Semantic Interoperability for Health Network

Deliverable 8.1
Business Plan and Roadmap

Version 1.0, 29 May 2015

Call: FP7-ICT-2011-7
Grant agreement for: Network of Excellence (NoE)
Project acronym: SemanticHealthNet
Project full title: Semantic Interoperability for Health Network
Grant agreement no.: 288408
Budget: 3.222.380 EURO
Funding: 2.945.364 EURO
Start: 01.12.2011 - End: 31.05.2015
Website: www.semantichealthnet.eu
Coordinators:

The SemanticHealthNet project is partially funded by the European Commission.
In the SemanticHealthNet Description of Work it was foreseen that the project would end by establishing a virtual organisation to connect the stakeholders who had contributed to the development of semantic interoperability assets during the project. This virtual organisation would sustain the Network of Excellence and promote the ongoing development of further semantic interoperability assets.

Through multi stakeholder engagements, primarily through highly successful workshops led by WP7 and reported in deliverables D7.1 - 7.3, we have instead founded a real legal Institute to fulfil the objectives of the NoE, and many others: the European Institute for Innovation through Health Data (i~HD).

The momentum, commitments and expected financing of this new Institute have come from an alignment of interests between eHealth and clinical research, and a fusion of ideas primarily between SHN and the EHR4CR projects, supported by several other European FP7 and Horizon 2020 projects.

i~HD has been registered as a not for profit international association in Belgium, by Royal Assent. This deliverable presents the business plan for its formation, its work plan over the next 3 years and its initial milestones, minus the confidential financial annex. The web site and other materials will be set up during June 2015.

| Status:       | FINAL          |
| Version:      | 1.0            |
| Public:       | Yes – after approval by the EC |
| Deadline:     | May 31, 2015   |
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**Document history**

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<th>Date</th>
<th>Revision</th>
<th>Author(s)</th>
<th>Changes</th>
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<tr>
<td>May 23, 2015</td>
<td>V0.1</td>
<td>Dipak Kalra</td>
<td>Insertion of version 0.7 of the i~HD Business Plan</td>
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Business plan

Draft 0.7, 23rd May 2015
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Executive Summary

The European Institute for Innovation through Health Data (i^HD) has been formed as one of the key sustainable entities arising from the Electronic Health Records for Clinical Research (EHR4CR) and SemanticHealthNet projects, in collaboration with several other European projects and initiatives supported by the European Commission.

The vision of i^HD is to become the European organization of reference for guiding and catalyzing the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery.

i^HD has been established in recognition that there is a need to tackle areas of challenge in the successful scaling up of innovations that critically rely on high quality and interoperable health data, to sustain and propagate the results of health ICT research, and to specifically address obstacles to using health data that are not being addressed by other current initiatives. It has been formed after wide consultation and engagement of many stakeholders to fill a recognised gap, to develop products and services that can help to maximise the value obtained by all stakeholders from health data, to support innovations in health maintenance, health care delivery and in knowledge discovery. It will importantly bring multiple stakeholder groups together in order to ensure that future solutions serve their collective needs and can be readily adopted affordably and at scale.

i^HD has been established as a European not for profit body, registered in Belgium through Royal Assent. It will be governed by its member stakeholders, public and private, through an elected Board and officers. It will be financed by a mixture of membership subscriptions, fees from providing services such as certification and accreditation, specific project grants and other income from education, training and expert advisory roles.

This Business Plan defines the objectives, scope, organisational structure, governance and initial budget of i^HD. It will establish and manage two Centres of Excellence (CoEs): on the reuse of health data for research, and on semantic interoperability. This Business Plan specifies the main activities (projects) the two CoEs will initially undertake, defines budgets and milestones for these and their expected outcomes.

The main projects of the Centre of Excellence for Research Use of Health Data will be to collate and promote best practices in information governance, to certify health research platforms and service providers (starting with the first EHR4CR Service Providers), to provide governance oversight of the EHR4CR operating environment, and to grow a network of excellence comprising hospitals, research units and research sponsors.

The main projects of the Centre of Excellence for Semantic Interoperability will be to collate and promote good practices in the development of interoperability assets and a framework for quality labelling them, to develop and publish an online register of semantic interoperability assets, to develop an evidence base of benefits from semantic interoperability and to form an Alliance of eHealth stakeholders to work together on future semantic standards development and to promote good adoption practices.

In its first year i^HD and its CoEs will particularly focus on securing the trust of the public and patients in the re-use of health data for research and on presenting the value to society from clinical research. They will also promote best practices in interoperability asset development and information governance.
The European Institute for Innovation Through Health Data

Description and Scope

The European Institute for Innovation through Health Data (I^HD) is being formed as one of the key sustainable entities arising from the Electronic Health Records for Clinical Research (EHR4CR) and SemanticHealthNet projects, in collaboration with several other European projects and initiatives supported by the European Commission (see Appendix 4). I^HD has been established as a European not for profit body, registered in Belgium through Royal Assent. It will itself be governed by its member stakeholders, public and private, through an elected Board and officers. It will be financed by a mixture of membership subscriptions, fees from providing services including certification and accreditation, specific project grants and other income from education, training and expert advisory roles.

Vision

To become the European organization of reference for guiding and catalyzing the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery¹.

Mission

To enable, coordinate, and accelerate the efficient development and deployment of interoperable and seamless eHealth solutions² and research strategies, towards achieving best practices and sustainable integrated person-centred health care, to optimize health and wellness in Europe, and beyond.

Objectives

1. Championing harmonised health information and standards for capturing, curating, protecting and exchanging health data in a trustworthy, legally compliant and transparent manner using best practices. This is to enable complete and interoperable health records on individuals and populations to deliver benefits to all stakeholders³, supporting and guiding the best use of standards and assets for semantic interoperability and privacy protection.

¹ Knowledge discovery includes the use of health data to derive local knowledge (for example to determine quality of care) and generalisable knowledge. This knowledge may be derived directly from data, such as data mining, comparative effectiveness research and epidemiology, or using health data to identify patients to participate in research studies.
² eHealth solutions include software applications, medical devices, algorithms and analytic components, software tools and services, interfaces, repositories, networks and large scale infrastructures and info-structures.
³ These benefits will relate to the care give to individual patients, to the configuration of healthcare and wellness services for populations, and to the reuse of health data for knowledge discovery.
2. Providing and/or fostering capabilities to enable better quality health data, and the legitimate sharing and uses of health data, including:
   • Semantic interoperability info-structures and assets
   • Exchange and research platforms and tools
   • Informatics standards and resources to support standards adoption
   • De-identified health data repositories
   • Research data source catalogues and metadata

3. Facilitating, deriving and using intelligence from health data (scientific and clinical intelligence, research, knowledge discovery, service improvement and business intelligence) through advancing the uses of:
   • Electronic Health Records\(^4\) and Personal Health Records\(^5\)
   • Citizen sourced data
   • Mobile health sources
   • Social care records
   • Disease, device and quality registries
   • Reimbursement claims and reporting databases
   • Cohort studies and Bio Banks
   • Clinical trial and electronic case report forms (eCRF)
   • Other potential sources of health related data

4. Performing and commissioning quality assessments, and conducting or overseeing quality audits of:
   • Health related ICT systems and applications
   • Health data\(^6\)
   • Personnel using health data
   • Relevant organisational processes

5. Building synergy and consensus: acting as a focal point bringing stakeholders together to share experiences, agree common priorities and approaches for maximizing the benefits of good quality and interoperable health data and the trustworthy reuse of health data, working towards convergence and cross-fertilization between:
   • Patient associations

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\(^4\) An EHR comprises information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model.

\(^5\) A PHR is a health record, or part of a health record, for which the subject of care or a legal representative of the subject of care is the data controller.

\(^6\) Such audits may, for example, relate to the governance of the capture, usage and communication (sharing) of health data, or to the quality of health data at a given site such as a hospital.
6. Defining and supporting the adoption of best practices in information governance, including ethics, privacy protection, and codes of conduct, relating to the trustworthy use of health data including capture, processing and sharing.

7. Defining and driving a cohesive strategy and vision for ICT (eHealth, pHealth, mHealth) supported, person-centred care, wellness and prevention, especially from data and knowledge perspectives.

8. Creating awareness and promoting the Institute and its objectives, promoting the value of high quality health data, and delivering training and education in topics relating to its objectives.

9. Ensuring sustainability of the Institute and of initiatives within the health data ecosystem, through business model innovation and value assessment (including health benefits, cost-effectiveness, financial impact, etc.), by developing assessment frameworks and tools, and by collating and disseminating the existing and future evidence of value from catalysing the development and implementation of well-coordinated interoperable eHealth strategies and programmes.
Core Functions
The Institute will undertake several core functions relevant to its mission, and establish initially two Centres of Excellence (CoEs). These will dedicate domain-specific expertise to facilitate, drive and govern the use of health data for research and semantic interoperability.
Environment within Europe: the rationale for creating this Institute

i^HD responds to a convergence of needs between clinical research and health care, at European, national and local levels, for access to high quality and interoperable health data on a large scale, whilst complying with data and patient privacy protection legislation.

EHR4CR\(^7\), EMIF\(^8\), several other EC projects and future call topics for Horizon 2020 proposals all point to the growing interest amongst many stakeholders to collaborate, and tackle at a large scale, access to high-quality, integrated and appropriately protected health data to conduct research, at least at a European level but eventually on global populations. In parallel, healthcare organisations (funders, insurers, providers and patient representatives) need high-quality health data to improve the effectiveness and safety of health care, to improve equity of access and to better plan healthcare services.

Health data is captured today at a variable quality, is not collected or stored consistently, and standards adoption is far from ideal. Concerns about the protection of privacy when health data are integrated or shared, even for direct patient care as well as for aggregated

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\(^7\) Please see Appendix 4, and http://www.ehr4cr.eu

\(^8\) Please see http://www.emif.eu
data purposes, limit the extent to which even the data we have today can be combined, aggregated and analysed appropriately.

There are many organisations, initiatives and research projects tackling different aspects of this challenge. However, research results have not proved easy to sustain, and are therefore frequently reinvented by successor projects rather than enriched. Initiatives are often driven by individual stakeholder groups in isolation, such as health informatics standards bodies developing isolated standards, health professional bodies developing guidelines in a narrative form without specifying how conforming health records should be structured, performance targets being set for healthcare providers that require the specific collection of reporting data that is not related to the data that needs to be collected to support patient care.

The European Institute for Innovation Through Health Data has been established in recognition that there is a need to sustain and propagate the results of research, to tackle areas of challenge in the successful scaling up of innovations drawing on health data, to specifically address obstacles to using health data that are not being addressed by other current initiatives, and most importantly to bring multiple stakeholder groups together in order to ensure that future solutions serve their collective needs and can be readily adopted affordably and at scale, in a way that is societally acceptable.

There are other organisations, active at a European level, making contributions in this general direction. The eHealth Network brings together health ministries and other high level eHealth decision makers. EuroRec promotes the high-quality use of electronic health record systems and provides quality labelling and certification services for this. IHE defines interoperability profiles for user driven use cases, and provides testing and certification services for this. CEN is increasingly acting as a European forum for standards development organisations at a European level. ECRIN assures the quality of clinical research organisations. Many healthcare professions and specialties have European associations that agree good practices, and develop guidelines and audit data sets to promote best practices for their specific domains. There are specialist associations catering for particular stakeholder groups such as EFPIA, and umbrella organisations for patient associations. However, none are working across the rich range of domains and stakeholders who need to be involved in co-creating the solutions to complex problems.

This Institute is being formed, after an extensive consultation and engagement process involving many stakeholders, to fill a recognised gap: to develop and maintain products and services that can help to maximise the value obtained by all stakeholders from health data, to support innovations in health maintenance, health care delivery and in knowledge discovery. It wishes to work with the above groups, and others not mentioned here, to complement – not duplicate – their activities and to address issues that remain outstanding and of importance to be resolved. Whilst having a clear initial work-plan, described later in this document, the Institute will seek to respond in an agile way to new needs and opportunities that can enable its stakeholder members, and society as a whole, to maximise the value of health data.
Value Propositions
The following draft Value Propositions propose the specific activities that will be of greatest benefit to each of key stakeholder groups which may become members, and the value (benefits) that will be enabled through these Institute-led activities. These Value Propositions draw on previous versions that were developed (separately) by EHR4CR and SemanticHealthNet.
Value proposition for Pharma

- More efficient protocol feasibility assessment, faster patient recruitment
- Optimal clinical data exchange and study execution
- Lower cost of planning and conducting research
- Improved access to real world data for observational studies, comparative effectiveness, adaptive trials
- Achieving faster patient access to innovative medicines

Value proposition for Contract Research Organisations, Data Aggregators and Brokers

- More efficient protocol feasibility assessment, faster patient recruitment
- Optimal clinical data exchange and study execution
- Improved access to real world data for observational studies, comparative effectiveness, adaptive trials
- Lower cost of planning and conducting research

- Increased access to high-quality health data
- Wider adoption of interoperability standards, easing data aggregation
- Consistent clinical governance practices and expectations across Europe
- Greater societal endorsement of research uses of health data

Value proposition for Healthcare Funders and Policy Makers

- Optimised health care resources, improved efficiency and greater value for money
- Enhanced access to more integrated, interoperable and higher quality health data
- Value demonstration from investments in interoperable and cost-effective eHealth solutions
- Societally acceptable reuses of health data

- Better monitoring of effectiveness, safety and cost-effectiveness
- Optimised use of healthcare resources
- Greater capability to generate evidence for health policy, strategy and resource planning
- Greater capability to generate evidence of the added value of new treatments and pathways
**Value proposition for Health ICT Industry**

- Market growth through increased demand by procurers for value added interoperable solutions
- Product development efficiencies through standardisation
- Wider adoption of EHRs, PHRs and personal health systems
- Greater demand for systems to capture, communicate and analyse high quality health data

**Value proposition for SDOs**

- Better co-ordinated and well targeted standards development
- Enhanced adoption of standards and value derived from them
- Opportunity creation for new standards development
- Better potential to attract sponsorship for standards development, to enable integrated health care

**Value proposition for Scientific Associations**

- Facilitated health data and value evidence gathering for funding research proposals
- Easier process of setting up large clinical trials, especially multi-centre studies
- Enhanced opportunity for epidemiology, population health research, large scale comparative effectiveness research
- New types of clinical studies and impact assessments of complex interventions
- Wider adoption, sustainability and reuse of health informatics R&D results

- Enhanced access to more interoperable health data
- Better quality health data for clinical and epidemiology research
- Participation in Network of Excellence on clinical research, providing access to multiple data sources
- Sustainability and promotion of the interoperability assets developed through research projects
Organisational Structure

Governance

The governance of i^HD will ultimately be executed through its member organisations. In order to ensure that decision-making properly reflects the multiple stakeholder interests that the Institute wishes to reflect, individual member organisations will be clustered within member categories, as depicted on the diagram above. Each member category has an allocation of votes, as specified in the Articles of Association, which directly corresponds to the number of seats that may be nominated and elected by the General Assembly from each member category, to serve on the Executive Board. The General Assembly is the primary decision-making body of the Institute.

The Executive Board is expected to direct the activities of i^HD as a whole, to elect and appoint officers and oversee the execution of its mandates. This will include ensuring alignment with the strategic objectives of the Institute, financial planning and accounting, and liaison with other relevant bodies. The Executive Board may co-opt any additional expertise needed in order to inform its decision-making and strategy. The Board will also mandate and oversee the establishment, scope, budget allocation, objectives and work plan of each Centre of Excellence. It will also oversee the appointment of, and receive recommendations from, one or more Advisory Boards supporting the Institute and Centres of Excellence.

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9 The member category “Clinical and biomedical research companies” includes the pharmaceutical industry and companies developing new genetically targeted therapies. The member category “Scientific (academic) centres” includes for profit and not for profit organisations.
The Centres of Excellence (CoEs), the two initially to be formed and any future CoEs established later, will function as internal organisational units of i~HD, and adhere to its overall governance and accountability structures. The CoEs will largely run defined activities and projects that have a budget allocation or ring fenced funds (such as a research grant or sponsorship) and will also cover strategic roles in advising i~HD on areas relevant to their domains. By working together at the level of i~HD and by adopting a common operating model, the CoEs will be mutually aware of their activities, opportunities and also challenges, and will seek to collaborate wherever possible including pooling their resources and expertise on joint endeavours. i~HD will remain the sole legal and accountable entity responsible for the activities, financial sourcing, optimal alignment and interconnection of the CoEs.

It is recommended that the Executive Board, primarily through the President, appoints or reconfirms the appointment of a Director and a CEO (Secretary General). The Director will take responsibility for leading the fulfilment of the strategic and scientific roles of i~HD, and the CEO will take responsibility for ensuring the operation of i~HD’s activities and operation. These officers should, in turn, appoint other relevant officers (such as a CFO, CIO) and oversee the employment of administrative staff as needed. The President, Director and CEO will have day-to-day operational responsibility for running the Institute and providing oversight and support to the CoEs. Each CoE will nominate between one and three co-leads, on a full or part-time basis, who may include the Director and/or CEO, to be ratified by the Executive Board. These co-leads will have oversight of the activities and projects run by their respective CoE, might directly lead some or all of those projects, will represent the CoE on the Advisory Board(s), and be the primary persons responsible for the strategic roles of the Institute in their domain areas.¹⁰

The Director, CEO and CoE co-leads should be paid positions (by direct employment or through in-house consulting) unless their positions can be sponsored or supported by their primary employer. However it is recognised that, especially initially, these payments might be made for specified activities (including work on funded projects) rather than standing payments.

It is proposed that i~HD, at the earliest opportunity, applies to become a (pan-European, thematic) ProRec Centre ¹¹, enabling it to have a strategic influence in the EuroRec Institute. In any event, this Institute is invited to nominate a representative to the EuroRec Executive Board. It is understood that this supposed to be taken by a member of the Executive Board other than the member who represents EuroRec.

Details of the governance of the Institute are defined in the Articles of Association, and will in the near future be extended through Byelaws.

CoE Operating Model

i~HD being the sole legal and accountable entity, incomes will be generated centrally by the Institute (for example through direct membership fees, infrastructural grants, research

¹⁰ Initially, some of the roles described in this paragraph might be fulfilled by the same person, on a temporary or long term basis.
¹¹ Pan-European thematic ProRec Centres are complementary to the national ProRec Centres that operate in individual European countries, having a subject matter rather than geographical scope.
grants, services and direct sponsorships) and by leveraging each CoE activities and programmes (including research grants, CoE-specific services, advisory role, educational events etc.). The Executive Board will annually agree the budget for core i^HD costs and functions, and a base budget for each CoE. The incomes generated by i^HD will be re-channelled accordingly towards the operating annual budget of each CoE minus an overhead proportion, to be agreed by the Executive Board annually (for example, 10-20%). i^HD will in turn support the operation of each CoE with core facilities including book keeping, accounts and financial reporting, web site and standard dissemination channels, project administration including logistics support for meetings and events, tele-working and e-collaboration tools. The Institute will also execute a number of common activities such as the communications, the development of promotional material, lobbying, fund-raising etc.

Additional specified activities and services might be provided by the Institute to a CoE, or by one CoE to another, which will need to be negotiated on a case by case basis including the capacity to provide this and an agreed budget transfer.

Individuals working on Institute activities and projects will normally be classified as employees or in-house consultants, at an agreed daily rate which assumes that each professional will take personal responsibility for their taxation, personal computing, home working facilities, and any necessary logistic arrangements (but, for any directly incurred travel costs to be reimbursed according to a pre-approved travel policy and budget guidance).

All CoEs must promote only the brand name and image (e.g. logo, web site) of the Institute. Each CoE may additionally introduce the CoE name textually, in a way that always makes clear that the CoE is part of i^HD. Individual projects (especially multi-organisational consortia) often create project-specific logos, and it is permitted for project specific logos to be added to any publicity material, but not in place of the i^HD logos. Branding guidance will be taken on whether CoE specific “flavours” of the logo can be created, and used in place of the Institute logo. Until such “flavoured” logos have been agreed by the Executive Board, only the core Institute logos may be used.

In addition to reporting to, and contributing to, the Institute-level Advisory Board, each CoE may convene one or more expert Working Groups to support its specific activities. These Working Groups might only be required for the duration of a specific activity, and might or might not have funds to reimburse the time and costs of the participating experts, depending upon the funding scheme for the activity. The Institute management can support CoEs with establishing expert agreements and terms of reference for such Working Groups.

The case to establish a new CoE might be made by any party, to the Executive Board, normally through the President or the Director. The Executive Board’s decision to support the formation of a new CoE will need to take into account: the relevance of the subject matter to the Institute as a whole; the extent of overlap or complementarity to the scope and activities of the existing CoEs; the extent of overlap or complementarity to the scope and activities of other bodies active in Europe; the initial financial business case for viability of this proposed CoE; the suitability, reputation and capacity of the proposed lead or co-leads; the alignment and priority of this subject matter to the overall strategy of i^HD.
Establishing a Seamless Organisational Framework

In order to achieve a seamless, well integrated, highly performing and sustainable organisation, as illustrated below, i^HD will act as the governing entity that will foster a culture of strategic alignment and cooperation, towards establishing and promoting a 3-way synergistic collaborative framework, namely: Institute->CoE, CoE->Institute, and CoE<->CoE.

By enabling the optimal alignment, interconnection and cross-fertilisation with and between the CoEs, the Institute will be able to leverage their unique attributes and increase their respective scope, for mutually optimizing their reach towards ensuring high performance, growth and sustainability.
**Guiding Principles**

As illustrated below, the Institute and CoEs will implement and leverage an innovative operating model based on 4 guiding principles for establishing best practices in Management, Synergy, Convergence, and Optimization, towards achieving high performance, cooperation, accountability, and sustainability.

More specifically, these principles provide useful guidance for implementation, in line with the vision and mission of the Institute and of its CoEs.

- **Management**
  - Foster a culture of cooperation, team work, transparency and accountability
  - Define a sustainable financial model that will optimise revenue streams and costs

- **Synergy**
  - Build a progressive culture based on collaboration and healthy co–opetition
  - Incentivise win-win collaborations to deliver high quality innovative solutions efficiently

- **Convergence**
  - Provide cohesive cutting edge practices, assets and services meeting Member priorities & needs
  - Build a connected community and long-term commitment

- **Optimization**
  - Enhance performance through strategic portfolio assessment, alignment & risk management
  - Establish win–win–win strategic alliances & partnerships
The main activities of i~HD and the initial projects of its two Centres of Excellence are illustrated above, and listed below with their key objectives. These activities and projects are described in detail in Appendices 1-3.
**Institute strategy**

Promoting the Institute and its objectives, building synergy and consensus amongst stakeholders, fostering and enabling innovations through the better use of health data

- To represent the Institute on key bodies and events, participate in public engagement events, raise funds and promote memberships, develop strategic relationships with relevant bodies
- To promote the Centres of Excellence and the importance of the good practices, standards, certification schemes, auditing etc. developed by the Institute
- To work across stakeholders and decision makers on key priority uses of harmonised health data, for healthcare, for wellness and for research, gathering and disseminating intelligence on initiatives, projects and large-scale demonstrators of innovative health ICT solutions

**Institute management**

Running the Institute, supporting the CoEs, Executive and Advisory Boards and the General Assembly

- To manage office administration, office infrastructure, support to the Officers and other active Members
- To host and running the web site, public-facing channels, collaboration tools, specialist development and hosting tools
- To organise events, meetings, maintain key contact lists
- To manage Institute finances, reimbursements, book keeping and accounts, cost returns, support to the Treasurer

**Communications**

Developing communications materials

- To develop materials about the Institute’s mission, objectives and activities
- To develop materials promoting and supporting the work of the CoE projects
- To develop materials about the value of research findings and of high quality interoperable health data
- To oversee and maintain social network presence, and good use of all channels

Monitoring the Institute’s visibility and profile

- To develop, implement and co-ordinate communications strategies and campaigns, to monitor references to the Institute and respond to these
- To identify materials for consultation to which an Institute response is appropriate
- To conduct surveys amongst members and the public
Identifying and responding to research and innovation opportunities

Engaging in research

• To apply for research grants in response to call topics, and advise research sponsors of relevant areas needing research investment
• To work closely with the Centres of Excellence (CoEs) on research opportunities, and synergies with other organisations and initiatives
• To monitor the work of other research projects, and the literature, for the potential relevance of new results to the Institute

Engaging in innovation

• To establish strong links with Standards Development Organisations and with industry to promote the adoption of standards and the exploitation of the institutes work including good practices and certification
• To gather intelligence from stakeholders and initiatives about new challenges and opportunities for the Institute

Training and education

• To identify priority topics for education and training for various stakeholder groups, recommend good materials that exist elsewhere and develop educational materials where gaps exist
• To hold educational events, develop online courses and other training activities

Establishing the value of innovative solutions

• To define and maintain value propositions for the Institute and its activities, customised for each of the stakeholder groups with which it engages, including the benefits of membership
• To collate success strategies for scaling up eHealth innovations, and guide the development of sustainable business models for health care and research uses of health data
• To conduct cost benefit assessments, including financial assessments, of innovations in eHealth and clinical research

The detailed activities of the European Institute for Innovation Through Health Data are provided in Appendix 1.
Centre of Excellence for Research Use of Health Data

Vision, Mission and Values

**Vision**
To be the trusted gateway to eHealth information for research and knowledge discovery to transform healthcare worldwide.

**Values**
- Provide flexible, scalable and interoperable solutions
- Ensure full compliance with relevant ethical, legal, regulatory, and privacy protection standards and policies
- Deliver innovative, customer-focused and sustainable value-added services
- Optimize healthcare connectivity by enabling adoption, collaboration, accountability and transparency

**Mission**
Delivering sustainable value-added solutions for the trustworthy re-use of eHealth data and information to improve global clinical research.

Scope of activities

**Network of Excellence for research through health data**
- To foster and coordinate a multi stakeholder community involving those who collect, integrate, manage and analyse health data for research, in order to co-create and promote good practices, identify challenges needing new research and innovations, and within which to deliver education and provide accreditation

**Best practices in information governance**
- To maintain and promote codes of best practice in information governance, privacy protection and ethics for the uses for health data, especially for research but also for cross-border healthcare and public health
- To work with key decision makers and influencers to mutually agree good practices that balance societal benefit and personal privacy

**Certification of health research platforms, services and tools**
- To develop and deliver, primarily in partnership with EuroRec, quality labelling criteria, a test plan and certification process for platforms, services and tools supporting the reuse of health data for research. (This will initially focus on certifying conformance to the EHR4CR specifications)
• To maintain and publish the specifications of services and interfaces for clinical research platforms and tools, to which conformance can be tested

**Accreditation of clinical research staff**

• To develop and promote, primarily in partnership with UKCHIP and ECRIN, a code of practice for staff using health data for research, and provide an accreditation process to recognise the necessary skills in clinical research staff

**Governance oversight of clinical research platform service providers**

• To provide an independent oversight body governing the ecosystem in which health data are used for research, through Institute-certified ICT products, platforms and services

The detailed activities of the CoE for Research Use of Health Data are provided in Appendix 2.
## Project Milestones

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<th>2016 Q1</th>
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<td>Define terms of reference, value propositions for each stakeholder group</td>
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<td>Establish network infrastructure, replication materials and initial targeted deliverables</td>
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<td>Regularly review and extend the network, setting new priorities and objectives</td>
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<td>Final materials covering Evidence and EMIR use cases, to define good conduct and appropriate information security measures, accompanied by initial educational materials</td>
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<td>Literature review completed, and plans for its maintenance</td>
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<td>Stakeholder consultation programme defined and ready to commence</td>
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<td>Risk assessment matrix mapped to existing governance instruments</td>
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<td>Initial draft of quality labelling criteria extracted from the Protocol feasibility set, and a roadmap for finalising the complete set of criteria</td>
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<td>Framework between the Institute and Funded to enable uptake to undertake testing and certification</td>
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<td>Ongoing evolution of criteria, certifying new providers and products</td>
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<td>Final version of the code of practice</td>
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<td>Ongoing evaluation of criteria, accreditation of staff</td>
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<td>Certification of clinical research platforms, services and tools</td>
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<td>First meeting of the oversight body, and initial public materials about its function and approach</td>
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<td>Regular oversight activities, progressive enhancement of role and influence</td>
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Centre of Excellence for Semantic Interoperability

Vision, Mission and Values

**Vision**
To be the European CoE that catalyses and co-ordinates the European prioritization, co-ordinated development, certified implementation and successful adoption of high quality, trusted, semantic interoperability assets which enable rich health information exchange for safe and effective person centred care, the promotion of health, public health and research.

**Mission**
To promote and direct targeted collaborations amongst stakeholders to define European eHealth priorities requiring semantic interoperability and steer investments to deliver this, to foster co-ordination in the development of relevant semantic assets and a dissemination infrastructure for them, to accelerate and quality assure vendor adoption and multi-vendor collaboration, to guide effective procurements of interoperable solutions, and to champion the good use of interoperable information to enhance patient care, achieve better outcomes, population health, and more efficient research.

**Values**
- Faithfully preserving clinical meaning when exchanging health information (between systems and countries);
- Developing semantic interoperability assets aligned with European and national priority use cases;
- Ensuring seamless information sharing between actors contributing to shared patient care;
- Optimizing care efficiency through better information and knowledge exchange
- Empowering citizens to access and to richly use their health information;
- Enabling the discovery of new knowledge from consistently optimizing health data sharing;
- Ensuring timely information exchange and knowledge sharing between health care and life science research;
- Engaging all relevant stakeholders in optimizing the benefits from semantically interoperable resources;
- Ensuring that health information is consistently and securely captured, transferred, stored, organized, transformed and managed in compliance with applicable ethical, legal, regulatory and data privacy and personal information requirements
Scope of activities

Quality labelled interoperability asset register and infostructure
• To provide a central reference point to discover which interoperability assets may be used, together, to tackle a particular use case
• To develop and maintain a set of services that can support the publication, real-time discovery and access to interoperability asset bundles
• To thereby facilitate convergence and reuse of existing assets, in preference to reinvention

Best practices in interoperability asset development
• To foster the development of good quality semantic interoperability assets that are well-suited to addressing high priority use cases for sharing health information, and well-harmonised with other assets addressing the same use cases

Semantic interoperability evidence base
• To collate and synthesise worldwide experience and learning of success strategies for scaling up semantic interoperability, of demonstrating value and deriving benefits from sharing and analysing semantically interoperable health information. To contact the evidence in favour of the use of standards

SemanticHEALTH Alliance
• To host and co-ordinate a network of stakeholder communities that collaborate to enable the development and successful adoption of relevant and usable semantic interoperability standards

Semantic harmonisation services
• To maintain a list of data items and mappings across terminology systems, to support the harmonisation of data and queries in support of clinical research, especially clinical trial feasibility and patient recruitment, and patient summaries to support continuity of care across Europe
• To also maintain the service specification of a central semantic broker to support the construction of local mappings between the data dictionary of a hospital or GP EHR system and a centralised representation

The detailed activities of the CoE for Semantic Interoperability are provided in Appendix 3.
## Major milestones for the CoE for Semantic Interoperability

<table>
<thead>
<tr>
<th>Centre of Excellence for Semantic Interoperability</th>
<th>Activity</th>
<th>2015 Q1</th>
<th>2015 Q2</th>
<th>2015 Q3</th>
<th>2015 Q4</th>
<th>2016 Q1</th>
<th>2016 Q2</th>
<th>Ongoing</th>
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<tbody>
<tr>
<td>Quality labelled interoperability asset register</td>
<td>Finalised design and initial prototype version of the register, demonstrating</td>
<td>N/A</td>
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<td>and infrastructure</td>
<td>asset bundles and quality labelling visuals</td>
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<td>Defined content for a heart failure shared care asset bundle</td>
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<td>Quality assessment framework in place for all kinds of semantic</td>
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<td>Content creation roadmap in place and advanced progress being made on at least two other</td>
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<td>The register is acting as a focal point for European project sustainability and is a</td>
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<td>successful promotion vehicle for SOCs</td>
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<td>Best practices in interoperability asset</td>
<td>Conceptual framework for good practices and quality processes</td>
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<td>development</td>
<td>Inventory of existing published good practices, and initial correlation of key points from</td>
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<td>Establish collaboration agreements with key bodies working on semantic</td>
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<td>asset quality processes, design guidelines and training materials</td>
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<td>Published consolidated good practice guidelines in key areas of semantic</td>
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<td>asset development, accompanied by initial educational materials such as checklists and</td>
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<td>workflow diagrams</td>
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<td>Semantic interoperability evidence base</td>
<td>Established communities of practice, working to consistent guidelines and quality</td>
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<td>standards, and contributing to their evolution</td>
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<td>Initial videos and presentations emphasising the benefits of semantic interoperability, and</td>
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<td>of standards</td>
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<td>Editorial guidelines and overall design for the evidence base</td>
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<td>Completed design of the evidence library, master templates for the</td>
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<td>collection/extraction of evidence, and some example content</td>
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<td>Evidence base implemented and has enough content for strong promotion at a European level</td>
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<td>SemanticHEALTH Alliance</td>
<td>Sufficient sponsorship is identified, along with champion users, to enable</td>
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<td>continued development of content for another year</td>
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<td>Establish terms of reference for the Alliance</td>
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<td>Determine example priority areas to attract stakeholder engagement, such as safer</td>
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<td>prescribing, one or two long term conditions</td>
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<td>Establish simple bilateral and trilateral alignments, involving a modest number of</td>
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<td>Formally launch the Alliance, through an Inaugural Conference</td>
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<td>Establish the modus operandi for the Alliance and a roadmap of targets and activities</td>
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<td>Funding streams identified</td>
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<td>Strategic plan and business plan, roadmap for 2016</td>
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Appendix 1: Core activities of i^HD

**Promoting i^HD and its objectives**

- Representing i^HD on key bodies and fora, at events, lobbying, PR
- Participating in public engagement, conference and workshop events
- Raising funds - promoting memberships and other sponsoring activities, research grants, infrastructure funding, consultancy
- Developing and enriching strategic relationships with relevant bodies and initiatives, within Europe and globally
- Fostering cross-fertilisation between the CoEs and between their projects, ensuring convergence and synergy, promoting their projects and identifying opportunities for new projects
- Promoting the importance of good practices, certified ICT products and accredited staff, working in partnership with EuroRec and other strategic partners
- Promoting the importance of interoperability and standards, highlighting the evidence of benefit and the success strategies for scaling up adoption
- Contributing content for communications materials and social networks, blogs etc.
**Liaising with and reporting to Board Members and the General Assembly**

- Obtaining insights into Member priorities, needs and opportunities
- Accounting for, gaining support for and encouraging the wider dissemination of Institute activities and results through its Board and Members
- Managing the finances and accounts, budgeting for the Institute and CoEs, forward planning
- Responding to decisions and other mandates from the GA and Board
- Determining annually the membership fees and member benefits

**Building synergy and consensus amongst stakeholders, fostering and enabling innovations through the better use of health data**

- Establishing and overseeing an Advisory Board for each CoE, ensuring synergy and cross-representation between them as needed
- Overseeing the Network of Excellence and the SemanticHealth Alliance, working with the CoEs
- Collating Members’ networks of networks and spheres of influence
- Working across stakeholders and decision makers on key priority uses of harmonised health data, for healthcare, for wellness and for research
- Gathering and disseminating intelligence on initiatives, projects and large-scale demonstrators of innovative health ICT solutions
- Working with the EC, the eHealth Network, IMI and other transnational bodies about research and innovation priorities and needs, and the contribution of standards, certified ICT products and good practices to these. Supporting the implementation of the Multi-Annual Workprogramme of the eHealth Network (eHN)
- Providing advice to European and national decision-makers on maximising the value they obtain from health data
- Working with patient associations and other consumer groups, alongside other interested stakeholders, to better promote the roles of ICT and health data for health promotion and wellness, including self-management by patients and the evolution of more person centred care services

**Institute management**

**Running i^HD**

- Managing office administration, office infrastructure, support to the Officers and other active Members
- Managing staff appointments and HR functions, handling contracts
- Hosting and running the website, public-facing channels, collaboration tools, specialist development and hosting tools
- Organising and running events, meetings, handling contacts
- Maintaining key contact lists, lists of experts involved in projects and Boards, stakeholder group lists, NoE and Alliance administration
• Managing Institute finances, reimbursements, book keeping and accounts, cost returns, support to the Treasurer
• Advising on IP management

Supporting the Centres of Excellence
• Providing project specific support, as needed, including logistics support, channelling experts, sourcing development and hosting tools for work products, supporting stakeholder engagements and dissemination activities
• Reporting, financial administration, cost returns, project planning support and budgeting, risk and issue tracking
• Overseeing and taking legal responsibility for certification and accreditation schemes run by the CoEs

Supporting the Executive and Advisory Boards and the General Assembly
• Administration, finance, collaboration tools

Communications

Developing communications materials
• About the Institute, including branding and key messages per stakeholder group
• About the value of research findings obtained through health data
• About the value to health, healthcare and research of interoperable and high quality health data
• About specific CoE projects
• Specifically explaining the importance, benefits and safeguards, relating to the uses of health data, to the public
• Engaging the public and other stakeholders in discussion of key issues and priorities
• Developing stakeholder-specific messages, materials and campaigns
• Maintaining social networks and communities, monitoring content and alerting Officers as needed
• Developing information and promotional resources for Institute staff, Officers and Members to use

Monitoring the i^H^D’s visibility and profile
• Planning and coordinating promotion and dissemination activities, across the Institute, including its Members and its CoE project teams
• Monitoring and responding to references made to the Institute within external fora and channels
• Tracking complementary initiatives, alerting Officers to opportunities for collaboration, potential for competition or threat
• Alerting officers of the release of drafts for consultation or published materials, for contribution or a response
• Assessing the impact of Institute communications materials and campaigns
• Conducting surveys and other Member, stakeholder or general public studies

Identifying and responding to research and innovation opportunities

Engaging in research
• Applying for research grants in response to relevant call topics
• Working closely with the CoE’s on research opportunities, and synergies with other organisations and initiatives
• Developing expertise networks and other collaborations in anticipation of relevant calls
• Contributing to the strategy of research sponsors, call texts etc.
• Monitoring the work of other research projects, and the literature, for the potential relevance of new results to the Institute

Engaging in innovation
• Establishing strong links with Standards Development Organisations to promote the adoption of standards and the future standardisation of i^HD specifications
• Establishing strong links with industry (ICT, clinical research, etc.) to promote the exploitation of Institute work including good practices and certification
• Facilitating knowledge discovery through health data, for research, for health outcomes etc.
• Collecting intelligence from Members and other stakeholders about new challenges and opportunities for the Institute
• Partnering regional and national innovations in eHealth and clinical research, providing expertise on the best usage of health data
• Promoting the consultancy services of its Members and associated experts, further advancing the objectives of the Institute

Training and education
• Identifying priority topics for education and training, for each engaged stakeholder group
• Signposting and recommending good quality educational materials and courses produced by other bodies such as universities
• Developing educational materials where gaps exist
• Holding educational events on relevant topics, independently or in partnership with other bodies
• Developing and running online courses and other online educational activities
• Developing research fellowship programmes, in partnership with academia
• Curating and maintaining a definitive health informatics online glossary, and other reference resources
Establishing the value of innovative solutions

- Defining and maintaining value propositions for i^HD and its activities, customised for each of the stakeholder groups with which it engages, including the benefits of membership
- Developing business and funding models for assets and services provided by the Institute
- Evidencing the value of semantic interoperability for seamless care, and of research using health data
- Collating success strategies for scaling up eHealth innovations
- Guiding the development of innovative and sustainable business models for healthcare and research uses of health data
- Conducting cost benefit assessments, including financial assessments, of innovations in eHealth and clinical research
- Collating evaluation methods, metrics and key indicators used to assess the cost, impact, benefits and risks from the interoperability, communication, integration and uses of health data.
Appendix 2: Centre of Excellence for Research Use of Health Data: projects

Project 1: Network of Excellence for research through health data

Objective
To foster and coordinate a multi stakeholder community involving those who collect, integrate, manage and analyse health data for research, in order to co-create and promote good practices, identify challenges needing new research and innovations, and within which to deliver education and provide accreditation.

Problem area
Many of the actors involved in various stages of the health data life-cycle leading to research discoveries operate within relatively independent sub-communities. Many of their needs and challenges are not well understood by other actors, leading to the proliferation of preventable obstacles to the efficient and cost-effective conduct of clinical research. There is instead a need for the stakeholders to work to develop collective good practices and more efficient workflows, and to promote and disseminate these through education. There is also a misalignment of incentives between stakeholders, for example in data quality, where staff to collect health data directly from patients are disconnected from those who need the data to have a high enough quality to be fit for research purposes.
Current situation

External environment
There are existing fora and communities that unite particular stakeholder groups collectively, some operating at a European level or internationally. However there is a gap in the “market” for a multi-stakeholder network.

Capability and resources
Many of the partners involved in EHR4CR, and in some other European projects that are innovating in the research uses of health data, have started to gain an understanding of the perspectives of the different stakeholders involved in the health data life-cycle, and could be well-placed to help promote the importance of a network of excellence, and encourage membership of it.

Value

Sponsors
This NoE is likely to operate as a peer-to-peer network, and may not have a distinctive sponsor of the network as a whole.

Adopters, users
By necessity NoE needs to have multiple stakeholders involved, including but not limited to research sponsors, CROs, research units, health data aggregators and the ICT vendors of research platforms and products.

Collaborations, partnerships
The NoE will need to partner all of the engaged stakeholders, but may additionally partner educational establishments such as universities who deliver relevant courses that could be promoted by the network.

Activities
The first step will be to define the value proposition for participating in the NoE, for each of the key stakeholder communities. The Advisory Board for this CoE may provide valuable guidance on the value propositions, and on the top priorities that the network should engage in during its first year or so.

Milestones
To be determined

Communications
The network should be able to use many of the promotional materials and good practices developed through other activities of the Institute.
It will additionally need its own social network to help build up community interaction.

Resource needs
NoE co-ordinator 2 days per month
Administrative support and online tools support 1 person month
Other resources to be determined, depending upon the activities undertaken by the network additionally to those listed elsewhere in this plan
**Budget**
To be determined

**Revenue sources**
Initially this will need to be core funded from Institute (membership) revenues
**Project 2: Best practices in information governance**

**Objective**

To maintain and promote codes of best practice in information governance, privacy protection and ethics for the uses for health data, especially for research but also for cross-border healthcare and public health. To work with key decision makers and influencers to agree good practices that balance societal benefit and personal privacy.

**Problem area**

Despite increasing recognition of the value of reusing health data, when aggregated and de-identified, to discover new knowledge and to inform healthcare services and planning, anxieties about the protection of patient privacy seem to dominate attempts to develop appropriate policy and strategies. Individual initiatives, programmes and projects examine seemingly similar legislation at European and national levels, to tackle seemingly similar intentions for data reuse, and yet encounter obstacles that delay and hamper such reuse, without learning from others or growing a body of good practices that can be promoted and adopted at a European level. Publicity material about research tends to focus on the exciting discovery, and rarely mentions that health data have been used in order to discover that knowledge. Societal discourse about using health data, and personal data in general, focuses in an unbalanced way on the rights of individuals to privacy without exploring the benefits to populations from reusing the data, and the potential harms that are propagated through not using the data.

**Current situation**

**External environment**

The European Commission and IMI are concerned to help their sponsored projects to adopt common and trusted information governance practices, and to learn from each other. Meanwhile Europe is preparing a new Data Protection Regulation that is expected to tighten the constraints on pseudonymisation, which is a critical tool to support longitudinal and heterogeneous data linkage. Several countries have funded “big data” health projects, and are also embarking upon the development of codes of practice. In parallel, there is significant research being undertaken globally in privacy protection, privacy enhancing techniques, and privacy protecting linkage.

In parallel European and transatlantic eHealth initiatives are examining the consents and authorisations that are considered necessary, at a European level and across the Atlantic, to enable cross-border healthcare services that require the sharing of relevant patient-level health data.

For cross-border services, the Connecting Europe Facility (CEF) is defining a set of common identity and authorisation services that could be used by healthcare but which will need customisation to accommodate the implied consent model which predominates in health care, and to enable the communication of de-identified health data.

There is an increasing recognition of the important role of patients in supporting their own health and wellness, and also of their right to determine access to their health data. However the measures necessary to empower patients to decide upon healthcare data
disclosures, and to balance these rights with the need for largely automated information flows in urgent health care situations, are as yet poorly defined.

**Capability and resources**

Through the convergence initiative, and more recently through collaboration between EHR4CR and EMIF, useful information governance documents are being produced, including risk assessments and codes of practice. The projects are bringing together relevant European experts to examine how information governance best practice can be defined, and appropriate information security measures implemented, so as to demonstrably protect privacy whilst enabling knowledge discovery.

Several experts who are expected to work closely with the Institute have experience in the definition of access policies, privacy protecting and enhancing techniques, information governance, ethics and audit.

**Value**

**Sponsors**

Progress in this area is critical to the successful use of health data for research. Pharma and sponsors of “big data” research are expected to be significant sponsors of this activity. The solutions will be relevant to their interests in the improved efficiency of clinical trials, and uses of “real world data”.

**Adopters, users**

Ethics and information governance experts, and experts in information security, will be needed to define the codes of practice, policies, methods and other instruments. The ICT industry, healthcare professionals and patients are important users to consult with and to champion the developed solutions, since these stakeholders will be the primary implementation adopters and users.

**Collaborations, partnerships**

Patient associations and others representing the interests of patients and the public are important collaborators to consult with, and to ensure acceptability of the approaches and instruments developed. Health ministries and other public bodies will also need to endorse and promote the solutions, and so must be collaborators during their development.

**Activities**

The first step in producing a comprehensive approach is to conduct a risk assessment of the various types of health data, information flows and purposes of use that are in scope for this activity relating to the use of health data, initially for research and public health purposes. Since there is much ongoing work to develop good practices and codes, a parallel step is to construct an inventory and profile of the various instruments that exist or are in development through a number of European and national projects. This inventory should be supplemented by a literature review, which is regularly updated. From these a roadmap needs to be constructed for consolidating and harmonising the best of these existing instruments, and for identifying important gaps that need to be filled by the development of new instruments.

Throughout this process consultation with key stakeholder groups and public engagement activities should be undertaken, to prepare Europe for acceptance and support of using
health data more extensively for research, and to better understand the genuine concerns that need to be met through governance processes.

Provide advice to European and national governmental agencies on where to better harmonise legal and regulatory stipulations and policies.

**Milestones**

2015 04: risk assessment matrix covering the various life-cycle points of health data supporting its use for research, mapped to existing instruments either published or in development through existing projects.
2015 07: initial materials covering EHR4CR and EMIF use cases, to define good conduct and appropriate information security measures, accompanied by initial educational materials.
2015 07: stakeholder consultation programme defined and ready to commence.
2015 09: initial literature review completed, and plans for its maintenance
2015 10: gap analysis and roadmap for the development of key instruments that are outstanding in order to define a reasonable, pragmatic and acceptable information governance and information security framework using health data for research, at a European scale.
2015 11: funded work programme to develop the missing instruments, to refine the existing ones, and to develop materials derived from them for training, procurement, and the certification of research systems.

**Communications**

This activity needs to be communicated well. One category of materials are those that describe and explain the various instruments that have been developed, and educate various types of user in appropriate conduct. Another category of materials are those that promote the value of research, the appropriate ways in which health data can be used, and the ways in which good practices and security measures can protect the privacy of individuals whilst enabling that reuse.

**Resource needs**

Project lead 1 day per week
Experts to review or develop materials (probably up to 10 experts at ~ 12 days each)
Literature review(s) 1 person month
Production of educational materials and guidelines, public consultation channels ~ 20K
Production of certification related materials to be included within the costing of that activity

**Budget**

~150K

**Revenue sources**

Some support from existing projects, such as EHR4CR and EMIF, combined with income from Institute membership fees.
Project 3: Certification of health research platforms, services and tools

Objective
To develop and deliver, in partnership with EuroRec, quality labelling criteria, a test plan and certification process for platforms, services and tools supporting the reuse of health data for research. (This will initially focus on certifying conformance to the EHR4CR specifications.). To maintain and publish the specifications of services and interfaces for clinical research platforms and tools, to which conformance can be tested.

Problem area
The opportunities from reusing health data for research are well recognised, and there are an increasing number of vendor-specific and generic components that can support the analysis of health data, for example for data mining or specific research questions, or which use electronic health record information to improve clinical trial efficiency. Because most of these purposes are not supported by explicit patient consent, they are undertaken using some combination of anonymisation, pseudonymisation and data aggregation. The quality of these systems is important to ensure that high-quality research is conducted on the data, and also that public trust in the protection of privacy can be assured. The quality labelling and formal certification of such systems and system components will play an important role in safeguarding that quality and public trust.

Current situation
External environment
EuroRec has the most substantial collection of quality criteria for electronic health record systems, primarily supporting direct clinical care and to some extent public health purposes. EuroRec also has a suite of tools that can enable a profile of the quality criterion statements to be used for testing and certification purposes, as well as for procurement and system documentation. IHE is the other organisation at a European level that undertakes system testing, primarily limited to tests of technical interoperability in conformance to its published profiles. Apart from the US, no other parts of the world have established detailed definitions of EHR system quality, nor undertaken tests at a national level across suppliers for the purposes of certification or qualification for reimbursements.

Capability and resources
The EHR4CR Software Requirements Specifications for Protocol Feasibility and for Patient Identification for Recruitment are substantial and relatively mature specifications of the functional and non-functional requirements to be met by a clinical research platform supporting these two EHR4CR services. During the final year of the project conformance criteria are being derived from these requirements specifications. These conformance criteria are largely complementary to those already held by EuroRec for EHR systems, and could be combined with them for the testing and certification of clinical research functions when provided by an EHR system vendor.

The EHR4CR specifications will be updated and made publicly available by the end of the project, and the Institute will take over and maintain the specifications, updating them as necessary in the light of new requirements and of experience gained in their use.
Value

Sponsors
The direct sponsor of the establishment of a formal certification program, by paying for obtaining a certificate, will be suppliers of clinical research platforms and service interfaces. The indirect sponsors, who will probably support this function as part of the Institute as a whole, will be consumers of clinical research data: the Pharma industry, CROs and data aggregators.

Adopters, users
Health ICT companies that develop and sell clinical research platforms will be the primary users of this certification program. However the sponsors of clinical research may indirectly act as adopters by requiring certification products used to conduct their research.

Collaborations, partnerships
This activity primarily needs to be undertaken as a collaboration with EuroRec, initially drawing on partners of the EHR4CR consortium who have been active in the development of the SRS documents.

Activities
In-depth examination by relevant EHR4CR partners, of the EuroRec quality labelling statements, tools and testing workflows.
Reciprocal examination by EuroRec quality labelling experts at the EHR4CR SRS documents, to advise on the appropriate construction of practically testable quality criteria.
Development of a standalone profile of clinical research platform criteria, initially targeting conformance to the published EHR4CR specifications.
Development of an integrated profile for EHR system testing where the system offers clinical research functions, initially for protocol feasibility assessment and recruitment into clinical trials.
Active promotion of the importance of quality labelling and certification to all stakeholders involved in reusing health data for research.
Specific work with early platform service providers on a roadmap for extended clinical research functionality and for corresponding quality labelling criteria.
Specifications for other research components and services, usually developed by other European projects, are also expected to become part of the library of research specifications maintained by the Institute. These will in turn require complementary conformance criteria and certification processes.

Milestones
2015 03: initial draft of quality labelling criteria extracted from the Protocol Feasibility SRS, and a roadmap for compiling a complete set of criteria for both commercialised services during 2015
2015 06: proposed quality testing and certification process jointly agreed between relevant EHR4CR partners and EuroRec
2015 09: framework agreement between the Institute and EuroRec to enable EuroRec to undertake testing and certification of clinical research platforms, initially for EHR4CR Service
Providers.
2015 12: first certificates issued to operational EHR4CR Service Providers

Communications
Communications need to focus on promoting the importance of quality labelling of systems and services used for clinical research, and of the importance of using certified products. This Communications activity overlaps substantially with the role of EuroRec in promoting the importance of quality labelling for direct patient care, at a European level, and should be undertaken jointly.

Resource needs
Project lead 2 days per month
Development of quality labelling criteria: 3 person months
Development of testing program and certification procedure: 1 person month
Operation of testing and certification for initial service providers: 1 person month
Contribution to the joint promotion activities with EuroRec: 10 K

Budget
70k

Revenue sources
Most costs during 2015 should be met through a budget allocated by EHR4CR. Certification income estimated at 20 K in 2015 (due to limited number of Service Providers and products to be certified).
Project 4: Accreditation of clinical research staff

Objective
To develop and promote, in partnership with UKCHIP and ECRIN, a code of practice for staff using health data for research, and provide an accreditation process to recognise the necessary skills in clinical research staff.

Problem area
There are important information governance, privacy protection and research governance (data and analysis integrity) expectations on staff who handle health data during the course of conducting clinical research, whether working only with data or also in the conduct of clinical trials. At present there is no way in which these skills can be formally recognised, at an individual level, and cited in CVs and job applications, or used by a research organisation to verify and demonstrate the competence of its staff.

Current situation
External environment
Existing clinical research accreditation primarily targets research organisations and centres, but not individual staff members. Existing health informatics certification primarily focuses on the appropriate training and skills to use health data and ICT systems in a direct care context. There is therefore a gap in the recognition of staff using health data for research purposes, who may be working within direct healthcare organisations or research centres.

Capability and resources
UKCHIP has been working within EHR4CR to develop a draft code of practice and assessment criteria. ECRIN has been consulted on this work and care has been taken to ensure that it does not duplicate the ECRIN accreditation procedure, except for criteria that are also appropriate to demonstrate the level of the individual.

Value
Sponsors
Although filling an obvious gap, the accreditation of staff in this context will introduce a new layer of accountability. It is therefore likely that accreditation will initially be voluntary, but promoted strongly to the sponsors of research in the hope that it will eventually become part of “good clinical practice”.

Adopters, users
Those seeking accreditation will be staff working in healthcare organisations or clinical research sites, responsible for handling identifiable, anonymised, pseudonymised and/or aggregated health data. Staff managing the clinical research activities within research sponsor organisations are also candidates for this accreditation.

Collaborations, partnerships
The code of practice, accreditation criteria and process need to be well aligned with those already undertaken by ECRIN, by UKCHIP and by corresponding national bodies in other European Countries (such as HISI in Ireland), and ideally promoted by them.
Activities
Finalisation of the code of practice, initially within the EHR4CR project.
Finalisation of the assessment criteria and of an assessment process (initially likely to be a self declaration process with employer endorsement).
Development of tools, probably web-based, to enable staff to declare competence and trigger the awarding of a certificate of accreditation.
Active promotion of the value and importance of staff accreditation, targeting research sponsors, research centre managers and research staff.
Development of educational materials for staff about the accreditation process and development of, or pointers to, resources such as educational materials about the skills needed to meet the accreditation criteria.
Later, a widening of the assessment criteria to cover the skills needed for a wider range of research activities using health data.

Milestones
2015 03: final version of the code of practice
2015 05: final version of the assessment criteria and assessment process
2015 09: assessment tools and web site in place
2015 10: accreditation procedure is live
2015 10: roadmap for the evolution of the accreditation procedures and criteria

Communications
Promotional material is needed for research sponsors, research centre managers and staff about the value and importance of this accreditation. Some high-level educational material is needed about the content of the accreditation.

Resource needs
The initial development work is already funded through the EHR4CR ENSO contract. Some additional resources will be needed for finalising the materials, developing the online tools and for developing promotional material.

Budget
~ 20k

Revenue sources
Will initially need to be supported by the Institute from core funds, as direct sponsorship or accreditation fees are unlikely to be substantial
**Project 5: Governance oversight of clinical research platform service providers**

**Objective**
To provide an independent oversight body governing the ecosystem in which health data are used for research, through Institute-certified ICT products and services.

**Problem area**
It is important to secure and maintain public trust, and the trust of all organisations handling health data for research, when new-generation platforms and services are being used, such as those developed by EHR4CR (and in future other initiatives such as EMIF). The Institute will provide certification for products conforming to the specifications that it has published, but despite the use of certified products there are governance risks that may arise due to human error, or to unexpected issues with the systems, the specifications or the data. Although these may be detected and handled appropriately by service provider organisations, there is a need to provide an independent oversight in order to assure public confidence and to enable the research ecosystem to thrive.

**Current situation**

*External environment*
EHR4CR will be introducing a novel platform that connects multiple hospitals across Europe, to be operated by one or more certified service providers. There is no existing independent body to which the service providers would be accountable, nor any existing body equipped to monitor the information flows and potential for privacy breaches in a distributed European system.

Each participating hospital will have privacy protection officers and teams handling the security of health information within existing systems. It may be beyond the expertise or capacity of these parties to also monitor the EHR4CR information flows.

*Capability and resources*
EHR4CR is developing governance instruments that will include procedures for monitoring audit logs, receiving notification of potential or actual breaches of privacy, and for handling these including appropriate escalation measures.

**Value**

*Sponsors*
The sponsors of this body and its activities will be the research sponsors and service providers operating and using clinical research platforms, initially the EHR4CR platform.

*Adopters, users*
All of the stakeholders connected with the use of health data for research will be interested in endorsing the work of this oversight body, and possibly being members of it or reviewing its periodic reports.

*Collaborations, partnerships*
All of the stakeholders are important, but it will be especially valuable to forge strong links with patient associations and privacy protection agencies at a European level and within
individual being countries. Hospital privacy protection officers are also critically important. Healthcare professional associations and representatives of research investigators will also be important collaborating bodies, since they will require confidence as well, in making their data available through research platforms.

**Activities**

Establish the terms of reference and initial constitution of the oversight body.

Review and adapt as necessary the governance instruments developed by existing initiatives such as EHR4CR, to provide an acceptable framework for monitoring the clinical research data ecosystem.

Operate the oversight body, and publish reports of its activities via appropriate, publicly accessible, channels.

Consult with the oversight body on the key messages that promote the value of research conducted using our data, and the approaches being promoted as best practice in protecting privacy.

**Milestones**

2015 05: agreed terms of reference and initial constitution of the oversight body
2015 10: first meeting of the oversight body, and initial public materials about its function and approach

**Communications**

This body will need to explain its purpose, constitution and actions via regular publicly accessible bulletins, probably on the web. Members of the body may also contribute to publicity materials and promotional materials about the work of the Institute, in a number of areas.

**Resource needs**

Primarily fees for members participating in activities of the oversight body, estimated at 10 persons, 6 days per annum, plus some administration time.

Costs for developing promotional materials, website etc will be incorporated within the overall Institute communications costs.

**Budget**

~70k

**Revenue sources**

Institute membership fees
Appendix 3: Centre of Excellence for Semantic Interoperability: projects

Project 1: Quality labelled interoperability asset register and infrastructure

Objective
To provide a central reference point to discover which interoperability assets may be used, together, to tackle a particular use case. To develop and maintain a set of services that can support the publication, real-time discovery and access to interoperability asset bundles. To thereby facilitate convergence and reuse of existing assets, in preference to reinvention.

Problem area
Many different assets may be needed to address a particular interoperability use case. These will usually have been developed by different organisations, might not easily work together, be at different levels of maturity and vary in the extent to which they can be customised for particular needs. There is limited guidance on how to use individual assets, and how to use them together. Because individual assets come from different sources, some are hard to obtain, examine or adopt, and may require convoluted licensing arrangements. The lack of knowledge of what assets exist, or difficulties in gaining access to them, often result in research groups and other initiatives inventing their own equivalents. This leads to standards and specification fragmentation, hampering the scaling up of interoperability at a European level.
Current situation

External environment

The Joint Initiative Council provides a forum to enable SDOs to be mutually aware of forthcoming standards, and to collaborate where needed. This body does not seek to align the strategy of each SDO, and does not exert a strong influence to ensure harmonisation between standards that have overlapping scope or which will need to be used concurrently.

CEN is now seeking to position itself as a body that brings together SDOs at a European level, and is likely initially to focus on facilitating dialogue and mutual awareness of standards, and might coordinate the development of some future standards of strategic European importance. CEN has been proactive in developing concurrent use guidance on how to use multiple standards together.

IHE develops profiles of standards, and sometimes develops additional quasi standards, to solve technical interoperability use cases.

There is no single point of reference that maps interoperability use cases to the necessary assets, and none which includes assets that have been developed by non-SDOs. There is no easy way to acquire evidence of use or guidance on how to successfully use the assets.

Accessing the multiple assets that may be needed to address the particular use case can itself be challenging, due to the many different publishers involved, each having independent licensing agreements and possibly different charging structures. In the case of non-standards there maybe no robust maintenance organisation to ensure a potential user that they have the most up-to-date version of the asset.

Capability and resources

SHN and EXPAND are working jointly on an Interoperability Asset Register. Over 40 European experts have already contributed to brainstorming and focus groups, confirming the value of this proposed register and the kind of asset descriptors and register functions that would be most useful. A first pilot version of the register has been implemented, and critiqued. Both projects have a work plan and some funding to continue working on this.

During 2016 EXPAND will also focus on the quality labelling characteristics of assets.

The unique value of this proposed register will be in the way bundles are constructed and linked to use cases, and the supporting information that evidences the maturity and value of the assets, and facilitates their successful adoption.

Value

Sponsors

A register that maps diverse assets to use cases, as "asset bundles", and provides links to guidance and adoption experience, is most likely to be sponsored by national or regional eHealth programmes. This might be through annual support grants to the register as a whole, or through the commissioning of content to address a sponsor’s priority use cases.

Healthcare funders might sponsor the generic register or sponsor the development of specific bundles.

Patient organisations and other charities might also be sponsors or champions of particular use cases.

Research projects, for example focused on rare diseases, might also fund the development of an asset bundle.
Adopters, users

There are several envisaged users of the register:

- eHealth programs that wish to specify their intended approach to interoperability, or to specify conformance criteria
- Vendors of EHR or other eHealth ICT solutions
- Research projects or other initiatives that will take and build on some existing assets, with the intention that this thereby encourages convergence across projects on common assets and reduces reinvention of assets addressing similar purposes
- Those procuring systems and services, who wish to nominate the assets to which procured systems must conform
- User communities, academic research groups and students wishing to gain a better understanding of particular aspects of interoperability.

Collaborations, partnerships

The first critical partnership to establish must be with asset developers, including SDOs and European research projects. SDOs in particular must find that the register helps to promote their standards and encourages successful adoption experience. European projects should find that this register, as part of the Institute as a whole, helps support the sustainability of their interoperability results.

A second critical partnership must be some champion users, who will promote the value of the register as well as potentially sponsoring it.

Regional or national programs have the potential to contribute information about adoption experience, guidance on use and benefits obtained.

Activities

Finalise the specification of the descriptors of quality of an interoperability asset, tailored to different asset types, validated by example asset developers.

Specify constituents of an ideal asset bundle, as a fully integrated solution (toolkit) comprising the use case specification, relevant interoperability assets, translations of terms, guidelines for use, educational materials, legal frameworks and governance specifications, and evaluation metrics.

Formalise criteria and a multi-axial quality label for interoperability assets, along with useful visualisations, validated by example candidate end users.

Develop and implement a quality labelling process.

Implement the online asset register, with browse and search functions, meeting a consensus of user requirements. Develop import, export and service interfaces.

Agree priorities and a roadmap for the development of asset bundles, and identify champion users of them.

Establish a content creation and maintenance strategy that will result in the register being rich in useful content.

Seek sponsorship of, and actively promote, the register and grow a community of use, including ways to encourage community contributions to the evolution of assets.
If the register proves to be a useful resource, it may provide significant added value to also negotiate standard licenses for the assets of different organisations, so that a potential user can use this register as a “one-stop shop” to obtain legitimate access to multiple assets. Finally, if the register either contains or references the most up-to-date assets for each of its bundles, accessible through web services, it then becomes a European info-structure for interoperability assets.

**Milestones**

2015 05: finalised design and initial prototype version of the register, demonstrating asset bundles and quality labelling visuals.
2015 05: defined content for a heart failure shared care asset bundle.
2015 09: quality assessment framework in place for all kinds of semantic asset.
2015 10: content creation roadmap in place and advanced progress being made on at least two other asset bundles.
2015 12: national programme sponsorship package in place and well promoted.
2016 06: the register is acting as a focal point for European project sustainability and is a successful promotion vehicle for SDOs.
2016 09: specifications and agreements with standards publishing bodies to evolve the register into a one-stop access point to license and download interoperability assets, through online services.

**Communications**

Materials promoting the importance and value of semantic interoperability in general.
Video demonstration of the asset register.
Video interviews with standards developers, national programme architects and industry emphasising the importance of such a register.
Social media channel to attract proposals of, and gain consensus on, priority use cases, and to grow interest in sharing adoption experience and useful guidance on implementing the interoperability assets.
Demonstrations of the asset register at events where European projects are participating, to increase awareness and invite contributions of project results into the register.

**Resource needs**

Leader/champion: 2 days per month
Asset register design: 2-person months
Asset register implementation: 3 person months
Development of communications materials: 0.5 person months
Development tools and web hosting: may be supported by EuroRec and RAMIT.
Note: some of these costs will be chargeable to SHN, EXPAND and VALUeHEALTH.

**Budget**

50k in 2015, 20k per annum thereafter. This might largely come from SHN & EXPAND budgets. Estimate half of these sums will be needed as additional funds.

**Revenue sources**

Sponsorship target TBC
Project 2: Best practices in interoperability asset development

Objective
To foster the development of good quality semantic interoperability assets that are well-suited to addressing high priority use cases for sharing health information, and well-harmonised with other assets addressing the same use cases.

Problem area
Informatics standards have historically been developed by informatics experts, with moderate input from domain experts such as healthcare professionals. In contrast healthcare professionals have been largely sceptical or disinterested in contributing to the development of interoperability standards, even those representing the semantics of their domains of interest. Many of our present day datasets and terminology systems have been designed with the primary objective of directing healthcare resources or reimbursement, rather than supporting the direct care to individuals or the discovery of knowledge about populations of patients.

The practices for engaging healthcare professionals and other relevant stakeholders, and admittedly rarely patients, in the development of semantic assets is variable, and the method of their engagement is poorly documented. This limits the generalised acceptance and uptake of semantic assets that have been developed by dedicated communities. Healthcare professionals are now contributing to the development of professional guidelines, but these usually lack any semantic interoperability assets such as clinical models or term lists. The procurement of eHealth systems such as EHRs largely omits or glosses over the specification of semantic interoperability standards.

Current situation
External environment
Almost every stakeholder now involved in healthcare delivery recognises the importance of high-quality consistently structured and semantically computable health data. There is therefore a growing recognition of the need and a momentum, that is presently diffuse but could be focused at a European level, to grow capacity and instil good practices in the development of semantic assets.

There is emerging good practice from several sources, including ISO, the openEHR Foundation, CIMI and work championed by SHN. A little may be found in the academic literature. Some of this work is linked to specific kinds of asset, produced by particular bodies, and is not generalisable.

There is no single body collating good practices and developing educational materials that could allow more distributed sets of multi-professional teams to work to consistent quality practices when developing semantic assets.

Capability and resources
Many of the experts involved in the SHN SSI Task Force have been involved in the development of good practices and standards in this area. SHN has therefore already begun the process of consolidation, which could be widened and made more complete with modest effort. However, more empirical evidence is still needed on the most effective practices for wide-scale engagement and endorsement.
**Value**

**Sponsors**
The most likely sponsors of this work would be groups wishing to develop semantic interoperability assets and to do so by adopting good practice. Such sponsoring stakeholders would include national eHealth programmes, healthcare funders, bodies sponsoring the development of clinical guidelines, healthcare professional bodies and to a lesser extent EHR system vendors.

**Adopters, users**
Healthcare professionals would be the most important community to engage with when undertaking this work, since their domain expertise is required to create relevant assets and their support is needed to champion their wide adoption. Additional groups to involve are patients, public health bodies and healthcare funders who will need to ensure that the data collected using these assets will also serve their needs. The health ICT industry is also important, as this stakeholder will be responsible for implementing semantic assets and therefore making them available to end users.

**Collaborations, partnerships**
Key partnerships to undertake the work will be healthcare professional associations, guideline development agencies and SDOs.

**Activities**
Develop a conceptual framework for semantic assets and for their quality processes and assurance.

Collate existing good practices, guidelines and other empirical evidence, mapped to the conceptual framework. Focus on practices that have resulted in assets are readily implementable, and when deployed minimise disruption to health care professionals whilst facilitating the capture of good quality and consistently structured health data. Explore in particular how semantic assets can best support adoption of and adherence to guidelines and care pathways, and support health professionals with compliance to their professional standards.

Produce simple guides, checklists and tutorials to promote the importance of quality processes and help to grow awareness of the basic components of good practice, for different kinds of semantic asset.

Work with SDOs on how to optimise alignment of standards, especially across standards bodies, that will need to be used together.

Develop online educational materials, toolkits, a social network, and possibly online courses in semantic interoperability, in asset development and use.

Consider running workshops and focus groups, stand alone or as satellite events attached to mainstream conferences, including at least one high-profile event per annum.

Work with the Alliance to establish communities of practice actively developing semantic assets across Europe, who will grow libraries of use cases, criteria for prioritisation, and experiences of success in meeting them, and also grow our evidence of effective practices.

Work with the developers of semantic asset tools to embed best practices within authoring tools.
Milestones
2015 03: conceptual framework for good practices and quality processes.
2015 04: inventory of existing published good practices, and initial correlation of key points from them.
2015 06: establish collaboration agreements with key bodies working on semantic asset quality processes, design guidelines and training materials.
2015 10: Publish consolidated good practice guidelines in key areas of semantic asset development, accompanied by initial educational materials such as checklists and workflow diagrams.
2015 12: hold a community building event such as “crossing the chasm”.
2016 03: establish communities of practice, working to consistent guidelines and quality standards, and contributing to their evolution.

Communications
Initial communications, for spring 2015, should focus on promoting the importance of semantic interoperability, and the need for clinical engagement in particular. It may also highlight the importance of semantic assets to complement the adoption of clinical guidelines.
Later in 2015 we should aim to have good educational materials about the main methodological aspects and quality processes required for the development of semantic assets. We should then use multiple channels to grow communities of engaged stakeholders developing or reviewing semantic assets.

Resource needs
Leader/co-ordinator: 2 days per month
Good practice evidence collation: 3 person months
Educational material production 1 person month

Budget
50k in 2015, 20k per annum thereafter

Revenue sources
Seek sponsorship for this activity as part of the Institute as a whole
Project 3: Semantic interoperability evidence base

Objective
To collate and synthesise worldwide experience and learning of success strategies for scaling up semantic interoperability, of demonstrating value and deriving benefits from sharing and analysing semantically interoperable health information. To contact the evidence in favour of the use of standards.

Problem area
It is expensive and complex to implement interoperable EHR systems, to develop and disseminate good practices in the systematic and consistent documentation of health data, and to grow the systems and culture of making good use of shareable computable health data. Most health ICT investments are slow to deliver benefits, and it is especially difficult to demonstrate benefits from ICT solutions when richer socio technical change is needed to achieve them.

There are many perverse incentives not to adopt standards, many of which are locked into antiquated models of health care reimbursement, antiquated models of procurement and antiquated supplier relationships with customers. Standards bodies publish standards, as individual assets, but we lack a multi-standard neutral organisation to promote the value of standards as a whole, and to highlight targeted use cases where standards can play an important enabling role.

There is a threat to the future investments in health ICT because large scale implementation projects are now perceived as high risk and not to deliver tangible benefits within a politically acceptable timeframe.

Many research projects and pilots that do undertake innovative interoperability initiatives lack the budget and time to undertake good-quality evaluations, limiting the global body of available evidence.

There is a need to better harness the best available evidence in order to optimise future strategic investments, to promote and direct standards adoption, and thereby to accelerate the delivery of benefits.

Current situation
External environment
Many of the scaling up challenges are common across diverse healthcare environments, but experience is difficult to share. Mistakes are rarely documented, and are therefore repeated all over Europe and globally.

The academic literature is the main published source of health informatics experience, but is biased towards successful endeavours and largely reports on pilots, without an adequate evaluation of them.

Management consulting firms tend to carry out ad hoc investigations from example case studies, but sometimes lack the domain expertise to extract the most important learning points from their investigations. They are rarely resourced to develop educational and dissemination materials from their reports.

The high turnover of personnel in public bodies and large industry makes experiential learning difficult to sustain and propagate.
There is therefore a need to formally capture the experience, learning, success strategies and warnings, from across large-scale pilots and large-scale deployments. This information needs to be collated in a systematic way, and provided through a single point of reference, although disseminated through many different media and channels. An important early focus for this evidence should be on strategies for the successful use of interoperability standards.

**Capability and resources**

Our existing collaborators, for example in the SSI-TF, comprise many experts who could provide advice on the kinds of evidence that would be most useful and most persuasive to decision-makers. They could provide guidance on the design of the database, its evidence descriptors and vocabularies. Several of us have experience of conducting literature reviews and of synthesising case studies and other evidence inputs, in this area. We also have expertise in supervising student research, for example at MSc and PhD level.

**Value**

**Sponsors**

Purchasers of health ICT solutions are the most likely sponsors of an evidence base to inform their strategic decisions. The link between better quality evidence and more successful procurements of interoperable functionality is at best tenuous, and sponsorship might therefore initially be through a consultancy route via the Institute, in which the consultants grow the evidence base as an underpinning to their consulting activities.

**Adopters, users**

Many stakeholders are likely to use a publicly accessible evidence library, and to access educational materials presenting good-quality guidance, such as videos, presentations and checklists. These would include health ministries, health care centres, health ICT vendors, professional bodies, public health authorities, patient associations, academic organisations and management consultants.

**Collaborations, partnerships**

The most important strategic partnerships to make will be with those bodies most likely to have useful experience and learning that could be documented and shared. This will include many of the stakeholders listed as users.

It will be especially important to find win-win collaborations with academic institutions, to enable them to also create and publish literature in this field that complements and probably feeds into this evidence base. It is important for this not to be seen as a competitive endeavour to academia. SDOs can also help contribute to this evidence base by finding and referring case studies that have successfully used their standards.

Procurers of health ICT solutions will be amongst the most important users of this evidence base. This will not be limited to see staff developing the procurement contracts themselves, but needs to include all of the advisory experts who contribute to a procurement decision. The Alliance (specified in another part of this work plan) may be used to obtain advice on the kind of information, granularity and formats of greatest impact to support procurement decisions.
Activities
Collect and synthesise evidence frameworks: existing systematic reviews, best practice guidelines, well-regarded case study reports and data collection templates. Also include evidence on quality and safety gaps in care caused by poor quality information sharing.
Define the overall structure of the evidence base library, including a conceptual model for needs, adoption, scale up and success strategies, incentives, lessons learned, costs and benefits.
Define the corresponding classification axes, descriptors and vocabularies, and key search functions.
Develop a content creation strategy and roadmap, and identify initial resources (persons and materials) for the early content. Develop templates to collate case study experiences.
Develop standards adoption guidelines, illustrated with successful case studies.
Actively promote the evidence of benefits, as these emerge, to help stimulate the market for good-quality health ICT products and for their successful use.
Promote the evidence base itself and its anticipated value to potential sponsors of it.
Develop some early example educational resources (presentations, diagrams, checklists, videos) to promote semantic interoperability, grow communities of practice, and also promote the Institute as a whole.

Milestones
2015 05: initial videos and presentations emphasising the benefits of semantic interoperability, and of standards, illustrating important lessons learned, using experience from existing network colleagues.
2015 09: editorial guidelines and overall design for the evidence base
2015 11: funding, in-kind support or student projects identified to generate initial content for the evidence base.
2015 12: completed design of the evidence library, master templates for the collection/extraction of evidence, and some example content extracted from well regarded publications.
2015 12: first version of standards adoption guidelines
2016 03: evidence base implemented and has enough content for strong promotion at a European level, accompanied by a wide range of educational resources.
2016 06: sufficient sponsorship is identified, along with champion users, to enable continued development of content for another year.

Communications
From summer 2015 this workplan should produce a steady stream of presentations, flyers, checklists, web blogs and videos showcasing success stories of different facets of semantic interoperability (design, standards adoption, deployment, benefits etc.)
In order to be successful and sustainable it must grow a momentum, and provide a channel, for self reporting by large-scale pilots and implementation programmes.
Consider hosting a social network dedicated to sharing experiences of tackling interoperability challenges, and of success strategies.
**Resource needs**
Leader/champion, preferably with academic skills, to oversee this endeavour: 2d per month. Potentially several people, could be junior, to carry out evidence extraction from published reports and websites, and potentially conducting structured interviews: 6 person months. May be able to use off-the-shelf (open source) tools to structure and host the evidence base itself. Development of materials such as videos and good-quality diagrams will need A/V support.

**Budget**
35k in 2015
35k in 2016
20k per annum thereafter. This work is not covered by existing project budgets or work plans.

**Revenue sources**
Consulting or sponsorship target TBC
Project 4: SemanticHEALTH Alliance

Objective
To host and co-ordinate a network of stakeholder communities that collaborate to enable the development and successful adoption of relevant and usable semantic interoperability standards

Problem area
Much of the development of semantic interoperability standards and other assets is led by informatics experts with modest input from domain experts and example users. Most asset development bodies have their own network of such domain experts, who are often also enthusiasts for health informatics, and therefore do not always represent the opinions and needs of the majority of users. Many stakeholders such as patient associations are notably absent from such fora, and other stakeholders such as healthcare funders have limited engagement.

Current situation
External environment
SDOs are starting to work together, and some bodies such as IHE help to bring SDOs and the health ICT industry together, but no organisation has yet taken the lead to bring multiple stakeholders together to ensure future standards are well suited to priorities and needs.

Capability and resources
SHN has already established an example network of stakeholders to collaborate on heart failure interoperability. This has proved challenging, and to some extent SHN has more experience of the difficulties than of success strategies, but is in a good position to build on this knowledge. The new Institute can offer a hosting environment that is largely neutral of vested interests, to facilitate multi-way discourse and joint working across stakeholder groups. It can also develop and promote good practices in such cross-stakeholder collaboration.

Value
Sponsors
There is no clear single sponsor of this Alliance, and it may require supporting funding from the Institute as part of its overall business case. However SDOs may be willing to provide in-kind contribution, through the secondment of experts to participate in Alliance activities. Once the Alliance becomes an active community for the development and creation of assets and asset bundles, those activities are likely to be sponsored by healthcare funders, as specific asset development projects.

Adopters, users
The products arising out of this Alliance are likely to be educational materials that the Institute can use, and standards and specifications produced by other bodies such as SDOs.

Collaborations, partnerships
By its very nature, this Alliance will require partnership with all relevant stakeholders, who will each need to perceive a value in participating.
**Activities**

Establish terms of reference for the Alliance, making clear how this will not replicate the existing activities of standards bodies or of standards harmonisation bodies such as the JIC. Include within these terms of reference strategies for cooperative licensing arrangements, and how to handle conflicts of interest.

Work with professional bodies, patient associations, payers and ministries to agree on a few initial national & EU priorities for seamless continuity of healthcare, that will benefit from cross stakeholder collaboration on semantic interoperability and make good use of existing standards but need additional input for semantic content. (Consider safer prescribing, long-term condition summaries, rare diseases, and/or public health issues such as obesity.)

Publish and promote these priority use cases, and establish channels for stakeholder feedback.

Establish a culture and practices for aligning relevant standards. Start by establishing simple bilateral and trilateral alignments, involving a modest number of stakeholders (especially healthcare professionals, industry and health ministries).

Develop strategic relationships with the eHealth network, the CEF, CEN, the JIC and relevant ICT industry and healthcare organisations.

Develop a sponsorship model for the development and bundling of assets, targeting healthcare funders as example sponsors.

Agree on the stakeholders required to work on asset development activities, to form virtual working groups to develop semantic content. Specifically target the inclusion of patient representatives, and for the assets to cater for health data creation and access by patients.

Consider aligning this activity with the VALUeHEALTH work plan.

**Milestones**

2015 04: Determine example priority areas to attract stakeholder engagement, such as safer prescribing, one or two long term conditions.

2015 06: agree a key event that can be held by the end of 2015 to bring stakeholders together to examine the chosen topics and work done by then towards interoperability.

2015 11: establish the modus operandi for the Alliance, terms of reference and a roadmap for 2016

**Communications**

The priority for communications will be to convince those stakeholders who traditionally do not participate in the development of semantic assets to play an active role. This will require education materials about semantic interoperability and evidence that promotes the importance of interoperability and information sharing, in particular for the example priority areas chosen.

Videos and extracts of convincing evidence will be most important.

**Resource needs**

Leader/co-ordinator 2 days per month.

Administrative support 4 days per month.

Communications 2 person months during 2015.

Event organisation will require 2 person months in mid-late 2015.
**Budget**
Estimate 30k in 2015, thereafter mainly for events and specific projects

**Revenue sources**
Seek sponsorship of the 2015 event, otherwise support from core Institute funds
Project 5: Semantic harmonisation services

Objective
To maintain a list of data items and mappings across terminology systems, to support the harmonisation of data and queries in support of clinical research, especially clinical trial feasibility and patient recruitment, and patient summaries to support continuity of care across Europe. To maintain an inventory of metadata descriptors of data sources that may be used for research, to help support the discovery of relevant research data sources, and possibly to run a federated discovery service. To also maintain the service specification of a central semantic broker to support the construction of local mappings between the data dictionary of a hospital or GP EHR system and a centralised representation.

Problem area
EHR4CR has developed a pivot terminology with the mappings to several other terminology systems, covering the data items so far identified as common across clinical trials protocols. This will need to be maintained, and enhanced in terms of the range of terminology systems, mappings, identifier handling, the list of data items covered, metadata etc. Other projects such as SALUS, INTEGRATE, EUREKA and TRANSFoRm have developed other semantic brokers that offer complementary functions, but are at present separate components without clear maintenance strategies. EMIF is also starting to develop semantic harmonisation tools and services, which will eventually also require maintenance. EMIF (and other projects) have highlighted the need for a consistent way in which data sources that may be used for research can be described and discovered. SemanticHealthNet has specified the semantic content of a shared care summary for heart failure, which needs to be maintained, and extended for other long-term conditions.

Current situation
External environment
At present the only effort being applied to the maintenance of a semantic interoperability asset is for the epSOS Master Value Catalogue. There is no other known activity that is taking the results of successful European projects or other initiatives and providing a long-term maintenance solution. However many European projects are developing mapping tables, terminology services and other brokering services, including metadata registries and discovery services. There will be a need for these to be sustained, in a vendor neutral way, made available for adoption by industry and for enrichment by future R&D projects.

Capability and resources
On the positive side, several projects have indicated they wish to donate their end results (components, tools and content) to the Institute for maintenance. On the downside, it is not clear what business model could support investments in their maintenance, nor is it clear what end product or products the Institute should offer to take responsibility for i.e. the market needs are not clear.

Value
Sponsors
The most likely sponsors for a research semantic broker will be research consumers of health data, such as the pharmaceutical industry and large-scale data brokers. However a convincing business case will need to be made for investments in each candidate service, to be maintained and managed centrally, for the benefit of multiple health ICT providers. Healthcare funders and health ministries are the most likely stakeholder to support and sponsor the development of new patient summary datasets for long-term conditions. However, guideline development agencies might also have a budget to develop a corresponding dataset and vocabularies.

**Adopters, users**

In addition to the stakeholders identified above, the most likely users of research data item catalogues, who therefore should be consulted on market needs, are the developers of clinical research platforms that operate across multiple health ICT vendors products. Patient summary specifications, once endorsed by relevant professional bodies and health ministries, will have a potentially wide user community of ICT vendors, Healthcare professionals and patients.

**Collaborations, partnerships**

If this activity proceeds it will need to work in close partnership with SDOs and the health ICT industry, especially those developing clinical research platforms and EHR systems.

**Activities**

The initial activities will need to be scoping ones. Firstly an appraisal will be needed of the semantic interoperability resources available through the contributing projects, including a quality assessment and an assessment of their maintenance requirements. In parallel, more market intelligence is needed on the ideal semantic harmonisation services, tools and content that could provide best value to stimulate and support the clinical research platform marketplace, and support other analytics purposes for health data such as public health and health service planning.

An ideal development process needs to be specified for patient summaries and other data sets, drawing on SHN and EHR4CR experience, including the domain expertise inputs that will be required, the necessary consultation and validation process including any possible demonstrations or piloting.

**Milestones**

2015 07: initial scoping activity complete
2015 09: funding stream identified to develop at least one new patient summary specification for a long-term condition

**Communications**

To be determined

**Resource needs**

A small number of experts will be needed to appraise be available components, and confirm their necessary maintenance requirements. Market intelligence should be primarily gathered through the Institute’s Advisory Boards.
Initiatives to develop specific content specifications, tools and services should be managed as discrete sub-projects through the relevant CoE.

**Budget**
To be determined

**Revenue sources**
To be determined
Appendix 4: 4-page Flyer

The European Institute for Innovation through Health Data (i-HD) is being formed as one of the key sustainable entities arising from the Electronic Health Records for Clinical Research (EHR4CR) and SemanticHealthNet projects, in collaboration with several other European projects and initiatives supported by the European Commission. (These projects are summarised on the last page.)

i-HD is being established as a trusted not-for-profit organisation. Its mission is to coordinate, and accelerate the efficient development and deployment of interoperable health ICT solutions and clinical research strategies.

i-HD responds to a convergence of needs between clinical research and health care, at European, national and local levels, for access to high quality and interoperable health data on a large scale, whilst complying with data and patient privacy protection legislation.

Clinical Research needs
- Optimise clinical research processes
  - Identify sites that have access to the most suitable patients
  - Achieve faster and more accurate patient identification
  - Reduce protocol amendments
- Enhance access to Real World Data
  - Study the use of new medicines in real populations
  - Conduct comparative effectiveness studies
  - Monitor long term safety
  - Gather evidence for adaptive licensing

Healthcare needs
- Improve quality and safety of care
  - Enhance care co-ordination
  - Increase adherence to clinical evidence
  - Reduce medical errors and treatment delays
- Support patients in self-care and health maintenance
- Improve efficiency of care
  - Optimize care pathways to improve outcomes
  - Collate evidence for public health strategy and decision-making

Need to remove the bottlenecks to accessing and combining health data from diverse sources across Europe
**HD** will undertake several core functions relevant to its mission, and establish initially two Centres of Excellence. These will dedicate domain-specific expertise to facilitate and govern the use of health data for research and semantic interoperability.

Developing guidelines and promoting best practices in:
- information governance, privacy protection and ethics
- data quality and provenance, data sharing
- standards development and adoption
- research uses of health data

Developing and delivering training and education

Building synergy and consensus amongst stakeholders

Promoting the convergence of health informatics standards

Participating in funded research improving the uses of health data

Facilitating knowledge discovery from health data

Collating success strategies for scaling up eHealth innovations

Disseminating evidence of benefit, and demonstrating value, from the collection and use of high quality, interoperable, health data

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**Centre of Excellence for the Research Use of Health Data**

- Sustaining a Network of Excellence for research sponsors and research units
- Maintaining open specifications for clinical research platforms and service interfaces
- Certifying and auditing health research ICT products and service providers, starting with the EHR4CR platform (in partnership with EuroRec)
- Accrediting staff using health data for research (in partnership with ECRIN, UKCHIP, ...)

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**Centre of Excellence for Semantic Interoperability**

- Fostering the design and validation of assets by clinicians
- Quality labelling and registering interoperability assets
- Designing quality processes for clinical information models
- Promoting interoperability standards implementation and adoption
- Leading an Alliance of standards developers, implementers, purchasers and users
- Providing tools to support semantic harmonisation
i−HD is being established as a European not for profit body, registered in Belgium. It will itself be governed by its member stakeholders, public and private, through an elected Board and officers. It will be financed by a mixture of membership subscriptions, fees from providing certification and accreditation, specific project grants and other income from education, training and expert advisory roles.

In its first year i−HD will particularly focus on securing the trust of the public and patients in the re-use of health data for research and on presenting the value to society from clinical research. It will also promote best practices in interoperability asset development and information governance.
FOUNDING PROJECTS

EHRCR has developed an innovative platform that can connect securely to the data within multiple hospital EHR systems across Europe, to enable a trial sponsor to estimate, in close to real time, the patient numbers corresponding to the inclusion and exclusion criteria of a candidate clinical trial protocol, to assess its feasibility and to locate the most relevant sites. Tools deployed locally can assist each participating hospital to efficiently identify and contact the relevant patients. This platform and services are now being launched by the first commercial service provider, Custodix, ready for Europe-wide deployment and use. EHR-DR will ensure that all parties involved in this emerging environment operate in full compliance with all applicable requirements and policies, by certifying the ICT systems, overseeing their operation, auditing the information flows and establishing good practices in information governance for all service providers, hospitals, and research sponsors. It will promote and develop best practices for the wider use of EHRs for research, including engagement with patient associations, privacy protection agencies and regulatory authorities to ensure the solution is well accepted by all of them, and generates benefits.

SemanticHealthNet is establishing high quality design processes and assessment criteria for interoperability assets, such as clinical models and terminology value sets, to ensure that they will enable the benefits of interoperable electronic health records to be realised. EHR-DR will support a Europe wide register and quality labelling process for interoperability assets, and establish a multi-stakeholder alliance of health professionals, patients, healthcare providers, healthcare funders, standards developers and industry to focus future efforts on standards development and adoption to target the most relevant priorities at national and European levels. It will collate evidence of the benefits from interoperable health data, and promote data quality initiatives and innovations in health care and research from using health data.

CONTRIBUTING PROJECTS