4.1 and 4.2 will materialise.

Special attention will be paid to proven product functionality and scalable solutions taking into account the current Irish/European context organizational and fiscal constraints.

Steps: (Month 1-3)

- ERS will do desktop research on governance, toolsets and management approaches for governance of the data model, data dictionary and terminology service.
- ERS will provide a first draft document on a recommendation of an established toolset and management approach for governance of the data model, data dictionary and terminological service
- Stakeholder Groups' representatives will be selected by HSE.
- In minimally 1, maximally 2 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group.
- ERS will send a pre-final version of the document to HSE for acceptance.

2.2 Functional Merit

Tenderers are required to demonstrate how their Tender fulfils this criterion. Consideration will be given to the comprehensiveness of solution, ease of adoptability, cohesiveness of standards, cost effectiveness, compatibility with existing systems and structures and compatibility with corporate strategy.

Part-1 Determination of the Information Model Comprehensives of the solution

The IA-RM will be based on a set of interrelated open International standards. The IA-RM supports an Infostructure service that facilitates the transformation of existing proprietary data to a neutral standards based SAM format as present in HSE Data Dictionary. Due to the flexibility in which this Infostructure can be deployed (all or parts of the Infostructure centrally provided as a service in messages exchange networks or de-central available in systems (interfaces)) an evolutionary process of implementing the IA-RM will be possible. Also an evolutionary process of migration from present data exchange via messages to data sharing by Infostructure standards supporting IT-systems, which can be federated, will become possible. Maximum inclusion of IT-systems will be possible at the start of deployment. When new IT-systems are designed with and deploy these Infostructure standards inside those systems, those IT-systems will be capable to be semantically interoperable according to the IA-RM instantly. Allowing re-use for reporting, research and clinical decision support.

Ease of adoptability

ERS' mentioned standards, in the realm of semantic interoperability, by design are capable to facilitate local user groups to express their temporal and local information needs.

Cohesiveness of standards

ERS' mentioned standards are capable:

- to be mapped from the proprietary database format to standards based neutral format and vice versa, and at the same time allow the use of all possible terminologies and classifications.
- to allow It-systems and users to become interoperable at the level of clinical, and organisational work processes.

- to be used in technical transport environments such as IHE.

The standards will be compatible with the Base Standards as defined in the European Interoperability Framework.

Cost effectiveness

An Infostructure based on standards, using common semantic interoperability artefacts and services not only produce one level playing field but help assure better re-use of existing data thereby reducing cost in healthcare. The common use of the standardised artefacts and services will generate better data quality. In particular the need for resources will be reduced because of a standard SAM, the Data Dictionary and coding systems. Because of the availability of normalised data clinical decision support will become generally possible and viable.

The process followed by ERS in this proposal will enhance the buy-in of all stakeholders from the start. As part of the process, knowledge transfers to active stakeholders will take place.

Compatibility with existing systems and structures

ERS' mentioned standards will allow existing systems to use their present communication capabilities and interfaces and/or the extraction of the data and transformation to a standards based neutral format processable by others. Existing systems can be fitted out with standards based, model driven, interfaces that extract and transform the data and vice versa.

Compatibility with corporate strategy

Since the data to be re-used is defined using standards based semantic interoperability artefacts including the Data Dictionary and bindings to coding systems, flexibly new reporting requirements can be met in a reduced period of time.

Not only corporate strategies can be accommodated in this way. Also individual needs can be met.

Part 2 Data Dictionary

In addition to the Functional Merit as written for part 1 the following can be added.

As the result of the execution of part 2 HSE will have:

- A document with a list of relevant standards.
- A document describing the HSE Data Dictionary plus guidance on its use.
- Two sets of artefacts and initial filling of the Data Dictionary for use as a PoC.
- A functioning Data Dictionary that corresponds to the artefacts produced.
- A document describing the Governance of the Data Dictionary and the constituting artefacts
- The interactions with the stakeholders will inform them, create buy-in and try to make the champions for the HSE National project.

The solutions provided will be largely based on existing open International standards creating a level playing field for all actors and some standards will be listed as part of the European Interoperability Framework (EIF).

Proposed tooling will be based on existing running It-systems.

All of the above will result in a catalogue describing: a comprehensive solution, which is easy

to adapt, use as a cohesive set of standards, which will be cost effective, compatible with existing systems and structures plus compatible with corporate strategies.

Part-3 Terminology Assurance

In addition to the Functional Merit for part 1 the following can be noted.

As the result of Part 3 will provide insight in the use and pros and cons of SNOMED inside the semantic interoperability artefacts and the Data Dictionary in the context of two domains and their data sets.

All of the above will result in a catalogue describing: a comprehensive solution, which is easy to adapt, use as a cohesive set of standards, which will be cost effective, compatible with existing systems and structures plus compatible with corporate strategies.

Part 4: Support Process and Services

In addition to the Functional Merit as written for part 1 the following can be added.

All of the above will result in a catalogue describing: a comprehensive solution, which is easy to adapt, use as a cohesive set of standards, which will be cost effective, compatible with existing systems and structures plus compatible with corporate strategies.

2.3 Project Management / Delivery Schedule

Tenderers are required to demonstrate how their Tender fulfils this criterion. Tenderers should provide details of the proposed Project Manager and the Proposed Team. The relevant experience, education, professional qualifications, skills and suitability of the proposed team or key staff per Work Component must be provided. The order of approach and alignment for optimal project delivery should also be expressed, with a rationale provided for any variation against the proposed timelines and order of approach. Marks will be allocated on the basis of the overall response provided taking into account all of these support requirements.

Part-1 Determination of the Information Model

Project Management for HSE to interface with

René Schippers administrative and general project management.
Gerard Freriks for content management and deliverables.

Contributors: David Moner, Jose Maldonado.

It is expected that we use support by the NHS Coding Center under the MoU as described in the tender documentation.

Project Deployment:

René Schippers and Gerard Freriks: all tasks and deliveries
David Moner and Jose Maldonado: Parts 1, 2 and 3

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NHS Coding Center: Parts 2 and 3

CV:s:

Name	Gerard Freriks
Position in Company	Co-owner, Director
Role	Scientific Director / CEN/ISO Standards Expert (Clinical and Technical)
Number of Years in Industry	36 years

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
Medical degree	1974	
General practitioner	1974	

Please Detail Employment Relevant to this Service Requirement

Employer	Period	Description of Role and Expertise gained which will assist in the delivery of this contract
TNO	1971-1979	researcher, cancer research, heamatology, statistical adviser, head of the IT department for 3 research institutes
GP-practice	1979-1999	
TNO	1999-2007	Standardisation EHR systems
Electronic Record Services B.V.	2007-	Co-owner, director

HL7-SGML, XML, Structured documents, templates	1996-2002	active participant
CEN/TC251 wg1	1996-2007	convenor CEN/tc251 wg1, participant wg1, wg2 and wg3
ISO/tc215	2002-2007	participant various wg's
NEN	1996-2007	participant and chairman of various mirror panels Co-author of the NEN 7510 Information security in healthcare
Active knowledge:		13606 EHR communication 13940 System of Concepts for Continuity of Care 12769 Health Information Services Architecture 14822 General Purpose Information Components HL7 standardisation organisation
Activities		Renewal 13606 Integration 13606 with ContSys and Hisa Integration 13606 with coding systems and ontologies Development of a standard on production of (13606) archetypes Member of the Board of the EN13606 Association The EN13606 Association is about to become a liaison organisation of CEN-CENELEC (Tc251) and ISO (Tc215)

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		At present active in the Clinical Information Modeling Initiative together with from the USA: DoD, Kaiser permanente, Mayo Clinics, GE/InterMountain Health, National projects of Canada, Singapore, England, Australia, etc.
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Name	René Schippers
Position in Company	Co-owner, Director
Role	Commercial Director / eHealth Strategies and Business Case Expert (Managerial)
Number of Years in Industry	24 years

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
Master of Public Health	1988	Rijks Universiteit Groningen

Please Detail Employment Relevant to this Service Requirement

Employer	Period	Description of Role and Expertise gained which will assist in the delivery of this contract
University Medical Center Groningen (1100 beds)	1990-1995	Member of staff to the Board with focus on change management as Program manager, Project leader and Interim Manager. Results: 30 months gain in 15 year (~1,0 B Euro) building programme; Delivery of integrated hospital medical record; Privatising hospital laundry; reorganised Department of Anaesthetics and Operating Centre.
Dutch Ministry of Health / All University Medical Centers	1995-2004	Monitor on behalf of Ministry of Health of the program on dissemination of knowledge on the treatment of chronic benign pain and advisor for the involved centres of excellence of the University Hospitals. Development of multi disciplinary EHR to support the treatment of chronic pain patients was part of program.
Ness Technologies Inc.	2004-2007	Launch of dbMotion outside Israel (successful)
Electronic Record Services B.V.	2007-	Co-owner, director. Launch of openEHR (successful); Launch of CEN/ISO based platform and tools (successful)

Please provide information regarding the staff member's experience in healthcare informatics including healthcare informatics standards.

CEN/ISO 13606	2010-	Founder and President of EN13606 Association. Strategy definition to speed up uptake of CEN standards (in particular 13606) in collaboration with EU Institutions and relevant stakeholders.
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Name	David Moner
Position in Company	Advisor / Consultant
Role	Software Engineer / Standards Implementation (Technical)
Number of Years in Industry	8 years

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
Computer Engineer	2004	Technical University of Valencia, Spain
Master on Software Engineering	2006	Technical University of Valencia, Spain

Please Detail Employment Relevant to this Service Requirement

Employer	Period	Description of Role and Expertise gained which will assist in the delivery of this contract
Technical University of Valencia	2005 -	Researcher on medical informatics, EHR standards, semantic interoperability and health information systems integration
VeraTech for Health SL	2010 -	Co-owner, advisor on semantic interoperability and health standards

Name	Alberto Maldonado
Position in Company	Advisor / Consultant
Role	Software Engineer / Systems Architect (Technical)
Number of Years in Industry	13

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
Bachelor in Computer Studies	1992	John Moores University, Liverpool
Computer Engineering	1997	Universidad Politécnica de Valencia
PhD	2005	Universidad Politécnica de Valencia

Please Detail Employment Relevant to this Service Requirement

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Employer	Period	Description of Role and Expertise gained which will assist in the delivery of this contract
Universidad Politécnica de Valencia	1999-2003	Researcher on EHR standardization and integration.
Hospital La Fe, Valencia	2003	Software engineer for the integration and normalization of health data.
Universidad Politécnica de Valencia	2004-	Senior Researcher on Medical Informatics. Leader of Information Engineering research line of Biomedical Informatics Group of ITACA Institute. Main topics: standardization, semantic description and integration of health data.

Please provide information regarding the staff member's experience in healthcare informatics including healthcare informatics standards.

Dr. Jose Alberto Maldonado received his B.Sc. in Computer Science from the John Moores University (UK) and the B.Sc. and the Ph.D. degrees in Computer Science from Universidad Politécnica de Valencia. He was an expert of the Technical Committee 251 of CEN that produced the standard EN13606 for the communication of Electronic Health Records. Currently, he is an expert of the Spanish Association for Standardization and Certification (AENOR). Dr. Maldonado is a Certified Specialist in HL7 CDA and HL7 RIM and specializes in healthcare record architectures, medical data normalization and semantic technologies applied to health data. He has been in charge of the technical coordination of several R&D projects concerned with the semantic description and integration of biomedical data, he is currently an advisor of the Valencian Regional Health Service on EHR description and normalization, and has co-authored several papers on medical informatics research.

General remarks

- It is expected that HSE will provide the project with representatives from the various stakeholder groups and facilitates the interaction and meeting with them.
- It is expected that a two-day session (ERS and HSE) will be the kick-off at the latest on or before the first of September.
- In contrast to the initial ERS' offering and because of the terms (deadlines) of the Mini Tender for Lot 4 ERS will produce initial draft documents for discussion in stakeholder sessions.
- ERS expects to interact with other work streams as they develop.
- ERS assumes that a 'Project Place' alike application, but not MS Sharepoint, will be used in this project; to be discussed with HSE.
- ERS expects a response time of 2 working days for HSE and 5 working days for stakeholders, after requested by ERS.
- ERS will be available as needed, but expects a need to be available for face to face meetings (discussing deliverables with stakeholders and demonstrations, and project management meetings with HSE) in Ireland for 2 consecutive days per 2 weeks, with slightly shorter iterations at the start of the project.
- Other communications will be via e-mail, and for instance Skype/Goto meetings.
- ERS expects guidance from HSE on the execution of the project to assure maximal

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buy-in from the stakeholders.

Part	Steps
1.1- The establishment of a suitable standards based Information Architecture Reference Model (IA-RM)	<ul style="list-style-type: none"> ERS will perform desktop research on Use Cases and requirements for an IA-RM. ERS will produce a first draft document on the Uses Cases and requirements and how they can be mapped to a selection of relevant open standards; meaning relevant for the IA-RM. Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
1.2- The provision of a standards based subject area model (SAM)	<ul style="list-style-type: none"> ERS produces a draft document, based on the IA-RM document, on a Subject Area Model (SAM). Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
1.3- The determination of which technical systems should participate in the subject area model (SAM)	<ul style="list-style-type: none"> HSE will define the list of 'core systems' that need to be evaluated; maximum 2 systems for 2 domains (Medication and Laboratory). ERS will use the validated questionnaires as received to validate the proposed model and investigates the viability of possible integration. Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
1.4- Recommendation of a Governance Framework and Tooling for Model maintenance and expansion	<ul style="list-style-type: none"> ERS will produce a draft document for a Governance Framework and Tooling for Model Maintenance and expansion. 2 Stakeholder groups' representatives (those responsible for the data architecture and business users) will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
1.5- A catalogue with the Standards and associated sub-sections for the Model	<ul style="list-style-type: none"> ERS will produce a draft document on Standards used plus guidance on their use Stakeholder groups' representatives will be selected by HSE. In minimally 1, maximally 2 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.

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<p>2.1- The determination of a Standards Based Data Dictionary including the specification of meta data structure, data classes, entities and attributes.</p>	<ul style="list-style-type: none"> ERS will deploy the ISO/IEC 11179 conformant Data Dictionary service. Stakeholder groups' representatives will be selected by HSE. ERS will demonstrate, explain, the deployed Data Dictionary service in minimally 2, maximally 3 sessions, with the stakeholder groups. ERS will describe how Nodes in semantic interoperability artefacts populate the data elements in the HSE Data Dictionary ERS will send a pre-final version of a report about the demonstrations to HSE for acceptance.
<p>2.2- Validation (Proof-of-Concept) of the Data Dictionary</p>	<ul style="list-style-type: none"> ERS will establish the two data sets to be used in the Validation of the Data Dictionary. ERS will convert into two artefact libraries with bindings to relevant coding systems. ERS will populate the HSE Data Dictionary. ERS will demonstrate the artefacts produced, data elements and their relationships in minimally 2, maximally 3 sessions, with the stakeholder groups' representatives as selected by HSE. ERS will send the pre-final Validation Document to HSE for acceptance.
<p>2.3- Recommendation of a Governance Framework and Tooling for Dictionary maintenance and expansion</p>	<ul style="list-style-type: none"> ERS will produce a recommendation on a Governance Framework and Tooling for a Data Dictionary, its maintenance and expansion, as a first draft document Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
<p>2.4- A catalogue with the Standards and associated sub-sections for the Dictionary</p>	<ul style="list-style-type: none"> ERS will produce a first draft document about the standards used. Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
<p>3.1- Provision of a blueprint for the deployment, management and maintenance of the terminology service</p>	<ul style="list-style-type: none"> ERS will perform desktop research. ERS will produce a first draft document on: tooling, deployment, management and maintenance of terminological services. Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance
<p>3.2- Validation of the proposed model thought the binding of SNOMED CT concepts to a specified clinical data set</p>	<ul style="list-style-type: none"> ERS will produce a draft document on the Governance of terminological services. ERS will produce a draft document on the correct deployment of the applied (SNOMED) codes. Stakeholder groups' representatives will be selected by HSE.

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	<ul style="list-style-type: none"> In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance. ERS will send a pre-final version of the document to HSE for acceptance
3.3- A catalogue with the Standards and linkages associated with its operation and maintenance	<ul style="list-style-type: none"> ERS will produce a draft document on Standards used plus guidance on their use Stakeholder groups' representatives will be selected by HSE. In minimally 2, maximally 3 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. A pre-final version of the document is sent to HSE.
4.1 What standards based toolsets and support structure are required and available to manage the collective practical outputs and relationships of the information components listed above	<ul style="list-style-type: none"> Work performed in Parts 1, 2, and 3 will be used as input for desktop research by ERS. ERS will consult relevant international eHealth initiatives about relevant experiences with regards to appropriate quality toolsets and support systems to validate the desktop research. ERS will seek advice from relevant Irish organisations on the inclusion of any internal or external specialist skill-sets and service arrangements. ERS will produce a first draft document that can serve as an outline of the toolset in the HSE Infostructure and required specialist skill sets. Stakeholder Groups' representatives will be selected by HSE. In minimally 1, maximally 2 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
4.2 A brief comparison of the products that best meet this need including commercial and open source toolsets	<ul style="list-style-type: none"> ERS will use relevant parts of Parts 1, 2 and 3 as input for desktop research ERS will consult relevant international eHealth initiatives using the outline produced under Part 4.1. ERS will produce a first draft document for discussion with stakeholder groups Stakeholder Groups' representatives will be selected by HSE. In 1 session, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to HSE for acceptance.
4.3 The recommendation of an established toolset and management approach to facilitate integrated governance of the data model, data dictionary and terminology service	<ul style="list-style-type: none"> ERS will do desktop research on governance, toolsets and management approaches for governance of the data model, data dictionary and terminology service. ERS will provide a first draft document on a recommendation of an established toolset and management approach for governance of the data model, data dictionary and terminological service Stakeholder Groups' representatives will be selected by HSE. In minimally 1, maximally 2 sessions, with the stakeholder groups the draft document is discussed and fine-tuned for each stakeholder group. ERS will send a pre-final version of the document to

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	HSE for acceptance.
Deliverables Part 1	Due date
1. The establishment of a suitable standards based Information Architecture Reference Model (IA-RM)	31-10-2013
2. The provision of a standards based subject area model (SAM)	31-10-2013
3. The determination of which technical systems should participate in the subject area model (SAM)	31-10-2013
4. Recommendation of a Governance Framework and Tooling for Model maintenance and expansion	31-10-2013
5. A catalogue with the Standards and associated sub-sections for the Model	31-10-2013
Deliverables Part 2	Due date
1. The determination of a Standards Based Data Dictionary including the specification of meta data structure, data classes, entities and attributes	30-11-2013
2. Validation (Proof-of-Concept) of the Data Dictionary	30-11-2013
3. Recommendation of a Governance Framework and Tooling for Dictionary maintenance and expansion	30-11-2013
4. A catalogue with the Standards and associated sub-sections for the Dictionary	30-11-2013
Deliverables Part 3	Due date
1. Provision of a blueprint for the deployment, management and maintenance of the terminology service	31-12-2013
2. Validation of the proposed model through the binding of SNOMED CT concepts to a specified clinical data set	31-12-2013
3. A catalogue with the Standards and linkages associated with its operation and maintenance	31-12-2013
Deliverables Part 4	Due date
1. What standards based toolsets are required to manage the collective practical outputs and relationships of the information components listed above	31-12-2013

2. A brief comparison of the commercial and open source products that best meet this need	31-12-2013
3. The recommendation of an established toolset and management approach to facilitate integrated governance of the data model, data dictionary and terminology service.	31-12-2013

2.4 Ease of Implementation

Tenderers are required to demonstrate how their Tender fulfils this criterion. Consideration will be given to the complexity of solution, implementation risk and modular / scalable approach

The ease of implementation will be mainly a result of a successful joint project execution with HSE involving all stakeholder groups for sufficient knowledge transfer by ERS and to establish the perception at stakeholders that it is a project for them and by them, also.

The project process as described under proposed methodology will support their understanding of the solutions and the uptake of the solution.

The success, amongst others, hinges on the correct set of stakeholders to be selected and their willingness to co-operate.

ERS is of the opinion that its proposed method is the best possible. Our proposed set of initial draft deliverables for discussions with stakeholders, will be founded on open international standards and the use of proven approaches and working implementations in Spanish regions twice the size of Ireland. These Spanish solutions by design can be scaled up to National solutions (>40 M patient records). These solutions are designed as modules, not to be considered complex, and not triggering high maintenance costs, because those Spanish regions are facing the same fiscal constraints Ireland and most of Europe are.

The proposal as presented by ERS will make possible the needed supporting business cases. For instance a business case facilitating clinical research that can support a sustainable deployment of the Infostructure.

The solution ERS at present thinks is the best possible for the definition of SAM's artefacts, is supported by existing tooling. The artefacts produced by this tooling were tested for processability in an IT-system of ERS (EHR-kernel supporting multiple data formats). This tooling and IT-system are not produced by the same organisations or technicians as the artefact editors, but support the same set of base standards for content development as mentioned in the European Interoperability Framework.

An ISO 11179 conformant Data Dictionary solution is part of the product portfolio of ERS.

2.5 Ultimate Cost

Tenderers are required to complete the pricing schedule below (without qualification or amendment) and return it with the Response Document. Tenders submitted containing pricing in any other form will not be considered and may be rejected.

The fixed price quote by Electronic Record Services B.V. for all work asked for in the ICT ISF Information Architecture Mini-Competition Tender for LOT 4 Information Architecture, including all costs of travel, subsistence, material and full delivery costs, is 80.000,00 Euro (eighty thousand Euro), excluding VAT.

Appendix One

SUPPLIER DECLARATION (EXCLUSION CRITERIA)

Tenderers who fail to sign the declaration below **without amendment or qualification** will be excluded from this competition.

The undersigned as an officer of the stated tenderer:

1. Declares that the tenderer¹ has not been the subject of any of the offences set out in article 45(1) or 45(2) of directive 2004/18/EC http://ec.europa.eu/internal_market/publicprocurement/legislation_en.htm
2. Agrees to the HSE's Tender Competition Rules and all other tender documentation as issued or referenced as part of the tender competition.
3. Accepts that the HSE Conditions of Contract for ICT Procurement appended to this tender document, will form the basis of any resultant contract.
4. Confirms that the tender submission fully meets or exceeds those (minimum) requirements as specified by the HSE.
5. Agrees that the HSE tender documents and tender submission will, at the option of the HSE, become a legally binding and essential portion of any resultant contract.
6. Declares that the tenderer has no material conflict of interest affecting the delivery of any resultant contract(s), and/or that the tenderer has declared any potential conflict for consideration by the HSE.
7. Declares that the tender submission takes account of the obligations relating to employment protection and working conditions that are in force in the place where the works are to be carried out or the service is to be supplied.
8. Is prepared to put in place additional levels of insurance, if required and requested by the HSE.
9. Agrees to the HSE's Supplier Charter available to download on:
http://www.hse.ie/eng/about/Procurement/Supplier_Information/Supplier_Charter_12022010.pdf
10. Certifies that this is a bona fide Tender, intended to be competitive, and that the tenderer has not fixed or adjusted the amount of the Tender by or under or in accordance with any agreement or arrangement with any other person(s).

Signed.....

Block Letters.....Mr. R.M. Schippers.....

Position.....Director of Electronic Record Services B.V.....

Date.....June 14, 2013.....

¹ including all those who have powers of representation, decision or control in respect of this current tender

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Appendix Two Tender Submission Checklist

Tenderers are required to submit the following information in their proposal:

#	Item	Check
1.	Have you provided all relevant responses and supporting documentation as required in the Tender Response document?	x <input type="checkbox"/>
2.	Have you completed the Form of Tender / Pricing Schedule?	x <input type="checkbox"/>
3.	Have you completed the attached Statement of Compliance?	x <input type="checkbox"/>
4.	Have you completed the attached Acknowledgement & confirmation of Communication Protocol?	x <input type="checkbox"/>
5.	Have you completed the attached Certificate of bona fide tender?	x <input type="checkbox"/>
6.	Have you completed the Supplier Declaration?	x <input type="checkbox"/>

Appendix Three - Statement of Compliance

Re: ISF Information Architecture Mini Competition

The Tenderer agrees to submit this tender in accordance with the tender documents and all other relevant information referenced in the tender documentation and warrants that their proposal is fully compliant with all mandatory requirements, regulations and legislation in the tender documents.

Additionally, the tenderer agrees that all its bid documents and responses to the aforementioned tender will, at the option of the HSE, become a legally binding and essential portion of the final contract between the tenderer (if selected) and the HSE. The Tenderer further agrees to respect the tendering process and not to engage in predatory pricing if his/her tender submission is unsuccessful.

The Tenderer understands that failure to comply with this requirement may adversely affect inclusion on future bid lists.

Signed: _____

Date: June 14, 2013

Print Name: Mr. R.M. Schippers

Position: Director

Company Name: Electronic Record Services B.V.

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Appendix Four - Tenderer Statement

Tender Process	ISF Information Architecture Mini Competition
HSE Ref	HSE Ref. Project 2550

1. Acceptance of terms of Tender Documents

Each Tenderers acceptance of the terms of the Tender Documents, as evidenced by its duly authorised signature below, constitutes its agreement to, and acceptance of, the terms of the Tender Documents.

2. Communication Protocol

The sole point of contact in HSE for the above Tender Process shall be the person named in the table below (the “**HSE Contact**”). Tenderers must not contact any HSE personnel about the Tender between the issuance of the Tender Documents and the date of award of the Contract unless previously authorised to do so by the HSE Contact. HSE reserves the right to exclude from the Tender Process any Tenderer who fails to comply with these requirements.

Name of Portfolio and Category Management Contact	Miriam Rourke
Title	Category Specialist
Address of Portfolio and Category Management Contact	HSE Procurement St. Canice's Hospital Complex Dublin Road, Kilkenny
Email:	Miriam.rourke@hse.ie
Fax:	[+353 56 7784544]

3. Intention to Submit a Tender

Please indicate if you intend to submit a Tender for the above mentioned Tender Process.

X ☐ **Yes** ☐ **No**

4. Contact Details for Tenderer

Please complete in the table below the contact details of the Tenderer for this Tender Process. **(Please print or type in details)**

Name:	Mr. R.M. Schippers
Position:	Director
Telephone Number:	+31206761052
Mobile Number:	+31623961239
E-mail Address:	r.schippers@e-recordservices.eu
Postal Address:	PO Box 376, NL-2300 AJ, Leiden, The Netherlands

The undersigned as an officer of the Tenderer named below confirms the Tenderers acceptance of and agreement to the requirements set out above.

Signed: (Authorised Officer)	
Print Name:	Mr. R.M. Schippers
Position:	Director
Company:	Electronic Record Services B.V.
Tenderer Name:	ICT ISF Mini Competition Lot 4 Information Architecture
Date:	May 14, 2013

Please return this form completed (without qualification or amendment) within three days of receipt of the Tender Documents to fax number [+353 56 7784544]. Failure to do so may result in your tender submission not being considered.

Appendix Five - Certificate of Bona Fide Tender

The essence of tendering is that the client shall receive bona fide competitive tenders from all firms proposing. In recognition of this principle, we certify that this is a bona fide tender, intended to be competitive, and that we have not fixed or adjusted the amount of the tender by or under or in accordance with any agreement or arrangement with any other person. We also certify that we have not done and we undertake that we will not do at any time before the returnable time for this letter any of the following acts: -

- a) Communicating to a person other than the person calling for this tender the amount or approximate amount of the proposed tender.
- b) Entering into any arrangement or agreement with any other person that he shall refrain from proposing or as to the amount of any tender to be submitted.
- c) Offering or paying or giving or agreeing to pay or give any sum of money or valuable consideration directly or indirectly to any person for doing or having done or causing or have caused to be done in relation to any other tender or proposed tender for the said work any act or thing of the sort described above.

In this certificate the word "person" includes any person(s) and any body or association, corporate or unincorporated; and "agreement or arrangement" includes any such transaction, formal or informal, and whether legally binding or not, and the plural includes the singular.

Tenders' particular attention is drawn to the application of the Competition Act 2002 (as amended). The Competition Act makes it a criminal offence for Tenders to collude on prices or terms in a public tendering procedure. Should the Contracting Authorities become aware of direct or indirect communications, through trade associations or otherwise, between tenders relating to contract conditions or which might facilitate price collusion, it shall be the policy of the Contracting Authorities to disqualify such tenders and to notify the matter to the Competition Authority with the recommendation that action be taken against the tenderers involved.

Signed: Mr. R.M. Schippers, Director

Company Name: Electronic Record Services B.V.

Date: June 14, 2013