



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

TENDER RESPONSE DOCUMENT

NATIONAL FRAMEWORK AGREEMENT

ICT INTEGRATED SERVICES

HEALTH SERVICE EXECUTIVE

Health Service Executive (HSE) incorporating all HSE Hospitals, Member Hospitals of Hospital Procurement Services Group (HPSG), St James's Hospital and The Adelaide & Meath Hospital incorporating the National Children's Hospital (AMNCH) and all publicly funded statutory and non statutory Health Care Facilities in the Republic of Ireland.

HSE Ref 114 / 12

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

SUBMITTED FOR EVALUATION BY:

Electronic Record Services B.V.

Tender submitted for:

ICT INTEGRATED SERVICES FRAMEWORK AGREEMENT HSE REF 114 / 12

1) STANDARD TENDERER INFORMATION

1)1 Indicated Lots

Tenderers are requested to indicate each lot for which they are including a tender submission.

<u>Lot No</u>	<u>Lot Name</u>	<u>Yes/No</u>
Lot 1	EHR Integrated Services	Yes
Lot 2	Technical Infrastructure	Yes
Lot 3	High Level Business Process	Yes
Lot 4	Information Architecture	Yes
Lot 5	Access	Yes
Lot 6	Governance	Yes

1)2 Tender 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 has the Tenderer traded under this name?		Since 21-11-2007	
Tender Submission Contact			
Name		Telephone	Email
Mr. R.M. Schippers		+31206761052 or +31623961239	r.schippers@e-recordservices.eu
VAT Number		NL818661744B01	
Withholding Tax Number		NL818661744L01	
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	

Note: Please submit a copy of the current Tax Clearance Certificate as Addendum.

1)3 Insurance

Please provide details of your current insurance cover:

Insurance Type	HSE Requirement	Levels held by Tenderer
Product Liability	€6.5mil	€ 2.000.000
Public Liability	€6.5mil	€ 2.500.000
Employers Liability	€13 mil	€ 2.500.000
Name of Insurer	Liberty Mutual Insurance Europe Limited	

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

1)4 Consortium

If this submission is from a consortium, the tender should clearly state which Tenderers 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 the 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 submission, evidence is provided in each relevant section of this response document

1)5 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 this 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 tender from signing the supplier declaration. A tender will not be excluded unless the above statement is deemed by the HSE to be material to the contract.

1)6 Adherence to ICT Policies

It is a **mandatory** requirement that all successful tenderers must agree to sign up to all ICT policies prior to awarding of any contracts.

These policies are published on www.hse.ie - <http://www.hse.ie/eng/services/Publications/pp/ict/>

Response:
Electronic Record Services B.V. agrees to sign up to all ICT policies prior to awarding of any contract.

1)7 Additional Information

Please provide details of significant current or pending developments e.g. legal issues or challenges, changes in financial structure or ownership, prospective take-over bids, buy-outs and closures or other relevant financial/economic information etc which are currently in the public domain:

Response:
Electronic Record Services B.V. has no details to provide as referred to under paragraph 1.7. which are currently in the public domain.

2) SELECTION CRITERIA

Please note: A Tenderer may, where appropriate and for a particular contract, rely on the capacities of other entities; regardless of the legal standing it has with them. In such cases the Tenderer must prove to the HSE that it will have the necessary resources at its disposal e.g. producing an undertaking by those entities to that effect.

2)1 Economic and Financial Standing

If Tenderers are unable to provide sufficient details, as outlined below, they will be required to submit additional information and references that the HSE may consider appropriate.

2)1.1 Financial Summary

Please provide financial details for your company and any other entity upon which the tender response is based:

Year	Yr	Yr-1	Yr-2
Please Specify Year	2010	2009	2008
	€	€	€
<u>Income Statement</u>			
Turnover – Overall Company	211.780	151.322	10.185
Turnover – In Relation to the supply of the specified services	211.780	151.322	10.185
Total Costs	180.550	147.734	8.227
Profit - Current Year	28.253	5.038	1.941
Profit – Cumulative	35.232	6.979	1.941
<u>Balance Sheet</u>			
Current Assets	159.702	120.121	40.116
Current Liabilities	106.470	95.142	20.175
<u>Financing:</u>			
Share Holders Equity	18.000	18.000	18.000
Debt	0	1000	0
Retained Reserves	35.232	6.979	1.941

Please note that the HSE reserves the right to seek additional verification of the above information e.g. request most recent audited statements.

2)1.2 Professional Statement

The Tenderer should provide relevant and satisfactory independent professional opinion (i.e. Bank, Auditor or Accountant) assuring financial capacity to undertake this contract:

Response

DRV Accountants & Adviseurs, auditor of Electronic Record Services B.V. can assure that Electronic Record Services B.V. has the financial capacity to undertake this contract.

2)1.3 Additional Financial Information

Please provide details of significant pending developments, changes in financial structure or ownership, prospective take-over bids, buy-outs and closures or other relevant financial/economic information etc, *which are currently in the public domain.*

Response

There are no such significant pending developments as referred to under 2.1.3 which are currently in the public domain.

2)2 Technical and Professional Ability

Tenderers are required, if applicable, to replicate this information for each lot for which they wish to tender:

2)2.1 Tender Specific Company References

You must provide references where services **similar** to those required have been provided in the past three 3 years as detailed below provide information regarding the following:

- ⊕ The general description of supplies or services you provided to the Client/Contracting Authority
- ⊕ Your general approach and methodology to the Contract
- ⊕ The names of the tenderer's key personnel who were involved in the contract.
- ⊕ Identify which elements of the HSE's requirements were involved in the contract e.g. engaging with key stakeholders, provision of after sales and customer support service, provision of staff training and introduction to new products, delivery to multiple sites, provision of management reporting, etc.

LOT 1

Ref	Client (incl. name & address)	Referee Contact Details (incl. phone and email)	Comprehensive Description of Services and Support provided (incl. key performance indicators)	Value €	Start Date	Completion Date
1	Stichting Medisch Centrum Alkmaar, Wilhelminalaan 12, 1815 JD, Alkmaar, The Netherlands	Mr. J.Th. Kedzierski, former CEO MCA, Cell: +31622808034 Email: hanskedzierski@yahoo.com	Delivery of user license, training on system and archetype modeling implementation of EHR system based on openEHR including integration with Clinical Decision Support System and related maintenance & support services. KPI: acceptance for deployment of software licensed within 3 (three) months after signing date of agreement was positively matched. Standards used: EN13606-2	250.000	20-02-2009	31-03-2012

Framework Agreement Tender Response Document

2	<p>F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel Switzerland</p>	<p>Mr. A. Schmidt, eStrategy Leader Phone: +41 61 68 80766 Cell: +41 79 5590080 Office: CH Basel Hochstrasse Bldg 663E015</p> <p>Email: andreas.schmidt.as3@roche.com</p>	<p>EHR2Roche Proof of Concept on meaningful use (re-use) of data out of the EHR for Clinical Research by giving proof of direct from source (EHR) data-entry in Medidata RAVE eCRF system within existing Legal, Ethical and Regulatory framework. Research questions addressed:</p> <ul style="list-style-type: none"> - Technical interoperability; testing CESIL™ as technical solution for supported use case scenario - Criteria for Selection of Studies and Study Sites - Building of the Business Case - Project Management - Dissemination <p>http://www.medetel.lu/download/2011/parallel_sessions/presentation/day3/EHR2.pdf</p> <p>KPI: All defined KPI's (delivery of technical implementation, research & validation documents within timelines) were met successfully.</p> <p>Standards used: CEN/ISO 13606 (EHRcom) and CDISC ODM</p>	<p>>100.000 (we are not allowed to reveal the exact amount)</p>	18-10-2010	24-12-2010
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3	<p>European Commission Information Society and Media Directorate-General B-1049 Brussels Belgium</p>	<p>Gökçe Banu Laleci Ertürkmen, PhD., Coordinator Grant Agreement. Deputy Manager Software Research, Development and Consultancy Ltd. ODTÜ Teknokent Silikon Blok Kat:1 No: 14 06531 Cankaya - Ankara, Turkey Phone: +90 (312) 2101763 Fax: +90 (312) 2101837 Email: gokce@srdc.com.tr</p>	<p>EU Seventh Framework Programme Grant agreement no: 287800 SALUS: “Scalable, Standard based Interoperability Framework for Sustainable Pro-active Post Market Safety Studies”. SALUS will provide:</p> <ul style="list-style-type: none"> - Functional interoperability profiles enabling exchange of EHRs - Semantic interoperability solutions enabling meaningful interpretation of the exchanged EHRs - Security and Privacy mechanisms ensuring EHRs are shared in an ethical and safe way - A novel framework for open-ended temporal pattern discovery for safety studies on top of EHR Systems - Implementation of high potential use cases enabling secondary use of EHRs for post market safety studies <p>http://www.salusproject.eu KPI: All KPI's defined after First 6 (six) months were met. Standards used: HL7CDA, IHE profiles, CEN/ISO 13606, OMOP and mappings to ontologies and proprietary formats as i2b2. An Archetype Modeling Methodology, to become part of renewed 13606-3, is applied for the definition of Generic Semantic Patterns (supporting HL7CDA and openEHR too) and Intersections with Ontologies and Coding systems (W3C, BIOTOP, SNOMED-CT, LOINC, ICD9, ICPC-2), EN13940 System of concepts to support Continuity of Care (ContSys) and EN12967 Health Informatics - System Architecture (HISA).</p>	312.750	01-02-2012	31-01-2015
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1	Stichting Medisch Centrum Alkmaar, Wilhelminalaan 12, 1815 JD, Alkmaar, The Netherlands	Mr. J.Th. Kedzierski, former CEO MCA, Cell: +31622808034 Email: hanskedzierski@yahoo.com	Delivery of user license, training on system and archetype modeling implementation of EHR system based on openEHR including integration with Clinical Decision Support System and related maintenance & support services. KPI: acceptance for deployment of software licensed within 3 (three) months after signing date of agreement was positively matched. Standards used: EN13606-2	250.000	20-02-2009	31-03-2012
2	F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel Switzerland	Mr. A. Schmidt, eStrategy Leader Phone: +41 61 68 80766 Cell: +41 79 5590080 Office: CH Basel Hochstrasse Bldg 663E015 Email: andreas.schmidt.as3@roche.com	EHR2Roche Proof of Concept on meaningful use (re-use) of data out of the EHR for Clinical Research by giving proof of direct from source (EHR) data-entry in Medidata RAVE eCRF system within existing Legal, Ethical and Regulatory framework. Research questions addressed: <ul style="list-style-type: none"> - Technical interoperability; testing CESIL™ as technical solution for supported use case scenario - Criteria for Selection of Studies and Study Sites - Building of the Business Case - Project Management - Dissemination http://www.medetel.lu/download/2011/parallel_sessions/presentation/day3/EHR2.pdf KPI: All defined KPI's (delivery of technical implementation, research & validation documents within timelines) were met successfully. Standards used: CEN/ISO 13606 (EHRcom) and CDISC ODM	>100.000 (we are not allowed to reveal the exact amount)	18-10-2010	24-12-2010

3	<p>European Commission Information Society and Media Directorate-General B-1049 Brussels Belgium</p>	<p>Gökçe Banu Laleci Ertürkmen, PhD., Coordinator Grant Agreement. Deputy Manager Software Research, Development and Consultancy Ltd. ODTÜ Teknokent Silikon Blok Kat:1 No: 14 06531 Cankaya - Ankara, Turkey Phone: +90 (312) 2101763 Fax: +90 (312) 2101837 Email: gokce@srdc.com.tr</p>	<p>EU Seventh Framework Programme Grant agreement no: 287800 SALUS: "Scalable, Standard based Interoperability Framework for Sustainable Pro-active Post Market Safety Studies". SALUS will provide:</p> <ul style="list-style-type: none"> - Functional interoperability profiles enabling exchange of EHRs - Semantic interoperability solutions enabling meaningful interpretation of the exchanged EHRs - Security and Privacy mechanisms ensuring EHRs are shared in an ethical and safe way - A novel framework for open-ended temporal pattern discovery for safety studies on top of EHR Systems - Implementation of high potential use cases enabling secondary use of EHRs for post market safety studies <p>http://www.salusproject.eu KPI: All KPI's defined after First 6 (six) months were met. Standards used: HL7CDA, IHE profiles, CEN/ISO 13606, OMOP and mappings to ontologies and proprietary formats as i2b2. An Archetype Modeling Methodology, to become part of renewed 13606-3, is applied for the definition of Generic Semantic Patterns (supporting HL7CDA and openEHR too) and Intersections with Ontologies and Coding systems (W3C, BIOTOP, SNOMED-CT, LOINC, ICD9, ICPC-2), EN13940 System of concepts to support Continuity of Care (ContSys) and EN12967 Health Informatics - System Architecture (HISA).</p>	312.750	01-02-2012	31-01-2015
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Note: The information above may be given in the same format as an addendum.

2)2.2 Experience, Education and Professional Qualifications

Please use a separate page for each member of staff directly involved in managing the provision of the tendered requirements to the HSE under this Contract. The response should identify the member of staff who holds responsibility for providing lead support to the HSE for:

- (a) Clinical**
- (b) Managerial**
- (c) Technical**

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

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

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) At present active in the Clinical Information Modeling Initiative together with from the USA: DoD, Kaiser permammente, Mayo Clinics, GE/InterMountain Health, National projects of Canada, Singapore, England, Australia, etc.

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

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

David Moner has been involved in the research, implementation and deployment of health information systems and health standards for over eight years. His experience covers the analysis, design, implementation and deployment in real hospital settings of semantically interoperable health information systems using standards such as ISO 13606, HL7 v2.x, HL7 CDA, CDISC ODM, ASTM CCR, SNOMED CT and proprietary formats like openEHR. He has also worked in the development of integration solutions for building EHR record systems, including all needed security and privacy aspects of health information.

He is a Certified Specialist in HL7 CDA, HL7 v2.6 and HL7 RIM. He holds the position of Secretary of the EN 13606 Association and he is Chair of the Education Committee and is member of the Spanish Normalisation Association (AENOR).

He has participated as external advisor at the European epSOS project and in the Semantic Interoperability Advisory Group for the Spanish Ministry of Health. He has participated in over 15 research projects about data integration and standardisation of the EHR, with more than 30 publications in this topic.

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

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.

Name	Marcelo Rodrigues dos Santos
Position in Company	Advisor / Consultant
Role	Software Engineer / eHealth Infrastructure Architect (Technical)
Number of Years in Industry	27 years

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
Doctorate in Information Science – UFMG (due to 2010 June) – Thesis proposal: Shared EHR Service based on EN13606 standard. Made some disciplines on the program of postgraduate in Health Informatics	2010	University College London / UK.
Masters of Business Administration	2004	PUC Minas , Brasil
Post graduate in E-business – UNA / BH (2001)		
Post graduate in Information Management – I	1999	ETEC /BH , Brasil
Post graduate in Analysis of Information Systems–	1977	UNA /BH, Brasil
Degree in Mathematics –	1995	UNI-BH, Brasil

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
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Health Secretary of State of Minas Gerais – (Consultant of EHR Project)	2009-2010	<ul style="list-style-type: none"> • Development of study on generic requirements for EHR systems and analysis of the requirements established by the clinical team of Health Secretary of State of Minas Gerais; • Proposal for a model of interoperability and a technical framework for exchanging messages between EHR systems based on EN13606 standard and archetypes; • Proposal for a EHR extracts models in XML - based on the Reference Model of ISO 13606 and the use of archetypes - for exchanging messages between the solutions of RES and RES-B; • Consultancy for the clinical team on the archetypes modeling process of the concepts to compose the Patient Clinical Summary; • Consultancy for the PRODEMGE technical team on java framework development in order to work proper with archetype model and EHR extracts (syntactical and semantical validation); • Consultancy for the PRODEMGE technical team for the construction of the data model of the central repository to meet the EN13606 RM.
ST. JUDE MEDICAL	2008-2010	IT Co-ordinator
SOEICOM SA	1993-2005	IT Manager

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

Currently I'm invited Professor for postgraduate level programs of the computer science courses and information system. The main Universities I'm teaching are Fundação Dom Cabral (www.fdc.org.br); Faculdade Pitágoras (www.pitagoras.com.br); IETEC (www.ietec.com.br).

Mathematician, Masters in Business Administration and currently finishing PhD in research area of the semantic interoperability based on EN13606 standard. 18 years experience in the field of information systems and technologies; last ten years work as manager of information systems and technologies for large companies in Brazil. Member of the Health Informatics Group of ABNT (ABNT is a founding member of the International Organization for Standardization). Experience as EHR consultant of the Health Department of the State of Minas Gerais - Brazil, participating on the development of the central EHR repository for the State based on EN13606 standard. Experience as project manager of the large ERP projects including SAP implementations. Experience in restructuring of IT teams. Academic experience in teaching of postgraduate level of the computer science courses and information systems.

Name	Jesualdo Tomás Fernández Breis
Position in Company	Advisor / Consultant
Role	Computer Engineer / Ontology Expert (Technical)
Number of Years in Industry	12

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
Technical Computer Engineering	1997	Universidad de Murcia (Spain)
Computer Engineering	1999	Universidad de Murcia (Spain)
PhD in Computer Science	2003	Universidad de Murcia (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
Fundación Séneca	1999-2003	PhD Fellow. Research in Knowledge Management and Ontology Engineering, Ontology Integration, applications of ontologies in biomedical domains
Universidad de Murcia	2003-2008	Assistant Professor, Teaching, Research on Ontologies and Electronic Healthcare Records, Semantic Interoperability, EHR dual model architecture, Ontology Engineering, applications of ontologies in biomedical domains
Universidad de Murcia	2008-to date	Associate Professor, Teaching, Research on Ontologies and Electronic Healthcare Records, Semantic Interoperability, EHR dual model architecture, Ontology Engineering, applications of ontologies in biomedical domains

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

Research and development of ontologies for archetypes and information models.
Research and development of semantic interoperability solutions for dual model EHR architectures.
Research and development of semantic solutions for biomedical data normalization, integration and management.
Expertise in EN 13606, openEHR, HL7 and CEM.
Expertise in XML, OWL, ADL.
Expertise in biomedical terminologies like SNOMED-CT or UMLS.
External expert of the FP7 SemanticHealthNet.

Name	Karl-Henrik Lundell
Position in Company	Advisor / Consultant
Role	Medical Specialist / ContSys Expert (Clinical)
Number of Years in Industry	

Relevant Educational/Professional/Training Record

Description	Year Obtained	Accreditation Body
MD, Pediatrics		

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
Landstinget i Jönköpings län	2011-	MD Pediatrician, medical expert for eHealth
Center for eHealth Sweden	2007-	Work on CEN/ISO System of Concepts of Continuity of Care standard and its application in Sweden

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

Healthcare Hospitals, Clinical Research Healthcare, Information Technology, Patient Safety, Informatics, Medical Devices, Pharmaceutical Industry, Change Management, Strategic Planning, Team Leadership, Business Strategy, Microsoft SQL, Server, IT Strategy, Business Intelligence, SQL, Social Media, Marketing Strategy, ITIL, Healthcare Management

Note: Supplementary information may also be provided by Tenderers and submitted as Addendum.

2.2.3 Capacity / Manpower

In relation to the lots proposed for inclusion in the framework agreement, please provide details on the number of experienced staff providing support on similar services for the past 12 months

Organisation being provided service	No of personnel involved in support	Base of Staff	Type of service
ERS B.V.	all 7 as mentioned in §2.2.1	?	Software engineering, standards, technical implementation, business model consultancy,

Please outline if it is anticipated that the number of personnel will be reduced within the next two years.

Response
No.

Please outline if you feel it necessary to hire additional resources to support contracts under this national framework agreement.

Response
No.

If yes, please identify recruitment timescales and manner in which recruitment will be successfully carried out. Please include details of the type of staff which will need to be recruited.

Response
Not applicable.

If staff are self employed please advise if your insurance policies extend to providing cover for these people in terms of

- Product Liability
- Public Liability
- Employer Liability

Response
Yes, the insurance policies provide cover for each member of staff.

2.2.4 Benchmarking / Research Activities

Please outline your company's involvement in relevant benchmarking and research activities.

Response

As indicated in §2.2.1 major involvements in relevant projects are listed.
In addition many of those mentioned participate in local en regional projects in their countries and are involved in teaching and researching semantic interoperability.

2.2.5 Administrative Support & Management Reporting

Please outline your company's administrative support facilities including provision of reports.

Response

We want to rely to a large degree on administrative support by the Irish project.

2.3 *Quality Assurance Standards*

2.3.1 Internal and External Quality Assurance Procedures

Please detail your external & internal quality assurance mechanisms highlighting quality assurance procedures, accreditation body and validity period.

Response

Each of the experts are highly trained professionals (MD's, Software engineers, Ontologist, IT-specialist, educators, researches) that are used to function in national, regional, national and EU-projects for research and application development.

Internal cross-reviews are standard procedure.

Does your company have ISO 9000-2008 or similar? Please provide details

Response

ERS B.V. is not certified.

Are customer satisfaction surveys carried out? If yes how many and how often?

Response

Yes. In commercial projects the projects are evaluated using key performance indicators with the customer.

Do you have any outstanding contraventions that were identified by Health & Safety Authority? If yes, please give details.

Response
No

2)2.3 Staff Management Procedures

Tenderers are required to provide details of policies, procedures and practices in relation to training of staff:

Response
As SME there are no formal policies, procedures and practices. Because of the nature of our work in defined projects we follow the policies, etc. as defined by the projects/customers.

Each of us individually is responsible for its own training.

Tenderers are required to provide details of their vetting procedures used when recruiting and employing staff:

Response
Next to subjective personal criteria we value highly academic training and professional behavior. In the context of various projects and actual collaboration experiences, knowledge and experience new persons are recruited.

2)2.4 Data Protection

Details are required regarding Tenderer's policies and procedures in relation to maintaining data protection and security of information held by the Tenderer or within the Tenderer's company including but not limited to password protection, firewalls, encryption etc:

Response
All academically trained MD's, engineers and researchers are expected to respect all relevant ethical, legal and information security requirements as set out by their professional, organisations plus local, regional, national and European jurisdictions.

Tenderers are required to confirm if they are registered with the Data Protection Commissioner?

Yes [] No [X]

If yes, please submit proof of registration as Addendum.

3) AWARD CRITERIA

Please Note: Failure to provide sufficient information may result in your tender not being considered. Tenderers are requested to provide as much information as possible in each response to maximise the marks awarded under each section.

Scoring will be based on Tenderers responses and the full provision of information requested. The Evaluation Group will assess the information provided and attribute scoring on a rating of 1 – 10 as follows:

- . Excellent (9-10) – top score
- . Very good (7-8)
- . Good (5-6)
- . Fair (3-4)
- . Poor – lowest score (1-2)

3)1 *Technical Merit – 60%*

3)1.1 **Proposed Methodology and Approach – 30%**

Tenderers are asked to demonstrate the proposed approach in relation to delivering the requirement. This should include comprehensive details on how you propose to facilitate knowledge transfer to HSE staff, contract management and delivery of reporting documentation. Supporting information can be appended to this document but must be appropriately cross referenced.

Response:

Electronic Record Services B.V. proposes a staged approach in relation to delivering the requirements:

Stage 1: assessment of state of affairs and level of knowledge. (Report 1)

Stage 2: define a strategy in close collaboration with HSE staff to define steps for an evolutionary process from existing situation to desired functional outcomes in five years with the general idea to build on what is already available or in use. (Report 2)

Optionally a supporting business case could be defined for budget neutral or cost effective execution of the desired functional outcomes based on the re-use of clinical data for management, population and clinical research.

Stage 3: define the knowledge transfer to HSE to execute the evolutionary process. (Report 3)

Stage 4: define a knowledge resource at HSE that contains knowledge about standards, the applicable use cases for those standards and best practices to support the defined functional outcomes. (Report 4)

Stage 5: provide training on tools, using a train the trainer approach, necessary to execute the evolutionary process by healthcare providers and IT vendors with a 6 months period evaluation on take up of the use of tools and the quality of (modelling) work done. (Report 5.x)

Optionally we could involve the EN13606 Association to certify HSE and other staff working for healthcare providers and IT vendors on technical and knowledge aspects of the CEN/ISO 13606 standard.

Stage 6: provide guidance on the execution of the process and support to overall and periodic evaluations of the programme.

Stage 3, 4, 5 and 6 can (partial) be executed in parallel.

Contributions to reports will be based on:

- assessments of present situation in Ireland based on materials provided by HSE;
- provision of advice based on knowledge of state of the art implementations and knowledge of standards and
- review of draft reports.

The indicative quote's provide are anticipating the support of HSE as secretary and provider of draft reports.

3.1.2 Understanding the Requirement - 30%

Tenderers are asked to demonstrate a clear understanding of the HSE's requirements. Supporting information can be appended to this document but must be appropriately cross referenced.

Response:
See below

3.1.2 Understanding the requirement

Lot 1- EHR Integrated Services

As part of the process as described in 3.1.1 specific EHR related knowledge and expertise will be provided to review and validate the work performed on the Master document, produced so far.

Work stream 1- EHR Integrated Services - Overview & approach

- 1) Available expertise on CEN/ISO HISA, EHRcom, archetype production/design and the needed supporting terminological and ontological mediation services will be of use in the task of defining the facilitating EHR support services.
- 2) In particular the activities in CEN and ISO but also the participation in the EU SALUS and EU SemanticHealthNet projects need to be considered.
- 3) Available extensive experiences with large projects can be mobilised:
 - a CEN/ISO 13606 standard based /National/regional project (18 million persons)
 - a CDA-13606 based project in a Regional system (1,5 million persons)
- 6) Experience is available with the production of the Master document for the Dutch National project in 2002.
- 7) Via EuroRec and its EHR-Q project work has been done on requirements for libraries of Semantic interoperability artefacts.
- 8) There is experience with and availability of very flexible and rich Integration agile model driven tools that allow integration of feeder systems with a central/regional repository with normalised data. Also transformation from the normalised format to any other recipient specific form is possible and proven.
- 9) Training on the tools is part of the offering.

Lot 2- Technical Infrastructure

As part of the process as described in 3.1.1 specific EHR related knowledge and expertise will be provided to help define the technical infrastructure (e.g. payload transport, central persistence, supporting services such as terminologies, registries for semantic artefacts (archetypes/templates), etc.) and its operational aspects.

Work stream 2- Technical Infrastructure Work stream

- 1) Available expertise on CEN/ISO HISA, EHRcom, archetype production/design and the needed supporting terminological and ontological mediation services will be of use in the task of defining the facilitating technical Infrastructure.
- 2) Available software engineers have experience with the deployment of these standards.
- 3) Available extensive experiences with large projects can be mobilised:
 - a CEN/ISO 13606 standard based /National/regional project (18 million persons)
 - a CDA-13606 based project in a Regional system (1,5 million persons)
- 6) There is experience with and availability of very flexible and rich Integration agile model driven tools that allow integration of feeder systems with a central/regional repository with normalised data. Also transformation from the normalised format to any other recipient specific form is possible and proven.
- 7) Training on the tools is part of the offering,

Workstream 3- Applications Reference Base

- 1) Available expertise on CEN/ISO HISA, EHRcom, archetype production/design and the needed supporting terminological and ontological mediation services will be of use in the task of defining the facilitating technical Infrastructure.
- 2) Available software engineers have experience with the deployment of these standards and application and tools developments.
- 3) Available extensive experiences with large projects can be mobilised:
 - a CEN/ISO 13606 standard based /National/regional project (18 million persons)
 - a CDA-13606 based project in a Regional system (1,5 million persons)
- 6) There is experience with and availability of very flexible and rich Integration agile model driven tools that allow integration of feeder systems with a central/regional repository with normalised data. Also transformation from the normalised format to any other recipient specific form is possible and proven.
- 7) Training on the tools is part of the offering,

Work stream 4- Integrated Systems Management

- 1) Available extensive experiences with large projects can be mobilised:
 - a CEN/ISO 13606 standard based /National/regional project (18 million persons)
 - a CDA-13606 based project in a Regional system (1,5 million persons)

Lot 3- High level Business Process Specification

As part of the process as described in 3.1.1 specific EHR related knowledge and expertise will be provided to help define the generic business processes in healthcare (provision of health care, protocols, clinical path ways and organisational aspects of workflow and case management) using the CEN/ISO System of Concepts for Continuity of Care and its mapping on the CEN/ISO 13606 EHR communication standard in order to secure that both for the care provided to the patient and reporting needs for the organisations the correct items are documented.

Work stream 5- High Level Business Specification

- 1) Available experts about the CEN/ISO System of Concepts for Continuity of Care have intimate knowledge of the clinical work flow and processes and the intersection with the CEN/ISO 13606 EHRcom standard. This intersection has been mapped. In a National project the experiences will be deployed in the production of a library of 13606 artefacts.

Lot 4- Information Architecture

As part of the process as described in 3.1.1 specific EHR related knowledge and expertise will be provided to help define the library of semantic interoperability artefacts that are used in the context of the EHR and the exchange and re-use of data. The library must support the provision of care and the reporting needs.

The semantic artefacts describe the information needs in a way that is understandable for users and will be computer processable at the same time.

Exemplar Semantic Interoperability artefacts will be provided with codes from designated reference coding systems but local codes can be added to it, thereby a mapping to reference coding systems is documented.

The modeling methodology used to represent the clinical knowledge can be used in several technical expressions like EN13606, HL7CDA and openEHR and used as payload for instance for IHE profiles.

The library of semantic artefacts needs to support the storage, smart retrieval, publication, and quality assurance using various techniques. among other ontological ones.

Existing feeder and receiving systems use proprietary formats. Existing technology can transform to and from the normalise format based on CEN/ISO 13606 using the archetypes from the library. The integration platform that could be used is model driven and creates a very agile and very flexible way to perform transformations.

The use of the CEN/ISO 13606 standard to transform proprietary formats into the normalised format makes data more future proof. Feeder en receiving systems can migrate over time from using IHE

profiles and HL7v2.x messages to the CEN/ISO 13606 standard and its archetypes by adding an EN13606 interface to their systems. EHR-system can be integrated can create a more federated set of EHR-systems that can exchange without the need for transformations.

Eventually semantic mediation services will be needed to create full semantic interoperability.

Work stream 6- Information Architecture Model

- 1) Based on experiences in the production of 13606 and other archetypes a specification has been developed that will become part of standardisation in the renewal of the 13606 standard.
- 2) This specification allows the production of a library of artefacts all following one generic pattern that carries the intersections with the standards HISA, ContSys, but also the intersection with Coding Systems such as ICD-x, and SNOMED-CT and others, plus the intersections with supporting ontologies.

Work stream 7-Data- Information Repository

- 1) Tools are available for the production of semantic interoperability artefacts and their quality assurance (based on ontological and technical methods). The artefacts will be produced on the basis of the needs of the healthcare providers and other reporting requirements. The artefacts will define the information needs as expressed by users, but carry associated codes from relevant coding systems. In addition the implied semantics in these artefacts can be expressed explicitly to allow forms of reasoning with the data in the future. The tools allow to various degrees of complexity and detail the presentation of the artefacts: for healthcare providers, information specialists and software engineers.
- 2) For the use of healthcare providers a Mind Map can be generated.
- 3) Artefacts can be produced on the basis of any Reference Model. There is experience with 13606, CDA, CDISC.
- 4) Tools are available that allow the production, maintenance, QA, intelligent searching and publication of semantic interoperability artefacts. Because of interactions with the WHO, IHTSDO in EU projects the appropriate codes can be deployed in the artefacts. Local/regional/national codes can be inserted as well. The semantic artefacts carry the mapping of these local codes systems to the reference coding systems.
- 5) Training on the tools is part of the offering,

Work stream 8-Transformation, Interfacing & sourcing

- 1) There is experience with regional integration projects where data expressed in proprietary formats is transformed into the 13606 archetype based format and into formats the receiving system expects.
- 2) There is experience with very flexible and rich Integration agile model driven tools that allow integration of feeder systems with a central/regional repository with normalised data. Also transformation from the normalised format to any other recipient specific form is possible in a very flexible way in matter of days to weeks.

Lot 5- Access

As part of the process as described in 3.1.1 specific EHR related knowledge and expertise will be provided to help define the security aspects of the EHR. By Electronic Record Services B.V. it is assumed that the process of Identification , authentication of persons and organisations is handled by others.

A defining feature of the 13606 standard is that all data such as demographic data is handled outside the EHR-system. Inside the EHR system it will be possible to attach to data a Patient Mandate that defines who has access to the data. This Patient Mandate travels with the data while in transit. Patient Consent could become an extension to this Patient Mandate.

The CEN/ISO 13606 standard has as part of its feature set the audit trail where each commit to the record is fully recorded (author, committer, data and time stamped) In addition fingerprints can be stored next to the data.

When the data requirements are defined in archetypes the same archetypes can be used to generate screen and reports.

Work stream 9- Identity, Access & Consent Management

- 1) The EHRcom standard allows the specification of the Patient Mandate as a way to record and transport the Access Control details.
- 2) The available toolset allows the on the fly creation of screens and reports as defined by archetypes/templates based on the 13606 EHR com standard that are used for the definition of the information needs.
- 3) There is limited experience with Identity and Access methods

Work stream 10- EHR Portal & Presentation

- 1) There is experience with archetype driven generation of screens/reports that can be used in portals for presentation. Both XML transformation and/or ontology driven technologies can be used. Screens can be generated for a variety of platforms.

Lot 6- Governance

All components will be engineered meaning that requirements play a central role and will be used in the validation of the deliverables. All supporting services and their interfaces need to be described. The Health Information Services CEN and ISO standard will help create better plug-and-play interfaces and services.

Software used in healthcare can be seen as 'medical devices' according to the changed Medical Device Directive. In addition re-use of data implies re-use in the context of pharma research. Here additional EU and FDA Directives are in place and need to be followed as are national legislations and rulings.

Work stream 11- Architecture Documentation

- 1) Software engineering approaches will produce requirements documents that can be used in QA/validation processes.
- 2) Knowledge and experience of Prince II methods is available.
- 3) In addition the semantic artefacts are processed in an editing, publishing environment where they are technically tested and using ontological methods the consistency will be examined.

Work stream 12-Governance Model

- 1) Experiences with the medical device certification and webs-site qualification/certification ensure expertise and knowledge about validation and qualification/certification processes.

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3)2 Ultimate Cost – 40%

Tenderers are asked to complete the following table.

Pricing Schedule	Total Fixed Cost (Excl. VAT)	% VAT Rate applicable	Total Fixed Cost (Incl. VAT)
Indicative Costs to deliver Work stream 1	€33,000	0	€33,000
Indicative Costs to deliver Work stream 2	€33,000	0	€33,000
Indicative Costs to deliver Work stream 3	€33,000	0	€33,000
Indicative Costs to deliver Work stream 4	€21,000	0	€21,000
Indicative Costs to deliver Work stream 5	€30,000	0	€30,000
Indicative Costs to deliver Work stream 6	€33,000	0	€33,000
Indicative Costs to deliver Work stream 7	€33,000	0	€33,000
Indicative Costs to deliver Work stream 8	€30,000	0	€30,000
Indicative Costs to deliver Work stream 9	€33,000	0	€33,000
Indicative Costs to deliver Work stream 10	€30,000	0	€30,000
Indicative Costs to deliver Work stream 11	€30,000	0	€30,000
Indicative Costs to deliver Work stream 12	€21,000	0	€21,000
Add additional rows if required			
Maximum Per Diem Rate	€1,500	0	€1,500
Add additional rows if required			
<p>Per Diem - Please state the maximum rate per day that will apply for key staff involved in the delivery of these Work streams should the HSE request additional support.</p> <p>It is expected that the costs submitted for mini competitions will not exceed the Indicative Cost tendered under the Framework Agreement.</p> <p>Failure to provide sufficient information may result in your tender not being considered.</p>			

3 SUPPLIER DECLARATION (EXCLUSION CRITERIA)

Tenderers who fail to sign the declaration below **will** be excluded from this competition.

The undersigned as an officer of the stated tenderer:

1. Declares that the tenderer 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 HSE's Tender Competition Rules available to download on: www.hse.ie/eng/about/Procurement/Tenderinformation
3. Accepts the HSE ICT Terms and Conditions of Contract issued with this tender without material variation as judged by HSE will form the basis of any resultant contract.
4. Confirms that the tender submission fully meets or exceeds those (minimum) requirements as specified by HSE's.
5. Agrees that the HSE tender documents and tender submission will, at the option of HSE, become legally binding and essential portion of any resultant contract.
6. Declares that the tenderer has no material conflict of interest affecting the scope of this contract.
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 HSE's Supplier Charter available to download on: www.hse.ie/eng/about/Procurement/SupplierCharter
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...R.M. Schippers.....G. Freriks.....
Position.....Director.....Director.....

Date: 31 August 2012

Appendix 1 – Label for Return of Tender Submission

Completed sealed Tenders should be forwarded in a sealed envelope marked:

Tender Title	Tender for Framework Agreement - ICT Integrated Services
Tender Reference	HSE 114 / 12
Address	Assistant Head of Portfolio & Category Management
	HSE Procurement Portfolio & Category Management
	St. Canice's Hospital Complex
	Dublin Road
	Kilkenny