The European Institute for Innovation through Health Data

Annual Report 2016

Version 0.7 - 05 July 2017

Contents

Introduction

We are pleased to present our annual report for 2016, which describes our progress since our official launch at the inaugural conference in March 2016, nine months ago.

i~HD has accomplished a great deal. We have set in place several initiatives that are helping to promote a trustworthy ecosystem for reusing health data for research and learning health systems, as well as improving the quality of that health data. These especially focus on information governance, such as codes of practice, standard operating rules, conformance criteria for clinical research platforms, and plans for establishing an information governance board next year. We have also made great progress in establishing the dimensions of data quality that are most important for using health data for learning, and understanding the success factors for improving data quality. i~HD has been commissioned to undertake an evaluation of the post-EHR4CR Champion Programme, the methodology for which has now been developed. We have implemented a register for quality labelling and publicising interoperability assets. This report presents a summary of these initiatives, the teams of experts who are working on them, the achievements made this year and the plans for next year.

Our work has been possible through a dedicated office team, led by Geert Thienpont who has acted as the i~HD CFO but actually does much more than this to run our institute smoothly and efficiently, and to help us to develop new opportunities. We have a great web site and a growing library of content showcasing our activities and events, and now with a new area to promote the reusable results of EC projects. I am grateful to the dedication and commitment of our team, especially given the formative nature of i~HD which required each of them to be creative and agile in the contributions they have made.

We are also very grateful to the many experts who have contributed their time and state-of-the-art thinking to our different initiatives. They are listed against the different activities they have contributed to, and I look forward to also working closely with them in the year ahead. Since i~HD deliberately has a small fixed personnel base, our experts are our life blood, and we intend to grow this network in 2017. The success of i~HD lies in creatively fusing this multi-stakeholder expertise to generate solutions that are greater than the sum of their parts.

We have been fortunate in our memberships, which have in 2016 particularly targeted pharma and scientific associations. Their membership fees and their enthusiasm and in-kind support have enabled us to achieve a lot over the past year. Next year we will be growing our membership by targeting hospitals, patient associations and other industry sectors, to help balance our perspectives as well as to grow our income. We look forward to learning of the outputs that these stakeholders would like us to additionally deliver, towards our achieving overall mission.

Now that we have become firmly established, with a clear set of activities and emerging results, we are also well placed to form richer strategic partnerships with other organisations operating in our ecosystem. We have already forged good working relationships with some, and I look forward to the year ahead as an opportunity for us to grow a network of networks with these other organisations.

We were founded at the intersection of multiple European projects each of which had aspirations for a not-for-profit Institute, which we have become. There are still ambitions and visions that we have yet to tackle, and we will be scaling up our activities and our connectivities so that we can achieve even more in the years ahead.

Our ambition is for great health data to be captured, shared and used in trustworthy ways by all stakeholders, to enable better health for all citizens. Our mission is to eliminate the barriers, to develop the enablers and to drive the success factors to achieve that ambition.

Professor Dipak Kalra
President

Geert Thienpont
CFO

Our mission

The mission of i~HD is to enable, coordinate, and accelerate the efficient development and deployment of interoperable and seamless eHealth solutions and research strategies, towards achieving best practices and sustainable integrated person-centred health care, to optimize health and wellness in Europe, and beyond. It aims to guide and catalyse the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery.

i~HD has been established to tackle areas of challenge in the successful scaling up of innovations that critically rely on high quality and interoperable health data. It specifically addresses obstacles and opportunities to using health data by collating, developing and promoting best practices in information governance and in semantic interoperability. It is helping to sustain and propagate the results of health information and communication technology (ICT) research that enable better use of health data, assessing and optimizing their novel value wherever possible.

i~HD has been formed after wide consultation and engagement of many stakeholders to develop methods, solutions and services that can help to maximise the value obtained by all stakeholders from health data. It supports innovations in health maintenance, health care delivery and in knowledge discovery, while ensuring compliance with all legal prerequisites, especially regarding the insurance of patient's privacy protection. It unites multiple stakeholder groups in order to ensure that future solutions serve their collective needs and can be readily adopted affordably and at scale.

i~HD is a European not for profit body, registered in Belgium through Royal Assent.

Our activities

Initiatives launched during 2016, to continue in 2017

- Societally acceptable codes of good practice and SOPs governing the reuse of health data for research
- Quality labelling of clinical research platforms
- Data quality assessment and improvement strategies
- i-HD European Network of Excellence for Hospitals
- Evaluation of the Champion Programme
- Promotion to society of the benefits of using EHR data for research
- i~HD visibility and communications
- Conferences & workshops

Additional initiatives to be launched in 2017

- Information Governance Board
- Promoting "EHR-friendly" structured eligibility criteria
- Interoperability Asset Register
- Participation in European Projects

Report on initiatives launched during 2016

Societally acceptable codes of good practice and SOPs governing the reuse of health data for research

Aims

- 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.
- Work with key decision makers and influencers to mutually agree good practices that balance societal benefit and personal privacy.

The Information Governance Task Force

- Peter Singleton, Cambridge Health Informatics, UK
- Nathan Lea, University College London, UK
- Irene Schlünder, Technologie und Methodenplattform für die vernetzte medizinische Forschung (TMF), Germany
- Dipak Kalra, i~HD, Belgium

Summary

The i~HD governance team has examined multiple sources of good practice in governing the research use of health data, from projects such as EHR4CR, EMIF, TRANSFoRm, ETRIKS. An important governance starting point is the recently published Innovative Medicines Initiative Code of practice on the secondary use of medical data in European scientific research projects. The team have developed an overarching set of high-level principles and standard operating rules that bring together these project results, combining them with other relevant instruments developed within the informatics and bioinformatics communities. These are now being finalised and will be initially adopted by the post-EHR4CR Champion Programme running the InSite Platform.

Achievements during 2016

- Completed draft of the i~HD Governance Principles and advance drafts of the i~HD Standard Operating Rules for research sponsors, service providers and hospitals.
- Active promotion at many European conferences and policy events of the importance of the trustworthy reuse of health data for research and the role of i~HD in developing instruments and other measures to support this.

Plans for 2017

- Finalise the Codes of Practice, after consultation with key hospital and patient representatives starting at the Hospital Network Workshop.
- Develop educational materials to support staff in adhering to them.
- Evolve these codes in the light of experience and new legislation, especially following the GDPR.
- Collaborate with other groups developing parallel codes for other scientific areas such as life sciences research.
- Liaise especially with EMIF on the sustainability of its Code of Practice and Data Sharing templates, and their promotion across the IMI BD4BO programme.

Quality labelling of clinical research platforms

Aims

- Develop and deliver, primarily in contract with EuroRec, quality labelling criteria, a test plan and quality labelling process for platforms, services and tools supporting the reuse of health data for research.
- Maintain and publish the specifications of services and interfaces for clinical research platforms and tools, to which conformance can be tested.

The i~HD Quality Seal team

- Geert Thienpont, i~HD, Belgium
- Dipak Kalra, i~HD, Belgium
- Inge Lamote, RAMIT, Belgium

The EuroRec quality labelling experts

- Pascal Coorevits, EuroRec, Belgium
- Nathan Lea, University College London, UK

Summary

i~HD has developed a Quality Seal for Research Platforms (QS4RP) in order to provide assurance to the market, especially to healthcare organisations, research centres and research sponsors, that ICT products and services used to conduct research analyses using EHR information do so in secure ways that protect data privacy. The purpose of the QS4CR Seal is to verify that such ICT products do restrict access in this way and that the information governance policies and information security measures adopted by the product vendor provide assurance of privacy protection.
I~HD has commissioned the EuroRec Institute to develop the content of this Seal and to conduct the formal assessments of products and services. EuroRec is Europe's leading body for quality labelling electronic health record systems, and brings nearly a decade of experience in developing quality seals and conformance-testing EHR systems. The seal criteria draw on the software requirements specifications and standard operating rules developed during the EHR4CR project, and also on the EMIF project's code of practice, instruments developed by the ETRIKs project, the IMI Secondary Use code and ISO/IEC 27000 series of standards on information security management systems.
On the basis of a test report issued by EuroRec, i~HD will issue a Certificate of Conformity to successful service providers. I~HD intends that the possession of this Certificate will give added confidence to healthcare organisations and to research sponsors about joining such research platforms and networks.

Achievements during 2016

- Developing conformance criteria and a detailed test plan for quality labelling clinical research platforms, through a contract with EuroRec.
- Pilot testing this and then preparing for the assessment of the first clinical research platforms.

Plans for 2017

- Publicly launch the availability of a seal of conformity (Quality Seal) for clinical research platforms.
- Actively promote this Quality Seal to the vendors of such platforms.
- Produce materials that help to convey the trustworthiness established through this quality labelling process, in particular to inform hospitals and patient associations.
- Begin work on a second-generation Quality Seal to be launched in 2018.

Data quality assessment and improvement strategies

Aims

- Develop data quality assessment methods and tools, and improvement strategies, with particular emphasis on maximising the quality of health data for learning health systems and clinical research.
- Promote the importance of data quality to healthcare providers, initially especially to hospitals, and help them to assess and improve their data quality.
- Scale up a multi-stakeholder understanding and commitment to maximising health data quality, for all primary and secondary use purposes.

The i~HD Data Quality Task Force

- Pascal Coorevits, EuroRec, Belgium
- Juan M Garcia-Gomez, Universitat Politècnica de València, Spain
- Carlos Sáez, Universitat Politècnica de València, Spain
- Murat Sariyar, Bern University of Applied Sciences, Switzerland
- Veli Stroetmann, empirica, Germany
- Diane Whitehouse, EHTEL, Belgium
- Geert Byttebier, Janssen Pharmaceuticals, Belgium
- Louis Schilders, Janssen Pharmaceuticals, Belgium
- Bart Vannieuwenhuyse, Janssen Pharmaceuticals, Belgium
- Dipak Kalra, i~HD, Belgium

Summary

i~HD is committed to supporting European hospitals and general practices to improve their data quality, for their own benefit as well as for wider societal benefits including clinical research. During 2016 we have launched a Data Quality Task Force. Members of the task force include experts across Europe in different aspects of the data quality improvement challenge. The Task Force is currently specifying the most relevant Data Quality Dimensions, developing educational materials and a series of assessment methodologies (e.g. qualitative and quantitative evaluations, tests based on statistical methods), and collating evidence of best practices in data quality improvement strategies. The Task Force will work with the i~HD Network of Excellence for Hospitals to develop a better understanding of the ways in which improvements in data quality can deliver measurable benefits to hospitals. During 2017 it will begin working with interested hospitals to deploy these tools and to help them to collaborate to implement effective data quality improvement strategies.

Achievements during 2016

- Establishing a data quality task force comprising European experts in different areas of assessment methodologies, improvement strategies and education about data quality.
- Preparing a data quality assessment framework focused especially on the reuse of EHR data for research and learning health systems.

Plans for 2017

- Run a dedicated break out group during the Hospital Network Workshop, enlarging the task force with hospital representatives.
- Develop educational resources and targeted improvement strategies for hospitals.
- Work with interested hospitals to support their data quality improvement strategies.
- Turn all of this into a European data quality service and a data quality campaign later in 2017.

i-HD European Network of Excellence for Hospitals

Aims

- Create a mutual support and shared learning community of hospitals wishing to accelerate their uses of health (EHR) data for clinical research and to become better learning health systems.
- Develop and deliver education, good practices and tools (such as data quality improvement measures) that maximise their capability to reuse their health data.
- Develop and promote good governance practices to enable trustworthy internal and external reuse of hospital EHR data for knowledge discovery.
- Help hospitals to optimise the ways in which they use and benefit from their EHR systems.
- Support hospitals with demonstrating the value to themselves and to other stakeholders from good uses of their health data.

Team

- Geert Thienpont
- Andrea Jahraus, CMAST, Belgium
- Karl Wouters, Sensus Communications

The i~HD Network of Excellence Steering Committee

- Dipak Kalra, i~HD, Belgium
- Pascal Garel, HOPE, Belgium
- Jacques Demote, ECRIN, France
- John O'Brien, former hospital CEO, Ireland
- Tine Lewi, Janssen Pharmaceuticals, Belgium
- Tony Amato, Executive Director, Clinical Trials Center, Policlinico Gemelli, Rome, Italy
- Giuseppe Banfi, General Director, Fondazione Centro San Raffaele, Milan, Italy
- Philippe Lechat, Director Clinical Research and Innovation, AP-HP, France
- Patient organisation representative, TBC

Summary

The eventual goal of this network is to support all European hospitals (and, later, other care providers such as general practice) to collect health data of the highest possible quality, and to make the best use of that data internally (for patient care and for organisational quality improvement) and externally (supporting continuity of care, public health strategy and research that is publicly funded and industry sponsored). There are many barriers to achieving this goal, some are concrete challenges and some are perception challenges. i~HD is developing some of the necessary solutions, and is connecting with other organisations that are also developing some of the solutions. This Network of Excellence will serve as a way of helping hospitals to support and encourage each other, to gain confidence in the trustworthiness of the EHR reuse ecosystem, to share solutions and benefits, to help guide i~HD to develop the solutions they need, and to contribute their perspectives to i~HD multi-stakeholder activities. This NoE will be launched at the February 9th workshop, and steered following that by a committee of hospital representatives and other advisers (as listed above). The NoE is likely to have further meetings during 2017, including some that are focused workshops on specific topics such as data quality, privacy protection, good EHR system use and benefits realisation.

Achievements during 2016

- Detailed planning of the Hospital Network Workshop being held in February 2017.
- Preparation of an ICT maturity and EHR use survey instrument.
- Participation in learning health systems events and publications that showcase the broader value of health data to hospitals and other healthcare providers.

Plans for 2017

- Hold the Hospital Network Workshop, in Brussels on February 9th, and use this as the springboard to launch a sustainable Network of Excellence for research-active and learning health system active hospitals across Europe.
- Establish a dedicated steering committee for this Network, mainly comprising representatives from leading European hospitals, but also including representatives from patient organisations and other hospital oriented networks such as ECRIN, HOPE.
- Hold similar or more focused events later in 2017.

Evaluation of the Champion Programme

Aims

- To gather evidence that can be used by research sponsors, platform service providers and data providers (e.g. hospitals) to demonstrate benefits and organisational value from reusing health data for research.
- To identify issues, obstacles and success factors for scaling up the reuse of health data for research, to inform future i~HD initiatives and other stakeholders about possible mitigations and incentives.
- Starting from the Champion Programme, to eventually develop and promote a standard set of evaluation indicators across clinical research platform networks, to enable findings to be pooled and shared.

The i~HD Evaluation Task Force

- Rainer Thiel, empirica, Germany
- Veli Stroetmann, empirica, Germany
- Dipak Kalra, i~HD, Belgium
- Pascal Coorevits, EuroRec, Belgium
- Christel Daniel, AP-HP, France
- Mats Sundgren, AstraZeneca, Sweden
- Nadir Ammour, Sanofi, France
- Philippe Rocolle, Sanofi, France
- Aurèle N'Dja, Sanofi, France
- Tine Lewi, Janssen Pharmaceuticals, Belgium
- Nicole Trewarthe, ICON, Ireland

Summary

The research sponsors of the Champion Programme (CP), and Custodix, agreed at the outset to collaborate on a joint and shared evaluation that would help generate evidence of the value of this innovative platform and of this novel method for optimising protocols and facilitating recruitment into studies. It is intended that this evidence will be used internally by each of the participating research sponsors to scale up future investments in this platform, will be used by Custodix (with agreed levels of de-identification and aggregation) to support their promotion of InSite to sponsors and hospitals, and will be used by i~HD to promote the positive value of this kind of clinical research ecosystem and also to better understand its strengths and weaknesses. The evaluation method and metrics will be generic to any clinical research platform. None of the criteria and indicators within the evaluation framework are specific to one platform provider. Methodologically, the evaluation of the CP consists of two tracks: a programme evaluation – to understand better drivers, incentives and barriers to join and implement the CP; a technology assessment – to capture usage and technical implementation of the platform. The evaluation framework comprises costs and benefits, monetary and non-monetary, for two stakeholder groups: research sponsors and hospitals.

Achievements during 2016

- Establishing an evaluation task force comprising industry representatives and academic representatives, developing a consensus set of evaluation indicators and progressing this towards a formal evaluation methodology.

Plans for 2017

- Finalising the evaluation methodology, employing a dedicated person part time at empirica to undertake much of the fieldwork throughout 2017-18, starting with baseline data gathering early in 2017.
- Periodically releasing interim findings to champion programme decision-makers.

Miscellaneous activities

Both of these documents were co-authored several EFPIA colleagues.

- i~HD submitted a written response to the FDA on the use of EHRs as source data for regulated clinical trials.
- I~HD has submitted a proposal to IMI (to Pierre Meulien, the Executive Director) for a Sustainability Service and Entity, to help promote the long-term sustainability and uptake of project results.

The i~HD Office

The i~HD office is mainly located in Ghent (Belgium) and with the support of RAMIT and the Department Medical Informatics of the Ghent University the office is responsible for:

- Administering memberships
- Exploitation of i~HD services and consultancy
- Supporting European experts in the development of the i~HD services
- Organisation of meetings, workshops and conferences
- Communication activities (website, newsletter)
- Implementing and fulfilling the Bylaws

Team

	Dipak Kalra, President
	Geert Thienpont, CFO
	Pascal Coorevits, Certification and Labelling Adviser, EuroRec Representative
	Inge Lamote, Web Developer, RAMIT
	Martine Vannevel, Administrative Officer, UGent
	Karl Wouters ~ Communication Officer, Sensus Communications

i~HD visibility and communications

Aims

- Promote to society the benefits of using EHR data for research
- Create awareness about i~HD and its mission to guide and catalyse the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery.
- Build trust & engage all stakeholders that are key for achieving this mission

Summary

We appointed an i~HD Communications Officer with many years of experience in pharma R&D and Global Public Health communications.
We created awareness by organizing conferences and workshops. On top of that several conference presentations were given about i~HD. Another key communication channel was the i~HD website featuring all sorts of information, and

news items including videos with key stakeholders explaining the potential of trustworthy uses of health data for optimising health and wellness in Europe and beyond. The i~HD e-newsletter serves the same purpose. Our newsletter, website and many of our conference presentations have been targeted at the different stakeholders we wish to bring into i~HD as future members, as well as key organisations and leading experts we wish to collaborate with all our initiatives. The website has also been an important vehicle for keeping our members up-to-date on our activities and successes.
During 2016 specific attention was paid to promoting to society the benefits of using EHR data for research. i~HD has made several interview-based videos and videos captured during conferences that feature patients or patient representatives emphasising the importance of clinical research and their confidence in the ability for their health data to be adequately protected. These are on our website, and usually at least one has been on our home page, since the spring.
During 2017 we hope to establish a specific collaboration with the European Patients' Forum, including the involvement of patient representatives from them in our task forces and Boards. We would like to work with the EPF on the planning of a more targeted patient and societal awareness campaign for later in the year, subject to funding.

I~HD Conferences and Workshops

We held a very successful inaugural conference in March 2016, in Paris, which is reported on our website including many video recordings and interviews.

We are holding a hospital network workshop in February 2017. We intend to hold our next main annual multi-stakeholder conference in June 2017, similar in scale to the inaugural conference. The details of this, including the date and location, are still being worked out.

i~HD publications

- Kalra, D, Stroetmann, V, Sundgren, M, Dupont, D, Schlünder, I, Thienpont, G, Coorevits, P, and De Moor, G. (2016) The European Institute for Innovation through Health Data. Learning Health Systems, doi: 10.1002/lrh2.10008
- Kalra D, Mats Sundgren M, Claerhout B, Meulien P, Vannieuwenhuyse B, Singleton P, Peetso T, Stroetmann V, Wilson P, Baker M, Coorevits P, O'Brien J, De Moor G. The Launch of the European Institute for Innovation through Health Data. Journal of Medicines Development Sciences (in press).

Conference presentations featuring i~HD

- EMIF conference: E-managing the Future of Health Data, Budapest, 17 March 2016
- International Society for Telemedicine & eHealth (Med-e-Tel), Luxembourg, 8 April 2016
- PRISME Forum, Prague, 17 May 2016
- Federation of European Academies of Medicine Spring Conference, Berne, 20 May 2016
- IMI States Representatives Group, Brussels, 26 May 2016
- Phenomenal Workshop, Barcelona, 27 May 2016
- Big Data en santè, French Ministry of Health and Social Affairs, Paris, 4 July 2016
- Medical Informatics Europe, Munich, 28 August 2016
- European Public-Private Partnerships Innovation Conference, Seville, 13 October 2016
- Medical Affairs Leaders Forum, London, 18 October 2016
- Medisch Informatica Congres, Antwerp, 25 November 2016

Promotion to society of the benefits of using EHR data for research

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Additional initiatives to be launched in 2017

i~HD Information Governance Board

Aims

- Serve as an independent advisory oversight body governing the ecosystem in which health data are used for research, through i~HD-labelled ICT products, platforms and services.
- Review the governance approach and instruments developed by or adopted by i~HD for use within this ecosystem.
- Provide i~HD with intelligence and recommendations on areas in which new or revised governance instruments or initiatives may be needed.
- Promote the best practices adopted by i~HD, and by other relevant organisations, across all stakeholder groups internationally.

Membership is TBC, but some external experts have informally agreed to serve

Summary

The i~HD Information Governance Board will act as an advisory body to the Institute on its activities that relate to promoting best practices in information governance and privacy protection, and in reviewing the occurrence of incidents and issues arising in any areas of the clinical research and learning health system ecosystem in which i~HD is invited to play a non-statutory oversight role. Membership of this Board will comprise individuals working for i~HD on its information governance instruments, and externally appointed experts who bring specialist expertise and complementary perspectives from relevant stakeholder groups. The Board will review i~HD information governance instruments and advise on additional instruments that are needed, and connect i~HD with parallel efforts developing information governance, good practices in privacy protection etc. The Board will note the occurrence of privacy breach or other governance incidents, on an information-only basis, and advise i~HD on any relevant changes that should be made to platform quality labelling conformance criteria, standard operating rules or other instruments, needs for stakeholder education or for coordinated activity with other organisations.

Plans for 2017

- Launch the i~HD Information Governance Board.
- Establish its terms of reference and ways of working.
- Begin its regular meetings including publishing regular transparency reports on the i~HD web site.

Educational resources and workshops on authoring “EHR-friendly” structured eligibility criteria

Aims

To provide education and training, and other forms of guidance to enable authors of clinical research protocols to optimise the design of eligibility criteria such that they can be represented as queries to be run on EHR systems with the maximum likelihood of generating valid patient counts or research results.

Plans for 2017

- Understand the learning needs of those who design clinical research protocols.
- Assemble relevant experts, developing educational resources
- Holding one or more physical or webinar-based workshops.

Interoperability Asset Register

Aims

- Publish an online register to act as a central reference point to discover which interoperability assets may be used, together, to tackle any particular use case.

i~HD interoperability Asset Register Editorial Board

- Alberto Moreno Conde, Hospital Universitario Virgen Macarena y Hospital Universitario Virgen del Rocío, Spain
- Brendan Delaney, Imperial College London, UK
- Geert Thienpont, i~HD, Belgium
- Inge Lamote, RAMIT, Belgium
- Dipak Kalra, i~HD, Belgium
- ICT industry and health ministry representatives to be identified

Summary

The Interoperability Asset Register is an online register and discovery service for interoperability assets. Interoperability assets are documents, templates, term lists, clinical models, technical specifications, software, multi-media resources that support the design, implementation or adoption of interoperability of health data. Each asset is documented using a standard set of descriptors, developed through an examination of many current methods and metadata specifications for assets, complemented by a wide consultation with many experts, initiatives, SDOs and profile development organisations. These asset descriptors aim to inform a potential downstream user of important aspects of the quality of each asset, as well as specifying its purpose and functional characteristics. The register is fully implemented, and on our website with some initial assets already documented.

Plans for 2017

- Formally established the editorial board, its terms of reference and operation.
- Promote the asset register and encourage projects and other bodies to register assets in it.
- Once a sufficient body of content is available, promote the use of the register to eHealth architecture decision-makers and to the health ICT industry.
- Monitor experience of asset providers and register users, to identify design improvements.

European projects and proposals

Trillim II

i~HD is a partner in this Horizon 2020 Co-ordination and Support Action, which launched on 1st January 2017. This project aims to coordinate, consolidate and support efforts towards an interoperable international patient summary. The consortium comprises EU and US partners. i~HD leads a work package to promote successful patient summary adoption, focusing on a strategy for identifying success factors including education for a range of stakeholders, who will implement or use patient summaries, or who will benefit from access to aggregated patient summary information.
An additional goal is to promote the social value of international patient summary standards. The i~HD budget is around €46,500 over two years.

HELICAL

i~HD is a supporting partner to this Innovative Training Network proposal to scale up research in rare vasculitis. This is primarily a proposal for PhD studentships, and the main beneficiaries are academic studentship hosts. However, i~HD will receive direct funding from the co-ordinators budget for enabling work: leading the development of information governance instruments, and running its information governance board. i~HD will also host 2 PhD student secondments in areas of ethics and information governance, and Dipak Kalra will act as a second supervisor to these students.

Downstream aims

The following activities do not yet have a concrete implementation strategy or allocated resource. They are additional areas of need that were identified when i~HD was formed.

Fostering the co-design of semantic interoperability assets by clinicians, patients, research

- Support the development of good quality semantic interoperability assets that are well-suited to addressing high priority needs for sharing health information.
- Design quality processes for clinical information models and terminology value sets.

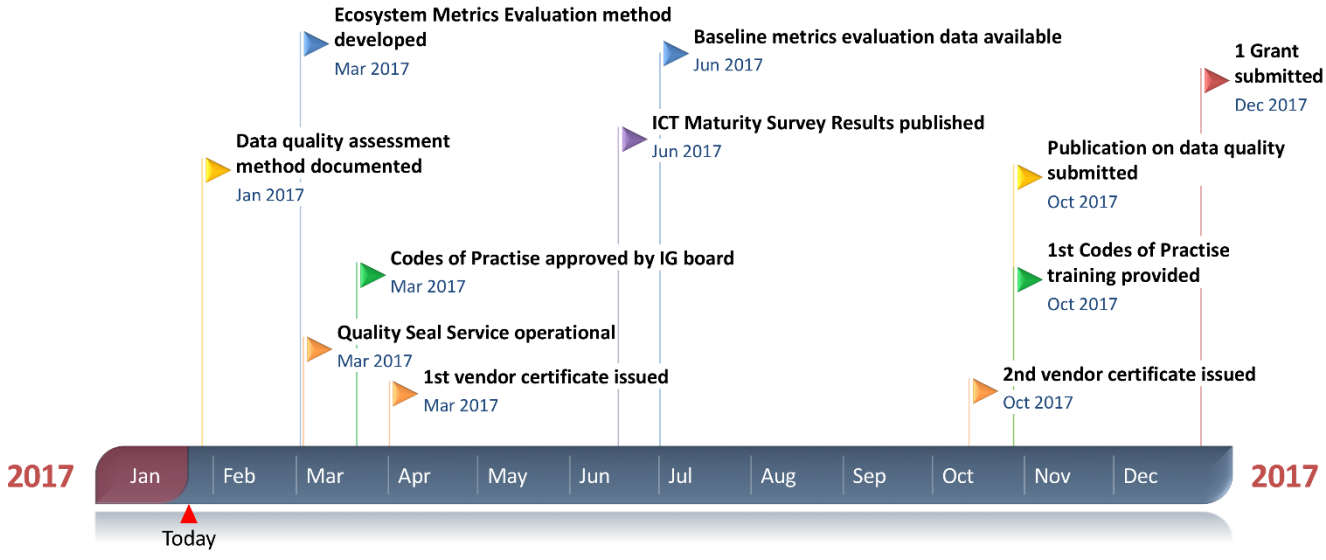
Semantic harmonisation services

- 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.

Accreditation of clinical research staff

- Develop and promote 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.

Milestones for 2017



Members List

- AMGEN UK
- AstraZeneca AB
- Empirica
- EuroRec
- F.HOFFMANN-LA ROCHE Ltd
- ICON plc
- King's College London
- RAMIT vzw
- Sanofi-Aventis Recherche et Developpement
- Technologie- und Methodenplattform fur die vernetzte medizinische Forschung (TMF)

Financial Statement for 2016

Income

Membership Pharma*	100 000 €
Membership Research centres	5 000 €
Membership CRO*	25 000 €
Sponsoring	15 000 €
Total	**145 000 €**

*Not yet fully paid:

Note payments were received:	Q1:	0 €
	Q2:	65 000 €
	Q3:	4 000€
	Q4:	26 000 €
	2017:	50 000 €
	Unpaid:	25 000 €

Costs

Staff cost	23 918 €
Bank costs	37.38 €
Domain names	677.60 €
Development Quality Seal for Research Platforms	12 200.00 €
Organisation meetings	126.20 €
PR materials	80.91 €
Inaugural Conference 10.03.2016 Paris	24 500.00 €
Hospital Network Workshop Feb 9, 2017 Brussels	5 220.00 €
Total	**66 659.59** €

In Kind

RAMIT	± 50% FTE
Janssen	± 10% FTE
Founding members	> 5% FTE

Membership fees charged in 2016

Commercial Companies active in the field of clinical and/or biomedical research (e.g. pharmaceutical or biotech industry, medical device manufacturers)

- ✓ Pharma - €25,000

Scientific centres active in the field of biomedical or clinical research, health informatics or equivalent (e.g. universities, departments of universities, non-profit research or research supporting organisations)

- ✓ Multi-national decision makers

  All the above, if for profit - €2000

  All the above, if not for profit - €1000

Budget for 2017

Income

Membership Pharma	125 000 €
Membership Research Centres	10 000 €
Membership other industry	30 000 €
QS4CR	80 000 €
EU R&D funding	18 634 €
Total	**263 634 €**

Costs

Staff cost - management (30% FTE)	66 430 €
Staff cost - research (20% FTE)	20 000 €
Staff cost (50% FTE)	85 000 €
Experts Task Forces	60 000 €
Hospital Network Workshop Feb 9, 2017 Brussels	35 000 €
Quality Seal for Research Platforms - subcontracting	50 000 €
Organisation meetings	15 000 €
PR materials	15 000 €
Annual Conference	30 000 €
Travel	20 000 €
Total	**396 430 €**

In Kind

RAMIT	±30% FTE
Janssen	±10% FTE
Founding members	±5% FTE

Proposed membership fees for 2017

- Supporting your voice towards other stakeholders in the health data reuse ecosystem (non-exhaustive list):
    - via i~HD website
    - by being (keynote) speaker at I~HD conferences
    - by participation in workshops
- Be the first to be informed about new collaboration opportunities
- Contribute to, and gain special access to, good governance practices to enable trustworthy internal and external reuse of hospital EHR data for knowledge discovery
- Benefit from reduced rates and prioritized registration/application for:
    - i~HD organised events
    - i~HD services
- Receive guidance on how to optimise the ways in which you use and can benefit most from EHR systems, demonstrating value from good uses of health data
- Access a members-only zone of the i~HD web site including our guidelines and good practices, working papers and results of the task forces, tutorial materials, i~HD conference presentations, video's etc.
- Have an influence over the strategy and management of the Institute
    - Participation in the annual General Assembly
    - Voting rights
    - Access to minutes of the Executive Board
    - Influence what you want i~HD to offer you and how best to involve other stakeholders in the health data reuse ecosystem.

Stakeholders	Membership Fee
Citizen- and Patients Organisations	
❖ patient associations ❖ citizen ❖ family and carer associations	➢ € 100
Healthcare providers	
❖ Hospitals with a capacity of over 500 beds ❖ Hospitals with a capacity up to 500 beds ❖ Medical centres (no beds) NOTE: GP practices are not yet provided for, but will have a lower fee	➢ €2000 ➢ €1500 ➢ €250 <u>except</u> Free membership for the current year for hospitals completing an ICT maturity survey. Please contact: Ms. Andrea Jahraus (hospital.survey@i-hd.eu)
Social and care associations (non-for-profit)	

❖ Health professional associations ❖ Social care provider associations ❖ Healthcare provider associations	➢ €500
Insurers and health ministries, associations representing health insurers	
❖ National health, care, eHealth and research decision makers ❖ Third party health and care payers, health insurance organisations	➢ Zero ➢ €5,000
Commercial Companies active in the field of clinical and/or biomedical research	
❖ Pharma, Bio-tech ❖ Medical Device vendors ❖ Health data brokers and analytics companies ❖ EHR system and applications vendors	➢ €25,000 ➢ €25,000 ➢ €25,000 ➢ Up to 250 employees: €5,000 From 251 up to 1000 employees: €15,000 Above 1000 employees: €25,000
Associations representing vendors of health ICT products and services, health informatics Standards Development Organisations	
❖ Standards development organisations ❖ Industrial associations	➢ €1,000 ➢ €5,000
Scientific centres active in the field of biomedical or clinical research, health informatics or equivalent (e.g. universities, departments of universities, non-profit research or research supporting organisations)	
❖ Clinical, clinical research and health informatics research and educational organisations ❖ Electronic health (eHealth) competence centers ❖ Regulators ❖ Multi-national decision makers	➢ if for profit €2000 ➢ if not for profit €1000

Appendix 1. i~HD Objectives

The following objectives are reflected within the Articles of Association that define i~HD. They are expressed here in a narrative format.

Defining and supporting the adoption of best practices in information governance, including complying with legislation and ethics, privacy protection, and codes of conduct, relating to the trustworthy use of health data including capture, processing and sharing.

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 stakeholders, supporting and guiding the best use of standards and assets for semantic interoperability and privacy protection. These benefits will relate to the care given to individual patients, to the configuration of healthcare and wellness services for populations, and to the reuse of health data for knowledge discovery.

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 and research data source catalogues and metadata.

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 a wide range of potential data sources. These sources primarily are: electronic health and care records and personal health records, citizen sourced and mobile health data, registries and claims databases, cohort studies and biobanks, and clinical trial and electronic case report forms.

Performing and commissioning quality assessments, and conducting quality audits of health data, ICT systems and applications, personnel competence and training and organisational processes relating to the use of health data. 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.

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. i~HD is working towards convergence and cross-fertilization between: healthcare providers, patients and families, health ministries and insurers, EHR system vendors and standards development organisations, pharma and the clinical research community, national and multi-national decision makers.

Appendix 2. i~HD factsheet

Short name	i~HD
Official name	The European Institute for Innovation Through Health Data AISBL
Legal status	The Association is governed by the provisions of Title III of the Belgian law of 27th June 1921 on non-profit organizations, international non-profit organizations and foundations, as modified
Registered office	165 Oude Mechelsestraat, B-1853 Strombeek-Bever (Belgium)
Registration no	628.646.310
VAT	No VAT registration
Working address	c/o Dept. Medical Informatics & Statistics, Ghent University Universitair ziekenhuis Gent, 5K3 De Pintelaan 185 9000 Gent - Belgium
Contact	Prof. Dipak Kalra, President, dipak.kalra@i-hd.eu
Phone	+32(9)332.40.67
E.C. PIC	Not yet registered
Website	www.i-hd.eu
Logos	i~HD The European Institute For Innovation Thr~ugh Health Data
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 EU 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 quality labelling and accreditation, specific project grants and other income from education, training and expert advisory roles. i~HD will establish and manage initially two Centres of Excellence (CoEs): on the reuse of health data for research, and on semantic interoperability.

	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 quality label 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 will concentrate on the development and delivery of services in support of the EHR4CR Champion Programme, on establishing a Network of Excellence for healthcare provider organisations, and measures to enrich data quality and semantic interoperability.
Bank details	IBAN: BE22 0017 5889 6047 BIC: GEBABEBB Bank: BNP PARIBAS FORTIS AG De Plaats 6, B - 9910 KNESSELARE