The European Institute For Innovation Thr~ugh Health Data

ANNUAL REPORT 2017

i~HD

April 2018

Contents

2017, a year of expansion

i~HD has expanded significantly during its second year. We are pleased to present you a summary of our activities during 2017 in this annual report, and our plans for 2018 and beyond.

In February 2017, we launched the *i*~HD Network of Excellence, initially for hospitals. The launch conference in Brussels was attended by over 50 hospital participants from across Europe who are keen to accelerate their use of Electronic Health Records to improve their quality of care, as Learning Health Systems, and to scale up their participation in research. We formed a multi-stakeholder steering committee which has guided our ongoing mission with hospitals, in areas such as data quality improvement and the assurance of trustworthy privacy protection. It has shaped our second annual hospital event which was held in March 2018. We can see a growing interest among hospitals to improve the quality of their data, and the electronic health record systems in which it is captured and used. This will bring benefits to all and will especially improve patient outcomes.

Our Data Quality Task Force has met frequently and held special hospital workshops during 2017. They have formalised the data quality indicators that are most important in making better use of health records for learning, and the strategies that hospitals can adopt to improve their data quality. This task force has progressively matured these resources into a Data Quality Seal and improvement service that is being launched in 2018, initially for hospitals. During 2018 we will expand our Network of Excellence to include general practices.

During 2016, another *i*~HD Task Force developed a Quality Seal for Clinical Research Platforms (QS4RP). This seal was launched in early 2017, and a first research platform service provider was formally assessed and has been awarded that seal. The QS4RP formally tests the company and the platform product to ensure that it provides robust privacy protection and trustworthy use of electronic health record data in a research context. We are in discussion with other research platform providers who are considering the QS4RP assessment and seal.

We have finalised our information governance principles and standard operating rules, and we are now working with different stakeholders to explore how we can best promote consistent and high-quality trustworthy practices across Europe, in the re-use of health data for research.

Patients are central to our mission, and we are pleased to have formed a working in partnership with the European Patients' Forum (EPF), and other patient representatives. We are collaborating with them to scale up engagement with patients and the promotion to patients and to other stakeholders of the importance of making better use of health data, and ensuring that this is always undertaken in respectful, trustworthy and societally beneficial ways. The centrality of patients to this mission surfaced strongly during our annual conference in Madrid, in September 2017. Around 250 people attended this event, held jointly with the EMIF project, which also focused on the importance of clinical and patient outcomes, and introduced the audience to the concept of value-based care. This topic has now become a complementary important mission for us, and we are pleased to have formed a working partnership with ICHOM, with whom we held our March 2018 hospital event.

> *" Our ambition in the year ahead is to scale up the ways in which we support healthcare organisations to collect and make better use of high-quality health data and to grow our relationship with patient organisations to promote the value of research. "*

Our ambition in the year ahead is to scale up the ways in which we support healthcare organisations to collect and make better use of high-quality health data and to grow our relationship with patient organisations to promote the value of research, and their active participation in it. We will work across our industry stakeholders to promote and scale up the value they can achieve from real-world health data, and start to grow a library of success stories and approaches that demonstrate that value. We are also pleased to announce a new joint project with EFPIA and ICHOM, starting in 2018, to define the multi-stakeholder success conditions and evidence in favour of value-based healthcare. This will help us in guiding hospitals on collecting high quality EHR data to improve their outcomes. *i*~HD is also starting to grow its portfolio of European research projects, and we are actively participating in new grant proposals.

We are very grateful to our sponsors and members, whose financial contributions through membership and in kind support, have enabled us to grow so substantially over the past year and to continue our mission in the year ahead. We are grateful to the many experts who contribute to our task forces, and to our office staff who have enabled *i*~HD to run efficiently, to hold successful and well appreciated events, and to have a great website and communications material.

We look forward to an exciting 2018, in which we continue to scale up achieving great value from health data for the benefit of all in society.

Professor Dipak Kalra
President

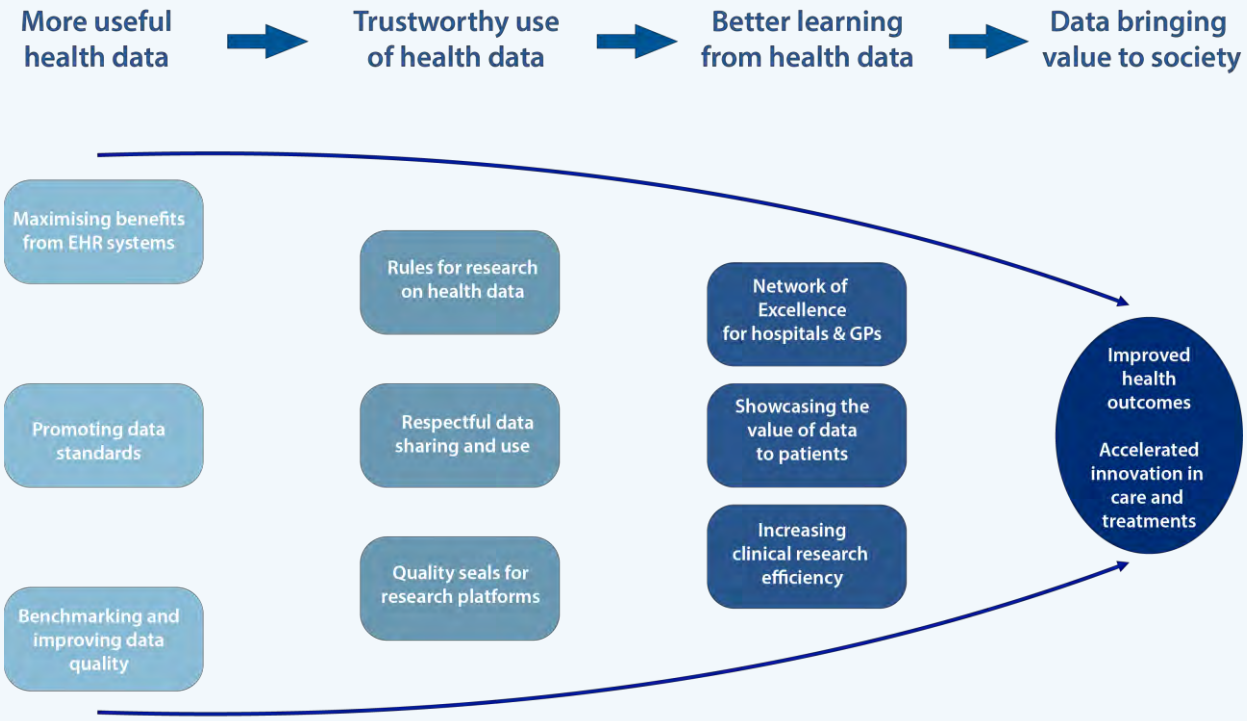
Geert Thienpont
Managing Director

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 optimise 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 optimising 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 optimising 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 to ensure that future solutions serve their collective needs and can be readily adopted affordably and at scale.



The activities of *i*~HD:
Enriching knowledge and enhancing care through health data

"Data sharing is a very complex area. If we can share experiences between European hospitals with differing regulation, this will be of great benefit for hospitals and their patients. i~HD will play a facilitating role in this sharing experience."

Phillippe Lechat
Assistance publique – Hôpitaux de Paris (AP-HP)

"i~HD is ready to involve the patient in the discussion, to lead to patient empowerment. Patients need to be involved in the discussion to move things forward in the right way. i~HD is at the forefront of this discussion: they are leading by bringing together all stakeholders to move forward the dialog."

Katie Gallagher
European Patients' Forum (EPF)

"i~HD plays a very important role. The institute will be instrumental in providing continuance in this field: how the research should be done and linking that with different applications of that research. "

Ain Aaviksoo
Ministry of Social Affairs, Estonia

"This initiative, the i~HD work, provides a particular insight into the different possibilities that innovations in data and data-use can provide. By working together, we can work out how best to harness that and show policy makers the opportunities, … enabling these innovations to thrive and become commonly used in healthcare. "

Daniel Furby
Foresight International Policy and Regulatory Advisers (FPIRA)

" i~HD can play a very important role as a neutral platform, a public-private platform, where all stakeholders can come together and work towards common goals: getting [the] interoperability and the data quality that is necessary… and make it work in a safe and secure way. "

Thomas Allvin
European Federation of Pharmaceutical Industries and Associations (EFPIA)

" i~HD is doing a great deal to help the field of data management and people using data in groups together, ensuring that we have trust between researchers and people who generate the data… It helps to reduce the silos that sometimes exist in science. "

Simon Lovestone
University of Oxford

Activities during 2017

- ✓ Data quality assessment and improvement strategies
- ✓ Quality labelling of clinical research platforms (QS4RP)
- ✓ Ensuring the trustworthy reuse of health data for research and learning health systems
- ✓ *i*~HD European Network of Excellence for Hospitals
- ✓ Conferences & workshops
- ✓ European projects and proposals
- ✓ *i*~HD's patient centric mission
- ✓ *i*~HD visibility and communications

Data quality assessment and improvement strategies

Aims

- Develop data quality assessment methods and tools, and improvement strategies, with 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
- Geert Byttebier, *i*~HD, Belgium
- Christel Daniel, AP-HP, France (since 2018)
- Juan M Garcia-Gomez, Universitat Politècnica de València, Spain
- Carlos Sáez, Universitat Politècnica de València, Spain
- Agustín Gómez de la Cámara, Hospital 12 de Octubre Research Institute, Spain (since 2018)
- Veli Stroetmann, empirica, Germany
- Diane Whitehouse, EHTEL, Belgium
- Bart Vannieuwenhuyse, Janssen, Belgium
- Dipak Kalra, *i*~HD, Belgium

Summary

During 2017, the *i*~HD Data Quality Task Force has further worked on the multiple data quality dimensions and their assessment methodologies. The focus has been on hospital data quality for re-using Electronic Health Record (EHR) data. A set of nine dimensions of data quality have been identified as the most important for the reuse of health data for organisational learning and for clinical research. These are: completeness, consistency, correctness, uniqueness, timeliness, stability, relevance, contextualisation and trustworthiness. A statistical assessment methodology has been defined for each of these dimensions, using algorithms that have been validated through prior research by Task Force members at the Universitat Politècnica de València. Through a further prioritisation three of these have been worked up in more detail to be offered as a benchmarking service for hospitals. The structure of a feedback report has been defined, which highlights to a hospital the areas of quality that need to be focused on. This analysis report can be generated from tools that the Task Force will use during hospital assessments from 2018. Emphasis was also put during the year on data quality improvement strategies, benefitting from the experiences of hospitals in our network.

Two data quality workshops were organised during 2017:

- Hospital Network Workshop (February 9th 2017, Brussels, Belgium)
- Data Quality Workshop (May 24th 2017, Brussels, Belgium)

A major milestone in 2018 will be the launch of the first, ***i*~HD** European Data Quality Service. The ***i*~HD** Data Quality Task Force is planning the piloting and further calibrating of the data quality services in a number of European hospitals. In order to scale-up activities, ***i*~HD** is expanding its membership of the Task Force and is exploring possible cooperation with an ISQUA certified organisation.

Achievements

- Regular meetings of the Data Quality Task Force
- A dedicated break-out session on Data Quality was organised during the hospital network Workshop in Brussels on February 9th 2017, with around 90 participants
- A one-day Data Quality Workshop was held in Brussels on May 24th 2017 with about 50 participants, including interactive breakout sessions
- A two-days Data Quality Task Force meeting in Bonn to prepare a Workshop in Paris in March 2018

Future plans

- Preparation of a Data Quality Workshop at "Assistance Publique – Hôpitaux de Paris" on Monday 5th and Tuesday 6th March
- Further calibration of the ***i*~HD** Data Quality services in pilot hospital sites (initially, Ghent University Hospital in Belgium, Hospital 12 de Octubre in Madrid and Hospital del Mar in Barcelona in Spain)
- Launch and promotion of the ***i*~HD** European Data Quality Assessment and Improvement Service
- Preparation of Data Quality tutorials for the next ***i*~HD** Annual Conference

Quality Seal for Research Platforms (QS4RP)

Aims

- Develop and deliver a Quality Seal for platforms, services and tools supporting the reuse of health data for research.
- Promote the QS4RP to ICT providers, healthcare organisations and research sponsors.
- 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
- Dipak Kalra
- Inge Lamote
- Daniel Schmidtmann (since 2018)

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) 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 Electronic Health Record (EHR) information, do so in secure ways that protect data privacy.

Products are now emerging that offer significant opportunities to accelerate the conduct of clinical research by enabling remote or on-site querying of EHRs – normally a de-identified extract of the operational EHR. These products help to optimise clinical research protocols before they are finalised and assist healthcare organisations to efficiently identify suitable trial recruitment candidates. The European General Data Protection Regulation (GDPR) places stricter obligations on organisations that hold personal data, such as healthcare organisations, to protect the privacy of their data subjects and to use personal (i.e. identifiable) information under strict controls. These new-generation research platforms use architectures that limit researcher access only to de-identified (and usually only aggregated) information and do not enable researchers to access personal health information at patient level.
The purpose of QS4RP is to verify:

(a) that such ICT products do indeed restrict access in this way, and
(b) that the information governance policies and information security measures adopted by the product vendor provide sufficient assurance of privacy protection.

***i*~HD** 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. It brings nearly a decade of experience in developing quality seals and conformance-testing of EHR systems. The seal criteria draw on the software requirements specifications developed during the EHR4CR project and ***i*~HD** standard operating rules, 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** issues a Quality Seal of Conformity to successful service providers. ***i*~HD** intends that the possession of this Quality Seal will give added confidence to healthcare organisations and to research sponsors about joining such research platforms and networks.

Achievements

- Development of conformance criteria and a detailed test plan for quality labelling clinical research platforms, through a contract with EuroRec.
- Public launch and active promotion of the QS4RP to the vendors of clinical research platforms.
- Testing and issuing the QS4RP to a first clinical research platform provider.

Future plans

- Promote the QS4RP to vendors and to clinical research stakeholders.
- Produce educational materials that help to convey the trustworthiness established through gaining the QS4RP, in particular, to inform hospitals and patient associations.

- Work on a new Quality Seal for research platforms that enable the re-use of EHR data as eSource within regulated clinical trials.

Ensuring the trustworthy reuse of health data for research and learning health systems

Aims

- Develop and promote codes of best practice and operating rules in information governance, privacy protection and ethics for the uses for health data, for research and for learning health systems.
- Guide best practices in data sharing, to protect privacy, promote FAIR data access principles and look after the interests of those who have invested in collecting and curating data sets.
- 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 Information Governance Task Force has developed a set of principles and standard operating rules for the reuse of health data for research, with particular emphasis on the way in which clinical research platforms access and analyse electronic health records (EHRs) to support clinical trial design and conduct. In preparing these, they consulted multiple published sources of good practice from projects such as EHR4CR, EMIF, TRANSFoRm, ETRIKS and the IMI Code of practice on the secondary use of medical data in European scientific research projects. These *i*~HD instruments aim to harmonise practice throughout the European innovation community so that site specific governance guidelines and policies can interoperate as data is captured in one context and the protection expectations can be honoured as it is shared and used in others. These instruments are now ready to be promoted across clinical research ecosystems, which will be the objective over the year ahead.

The *i*~HD Quality Seal for Research Platforms has been developed to complement these principles and rules, focusing on the privacy protection obligations of research platform vendors and a technical assessment of their platform products.

Given that the European General Data Protection Regulation (GDPR) comes into force in May 2018, *i*~HD has launched a new GDPR Task Force specifically to support our members with applying and adhering to this Regulation in the conduct of research using EHR data, and health system learning.

Achievements

- Development of *i*~HD Governance Principles and *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.
- Collaboration with other groups developing parallel codes for other scientific areas such as life sciences research and data sharing e.g. the CORBEL initiative.
- Collaboration with EMIF on the sustainability of its code of practice and data sharing templates

Future plans

- Promote adoption of the *i*~HD principles and rules amongst clinical research sponsors, research platform providers and hospital research staff.
- Develop educational materials to support all staff in adhering to them.
- Evolve these codes in the light of experience and new legislation, on the advice of the GDPR Task Force.

i-HD European Network of Excellence for Hospitals

Aims

- Foster 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, including support for GDPR compliance, 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
- Karl Wouters
- Daniel Schmidtmann

The i~HD Network of Excellence Steering Committee

- Tony Amato, Executive Director, Clinical Trials Center, Policlinico Gemelli, Rome, Italy
- Giuseppe Banfi, General Director, Fondazione Centro San Raffaele, Milan, Italy
- Juuso Blomster-Mäkinen, Turku University Hospital, Finland (since 2018)
- Rocio Diaz, Fundacion de investigacion HM Hospitales, Spain
- Jacques Demote, ECRIN, France
- Pascal Garel, HOPE, Belgium
- Dipak Kalra, i~HD, Belgium
- Morten Kildal, Uppsala University Hospital, Sweden (since 2018)
- Philippe Lechat, Director Clinical Research and Innovation, AP-HP, France
- Tine Lewi, Janssen, Belgium
- John O'Brien, former hospital CEO, Ireland

Summary

The 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 and *i*~HD is developing some of the necessary solutions with special focus on data quality and information governance. The Network of Excellence is helping the hospitals to share practical approaches and benefits within the EHR reuse ecosystem, and advise *i*~HD on additional solutions that they need. Our hospital members also contribute their perspectives to *i*~HD multi-stakeholder activities. The hospital network was formally launched in February 2017, and is steered by a committee of hospital representatives and other advisers (listed above). The NoE has participated in a further workshop in May 2017 on data quality assessment and improvement. The Steering Committee has helped highlight other priorities for the NoE to focus on in 2018, including the GDPR, working with ICHOM on using EHR data to help improve outcomes, support for hospitals to make the best use of their EHR systems. The second annual workshop on outcomes and benefits realisation was held in March 2018.

Achievements during 2017

- Launch of the Hospital Network of Excellence at a workshop in Brussels on February 9th, for research-active and learning health system active hospitals across Europe.
- Established a dedicated steering committee for this Network, comprising representatives from leading European hospitals, and including representatives from patient organisations and other hospital-oriented networks such as ECRIN, HOPE.
- A second data quality workshop held in May 2017.
- Established a collaboration with ICHOM to promote and support hospitals with using EHR data to measure and improve clinical and patient outcomes, leading to a 2-day workshop in March 2018.

Plans for 2018

- Establish a library of outcomes relevant EHR data elements, and data quality benchmarks, to support hospital NoE members with sharing efforts towards measuring and improving clinical and patient outcomes.
- Establish a library of business case studies demonstrating hospital benefits and return of investment from investments in EHR systems and EHR data quality, to support hospital NoE members with constructing future business cases.
- Promote the new *i*~HD data quality service across the NoE.
- Develop with hospitals a portfolio of guidance materials to support compliant practices in reusing EHRs for learning health systems and clinical research.
- Pilot the formation and value of national hospital networks within the *i*~HD NoE, to enable and support a complementary focus on nationally relevant topics.

i-HD Hospital Network Workshop – February 9th 2017, Brussels

***i*~HD** held its launch meeting of the Network of Excellence for hospitals in February 2017, in Brussels. This event was attended by approximately 85 delegates representing 50 hospitals from around Europe.

Participants learned of the challenges in providing coordinated and integrated healthcare that centres on the patient and optimises both healthcare and research processes. There was emphasis on the need for a strong partnership between the pharma industry and hospitals to improve clinical outcomes and accelerate healthcare innovation. The patients' perspective on the reusing of health data for research was considered including the roles that empowered patients can play in self-managing their health conditions, prevention and playing a greater part in clinical research.

Hospitals already integrating and reusing data for research and quality improvement, shared how they established a culture and governance around combining data from multiple local hospitals and developed clinical data warehouses. The speakers described how these systems made the conduct and monitoring of clinical research more efficient, enabled accelerated knowledge discovery and the translation of that knowledge into improved health care.

***i*~HD** presented the newly launched Quality Seal for Clinical Research Platforms (QS4RP) and explained how it is being applied to assess platform service providers and their products. The development of such good practices and support resources will help accelerate the capability of hospitals and other stakeholders to make maximum use of health data.

The workshop concluded by discussing how communities can work together to develop and promote better patient reported outcome measures and help these become the key focus of research and healthcare quality improvement.

A detailed report can be found in Appendix 3.

> *" The role of i~HD will be to bring all the knowledge from the different sources and to give it a structure. Someone who has the overall vision and who brings the right expertise at the right moment in the right place. I think that role can be very well played by i~HD. "*

Juan Fuertes
European Patients' Forum

i-HD Annual Conference – September 21st – 22nd 2017, Madrid

The ***i*~HD** Annual Conference was held in Madrid on September 21-22, 2107 and had over 250 delegates attend from different stakeholder communities. It was a joint event organised by ***i*~HD**, EMIF and the Research Institute of Hospital Universitario 12 de Octubre.

We began with talks from representatives of the Spanish and Estonian health ministries, who elaborated on the importance of reusing clinical data for improving health care and clinical research on national and European scales. They emphasised that we must provide feedback to patients when their clinical data has been used, showing them the research results and clinical care improvements that their data has contributed to.

Four speakers focused on the quality and value of healthcare, from the perspective of a health insurer, health policy, the pharma industry and health technology assessment. The speakers discussed the goals, and the challenges which will need to be addressed, to achieve outcomes-based health care systems on a wide scale. After a panel session, hospital representatives showed the approaches undertaken by three hospitals to enable the transformation to value-based care and to scaling up the capability to undertake clinical research. Then the focus moved to the patient perspective for reusing health care data and how patients can play a more active role in the ecosystem of clinical data.
The final session of the first day considered the topic: towards better health data. This included ***i*~HD**'s data quality assessment methods and improvement strategies, interoperability and key success factors for good looking data.

The second day of the conference was hosted by The European Medical Information Framework (EMIF) focusing on the use of real-world data for research. After these two conference days, the audience could conclude that although there has already been a lot of progress regarding the realisation of a 'health data ecosystem' there are a lot of opportunities for further R&D in this field.

A detailed report can be found in Appendix 3.

" i~HD can play a very big role by making sure that all the stakeholders are aligned, all the standards are agreed upon to work together and also to set a political framework, ethical framework and legislative framework that will make this happen. "

Mitchell Silva
Patient advocate, EUPATI, Belgium

European projects

Trillium 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.

EHR2EDC

i~HD is a partner in a new 2-year project launching in 2018, jointly funded by EIT Health and by some of our EFPIA member companies. This will examine how routinely collected health data can be directly reused within the conduct of clinical trials, if trial subjects have given their consent for this. *i*~HD will lead a Work package on governance, to develop a code of practice covering this aspect of EHR reuse, and also to lead on discussions with regulatory bodies on the acceptability criteria for EHR data acting as a source of information into regulated clinical trials (eSource). *i*~HD, in partnership with EuroRec, will develop a new Quality Seal for research platforms contributing eSource data. We will also contribute to the work package on semantic interoperability, and develop an extension to the Data Quality Seal for the EHR2EDC context.

We are involved in additional EC and IMI grant proposals, the outcomes of which will become known in early to mid-2018.

i~HD's patient centric mission

It is the ambition of ***i*~HD** to engage more strongly with patients about how they see the value of their data being used, how they wish to use their own health data, and what they would like our safeguards to focus on protecting. The perspectives and engagement of patients is central to establishing a trustworthy ecosystem for reusing health data for research and for learning health systems.

We are forming new connections with patient organisations and the public, working with other complementary European organisations. We are launching initiatives to promote greater societal awareness of how health data can be used to advance our understanding and to improve health and care, and the ways in which these uses can be undertaken in trustworthy ways. ***i*~HD** has recently joined the Twitter movement **#DataSavesLives**, which we are promoting to our members. ***i*~HD** will work closely with the European Patients' Forum to promote the value of research to patients and how digital health technologies can empower patients.

Health data is usually collected for direct healthcare purposes. This data can be reused for research provided that appropriate safeguards are met, especially protecting the identity and privacy of the individuals whose data are used. It is also vital to ensure that the data are used for purposes that are recognised in society as bringing public benefit, such as resulting in better quality and safety of care or new effective and safe treatments. This includes empowering patients to collect and use their own health data to optimise their health and wellness.

We are actively championing the **trustworthy** reuse of health data, for learning health systems and for clinical research. We are doing this by:

- developing codes of practice and rules of good conduct for research staff;
- developing technology assessments to verify the security and privacy protection measures provided by clinical research systems;
- supporting healthcare organisations with improving the quality of their electronic health record systems and data;
- promoting the better use of the data for all kinds of learning.

During 2018 we will explore with our members and collaborators how we can best establish new communications channels with patient organisations and the public so that we can most effectively contribute to a successful and well accepted ecosystem for making the best uses of health data, for the benefit of all.

> *" We at i~HD have a big task. We must absolutely make it clear to the data donors that they can trust us. That is essential to the whole of this project. Trust, built on trust. Then gradually the patient will understand that to share their data is the most precious gift they can make. "*

Mary Baker
Immediate past president of the European Brain Council

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
- Implementing and fulfilling the Bylaws

Recently two new colleagues have joined the *i*~HD office and brings the total up to nine.


Geert Byttebier


Pascal Coorevits


Dipak Kalra


Inge Lamote


Nathan Lea


Daniel Schmidtmann


Geert Thienpont


Martine Vannevel


Karl Wouters

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 optimising health and knowledge discovery.
- Build trust & engage all stakeholders that are key for achieving this mission

Summary

Since its creation ***i*~HD** has put a lot of effort into raising awareness of the benefits of health data for optimising health and knowledge discovery. We do so by organising conferences and workshops and by giving conference presentations. Additionally ***i*~HD** representatives give guest lectures featuring ***i*~HD**'s mission on several Masters and specialist courses across Europe.
In 2017, we have seen the first results of this approach as multiple stakeholders have come to our meetings with a clear intent to develop methods, solutions and services that can help to maximise the value obtained from health data. ***i*~HD** has become a forum where healthcare providers, patient organisations, health ministries and insurers, EHR system vendors and standards development organisations, pharma and the clinical research community join forces with this common goal in mind.
Also in 2017, ***i*~HD** started forming collaborations with the European Patients' Forum (EPF), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Consortium for Health Outcomes Measurement (ICHOM).
Alongside organising conferences and workshops, ***i*~HD** has continuously updated and improved its website featuring all sorts of information and news items including videos with key stakeholders. The website has been an important vehicle for keeping our members up-to-date on our activities and achievements. The ***i*~HD** e-newsletter serves the same purpose.
In 2017, ***i*~HD** also has made its first steps in the social media area and produced several interview-based videos.

i~HD related publications

- Ohmann C, Banzi R, Canham S, Battaglia S, Matei M, Ariyo C, Becnel L, Bierer B, Bowers S, Clivio L, Dias M, Druml C, Faure H, Fenner M, Galvez J, Ghersi D, Gluud C, Groves T, Houston P, Karam G, Kalra D, Knowles RL, Krleža-Jerić K, Kubiak C, Kuchinke W, Kush R, Lukkarinen A, Marques PS, Newbigging A, O'Callaghan J, Ravaud P, Schlünder I, Shanahan D, Sitter H, Spalding D, Tudur-Smith C, van Reusel P, van Veen EB, Visser GR, Wilson J, Demotes-Mainard J. Sharing and reuse of individual participant data from clinical trials: principles and recommendations. BMJ Open. 2017 Dec 14;7(12):e018647. doi: 10.1136/bmjopen-2017-018647. PubMed PMID: 29247106; PubMed Central PMCID: PMC5736032.
- Singh G, Schulthess D, Hughes N, Vannieuwenhuyse B, Kalra D. Real world big data for clinical research and drug development. Drug Discov Today. 2017 Dec 30. pii: S1359-6446(17)30595-0. doi: 10.1016/j.drudis.2017.12.002. PMID: 29294362
- Kalra D, Sundgren M, Claerhout B, et al. 2017, The launch of the European Institute for innovation through health data. Journal of Medicines Development Sciences, 3(1): 165. http://dx.doi.org/10.18063/jmds.v3i1.165
- Dupont D, Beresniak A, Sundgren M, Schmidt A, Ainsworth J, Coorevits P, Kalra D, Dewispelaere M, De Moor G. Business analysis for a sustainable, multi-stakeholder ecosystem for leveraging the Electronic Health Records for Clinical Research (EHR4CR) platform in Europe. Int J Med Inform 97:341-352 2017. doi: http://dx.doi.org/10.1016/j.ijmedinf.2016.11.003

Conference presentations featuring i~HD

- R&D Data Intelligence Leaders Forum, Basel, January 2017
- Drug Information Association (DIA) Conference, Glasgow, March 2017
- Learning Health Systems panel at Medical Informatics Europe (MIE), Manchester, April 2017
- AVOCA Consortium Summit, Dublin, May 2017
- PhenoMeNal Joint Stakeholder Meeting, Cambridge UK, June 2017
- i2b2 European Meeting, Paris, October 2017
- eHealth Week, Tallinn, October 2017
- BioData World Congress, Cambridge UK, October 2017
- Joint Conference on Medical Informatics (JCMI), Osaka, November 2017
- Healthcare Information, Tokyo, November 2017

Objectives for 2018

- **The trustworthy reuse of health data**
  - To enrich our portfolio of information governance instruments and good practices, and develop ways to promote and apply these to scaling up the trustworthy reuse of health data for research.
  - To develop and promote, through the GDPR Task Force, awareness and educational materials about the GDPR for all our member stakeholders, with special emphasis on compliance when reusing EHRs for research and in Learning Health Systems.
  - To widen the adoption of the QS4RP, and to work on a further Quality Seal for EHR2EDC (e.g. assessing eSource requirements).
  - To help establish, with regulators and other agencies, the realistic requirements for EHR data to act as an eSource in clinical trials.

- **Data Quality**
  - To establish a Data Quality (assessment) Seal and (improvement) Service, for hospitals.
  - To extend this into developing a Data Quality Mapping Seal and assessment service.

- **Network of Excellence**
  - To grow the hospital network of excellence, later expanding to include general practices.
  - To help establish the business value to hospitals of reusing their EHRs.
  - To grow a role in supporting EHR interoperability for data items of greatest value to research and learning health systems, using this to expand the role for our Interoperability Asset Register.

- **Patients and society**
  - To work more closely with patient organisations on communicating to the public about the assurances needed in society to trust greater use of health data.
  - to promote the societal value of reusing health data.
  - to explore how a public data donorship model can be defined, endorsed and promoted.

- **Members and community**
  - To work with our existing members to ensure value to each of them, and to attract new members across all stakeholder categories.
  - To hold the 2018 annual conference on a larger scale, including an industry exhibition area.

Members


AMGEN


ASSISTANCE
PUBLIQUE
HÔPITAUX
DE PARIS


AstraZeneca


NHS
Cambridge
University Hospitals
NHS Foundation Trust


CUSTODIX
WE PROTECT PRIVACY


ECRIN


empirica


EUROREC


Roche


Gemelli
Fondazione Policlinico Universitario A. Gemelli
Università Cattolica del Sacro Cuore


GHENT
UNIVERSITY


hope
European Hospital and
Healthcare Federation


ICON
A Symbol of Excellence


NHS
Imperial College Healthcare
NHS Trust


janssen


KING'S
College
LONDON


RAMIT


SANOFI


TMF


TYKS


universitätbonn


Universitätsklinikum
Erlangen


UNIVERSITY
HOSPITAL FRANKFURT
GOETHE UNIVERSITY


UKM


EBERHARD KARLS
UNIVERSITÄT
TÜBINGEN

Financial report

Financial statements for 2017

Income

	2016	2017
Membership Pharma	100 000 €	125 000 €
Membership Research centres	5 000 €	3 000 €
Membership CRO	25 000 €	25 000 €
Membership ICT vendors	0 €	5 000 €
Sponsoring	15 000 €	32 210 €
Services	0 €	74 000 €
EU funded research	0 €	34 940 €
Total	**145 000 €**	**299 150 €**

Costs

A.A TGroup (Accountant)	3 128 €
Annual Conference 2017 - Madrid	52 089 €
09.02.2017 *i*~HD Hospital Network Workshop - Brussels	26 943 €
19.04.2017 – Hospital Network of Excellence Meeting - Brussels	1 725 €
30.11.2017 - Data Quality Workshop - Liverpool (preparation)	875 €
QS4RP	26 784 €
24.05.2017 *i*~HD Hospital Network Workshop - Brussels	6 003 €
29-30.11.2017-Data Quality Task Force - Bonn	537 €
Experts	9 552 €
Dissemination materials	5 086 €
Other	15 134 €
Staff	102 090 €
Total	**249 946 €**

In Kind

RAMIT	~ 1 FTE
Janssen	~ 0.1 FTE
Dept. Medical Informatics and Statistics (UGent)	
Founding members	> 0.1 FTE

Budget for 2018

Income

	2016	2017	2018
Membership Pharma	100 000 €	125 000 €	150 000 €
Membership Research centres	5 000 €	3 000 €	5 000 €
Membership CRO	25 000 €	25 000 €	25 000 €
Membership ICT vendors	0 €	5 000 €	10 000 €
Sponsoring	15 000 €	32 210 €	40 000 €
Services	0 €	74 000 €	75 000 €
EU funded research	0 €	34 940 €	75 000 €
Total	**145 000 €**	**299 150 €**	**380 000 €**

Costs

Staff cost - management	60 000 €
Staff cost - research	90 000 €
Staff cost	100 000 €
Experts Task Forces	60 000 €
Conferences	80 000 €
Subcontracting	40 000 €
Organisation meetings	15 000 €
PR materials	15 000 €
Travel	20 000 €
Total	**480 000 €**

In Kind

RAMIT	~ 30% FTE
Founding members	~ 5% FTE

Membership fees in 2017 and 2018

In the table below you will find the annual membership fee for every kind of organisation.

Citizen- and Patients Organisations

- Patient associations — Zero
- Citizen associations — € 100
- Family and carer associations — € 100

Healthcare providers

- General Practitioners — Zero
- Hospitals with a capacity of over 500 beds — Zero
- Hospitals with a capacity up to 500 beds — Zero

- Medical centres (no beds) Zero

Social and care associations (not-for-profit)

- Health professional associations €500
- Social care provider associations €500
- Healthcare provider associations €500

Insurers and health ministries, associations representing health insurers

- National health, care, eHealth and research decision makers Zero
- Third party health and care payers, health insurance organisations €5,000

Commercial Companies active in the field of clinical and/or biomedical research

- Pharma, Bio-tech €25,000
- Medical Device vendors €25,000
- Health data brokers and analytics companies €25,000
- EHR system and applications vendors
  - 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 €1,000
- Industrial associations €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
  - if for profit €2000
  - if not-for-profit €1000
- Electronic health (eHealth) competence centres
- Regulators
- Multi-national decision makers

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 maximising the benefits of good quality and interoperable health data and the trustworthy reuse of health data. ***i*~HD** is working towards convergence and cross-fertilisation 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 organisations, international non-profit organisations and foundations, as modified
Registered office	165 Oude Mechelsestraat, B-1853 Strombeek-Bever (Belgium)
Registration no	628.646.310
VAT	BE0628.646.310
Working address	c/o Dept. Medical Informatics & Statistics, Ghent University Universitair ziekenhuis Gent, 5K3 C. Heymanslaan 10 9000 Gent - Belgium
Contact	Prof. Dipak Kalra, President, dipak.kalra@i-hd.eu
Phone	+32(9)332.40.67
E.C. PIC	923112723
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 organisation of reference for guiding and catalysing the best, most efficient and trustworthy uses of health data and interoperability, for optimising 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. ***i~HD*** importantly brings multiple stakeholder groups together 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 is being governed by its member stakeholders, public and private, through an elected Board and officers. It is 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.
Bank details	IBAN: BE22 0017 5889 6047 BIC: GEBABEBB Bank: BNP PARIBAS FORTIS AG De Plaats 6, B - 9910 KNESSELARE

Appendix 3. i~HD meeting reports

i-HD Hospital Network Workshop – February 9th 2017, Brussels

***i*~HD** held its launch meeting of the Network of Excellence for hospitals in February 2017, in Brussels. This event was attended by approximately 85 delegates representing 50 hospitals from around Europe.

The workshop began with constructing a broad understanding of research opportunities for hospitals. Participants learned of the challenges in providing coordinated and integrated healthcare that centres on the patient and optimises both healthcare and research processes. There was emphasis on the need for a strong partnership between the pharma industry and hospitals to improve clinical outcomes and accelerate healthcare innovation. The patients' perspective on the reusing of health data for research was considered including the roles that empowered patients can play in self-managing their health conditions, prevention and playing a greater part in clinical research. There was emphasis on clinical research being undertaken to a high standard, with respect to training staff appropriately and having well organised research facilities. A vision of the future was given, asserting the need for innovation within hospitals all over Europe to be able to take advantage of the benefits offered through health ICT, robotics and machine learning technologies and to deliver more personalised medicine. This includes providing more integrated and patient centred care.

There were presentations from hospitals already integrating and reusing data for research and quality improvement. They shared how they have established a culture and governance around combining data from multiple local hospitals and developed clinical data warehouses that can be analysed securely using advanced electronic health record systems and clinical research workflow systems. The speakers described how these systems have made the conduct and monitoring of clinical research more efficient, enabled accelerated knowledge discovery and the translation of that knowledge into improved health care. Good quality data is vital for hospitals to deliver a high quality and efficient service. Health information and EHR systems are a critical part of hospital operation. However, it is essential that these systems are quality assured and that the information workforce is suitably trained and credentialed.

***i*~HD** presented the newly launched Quality Seal for Clinical Research Platforms (QS4RP) and explained how it is being applied to assess platform service providers and their products. The development of such good practices and support resources will help accelerate the capability of hospitals and other stakeholders to make maximum use of health data. This includes addressing the issues around trust and trustworthiness in

the reuse of EHRs and the importance of good quality data. The *i*~HD Data Quality Task Force is developing assessment methods and improvement strategies to tackle such challenges. There was very strong interest among many of the hospitals present to form a data quality improvement community, which the Task Force will support.

Participants learned about the challenges of meeting societal concerns and complying with an evolving legal landscape, in the light of the new GDPR. They heard about the approach to these challenges being taken by *i*~HD, and the resources it has been developing to help promote legally acceptable and societally trusted reuse of EHRs for research. It was recognised that this is an ongoing challenge, and many of the hospital participants would like to collaborate with each other through *i*~HD to enable sharing and co-creation of best practices. Working with patient organisations was considered vital to this success.

The workshop concluded by discussing how communities can work together to develop and promote better patient reported outcome measures and help these become the key focus of research and healthcare quality improvement.

All participating hospitals were committed to making better use of their routinely collected electronic health records, to improving learning health systems, to improving quality and safety of care and the re-using of health data for research.

Following this event *i*~HD formed a Hospital Network of Excellence Steering Committee, which has met regularly to advise on future topics, events and initiatives that will be important to help hospitals to accelerate their quality improvement and research.

The Data Quality Task Force has held further workshops and has developed a data quality support service that is being launched in 2018.

i-HD Annual Conference – September 21st – 22nd 2017, Madrid

Our annual conference was held in Madrid on September 21-22, 2107 and had over 250 delegates attend from different stakeholder communities. It was a joint event organised by ***i*~HD**, EMIF and the Research Institute of Hospital Universitario 12 de Octubre.

We began with talks from representatives of the Spanish and Estonian health ministries, who elaborated on the importance of reusing clinical data for improving health care and clinical research on national and European scale. They emphasised that we must provide feedback to patients when their clinical data has been used, showing them the research results and clinical care improvements that their data has contributed to.

We then heard from four speakers focused on the quality and value of healthcare, from the perspective of a health insurer, health policy, the pharma industry and health technology assessment. The speakers discussed the goals, and the challenges which will need to be addressed, to achieve outcomes-based health care systems on a wide scale. Mary Baker led a Q&A panel session with them regarding the practical steps towards achieving value based outcomes based care.

The next session focused on learning health system hospitals. A committee member of ***i*~HD**'s Network of Excellence for hospitals presented the mission and the role of the steering committee. Presentations from hospital representatives were given showing the approaches being undertaken by three hospitals to enable the transformation to value-based care and to scaling up the capability to undertake clinical research. We learned about challenges to the improvement of care pathways through health outcomes measurement and hospital experience in the use of health data for improvement and research.

The focus then moved to the patient perspective for reusing healthcare data and how patients can play a more active role in the ecosystem of clinical data. It was emphasised that the key to achieving an ecosystem of health data use is to develop principles and solutions that are considered trustworthy by patients and by health care professionals. There was an informative panel discussion revolving around the question: How do we agree and deliver the optimum levels of patient control over uses of their health data?

The final session of the first day considered the topic: towards better health data. This included *i*~HD's data quality assessment methods and improvement strategies, interoperability and key success factors for good looking data.

Day 2

The second day of the conference was hosted by The European Medical Information Framework (EMIF). The talks for the day focused on the use of real-world (big) data for research. It began with reporting EMIF developments, progress and showcasing results. This included a common technology and governance framework, and an innovative online platform for identification, assessment, access and (re)use of health data between clinical organisations and research institutes.

The EMIF-speakers presented their existing and ongoing research on Alzheimer's Disease and understanding obesity. The public learned about the EMIF platform and its internal semantic harmonisation mechanisms. State-of-the-art challenges and approaches in establishing a European scale federation of data sources were presented. The EMIF ethical code of practice was explained. The audience heard about the future possibilities for real world data research that could use the EMIF platform and about new opportunities for scaling up big data research.

The day included a panel discussion considering the questions: What have we learned from EMIF in support of health data research? What is the future beyond EMIF?

After these two conference days, the audience could conclude that although there has already been a lot of progress regarding the realisation of a 'health data ecosystem' there are a lot of opportunities for further R&D in this field.

Appendix 4 Referenced organisations and projects

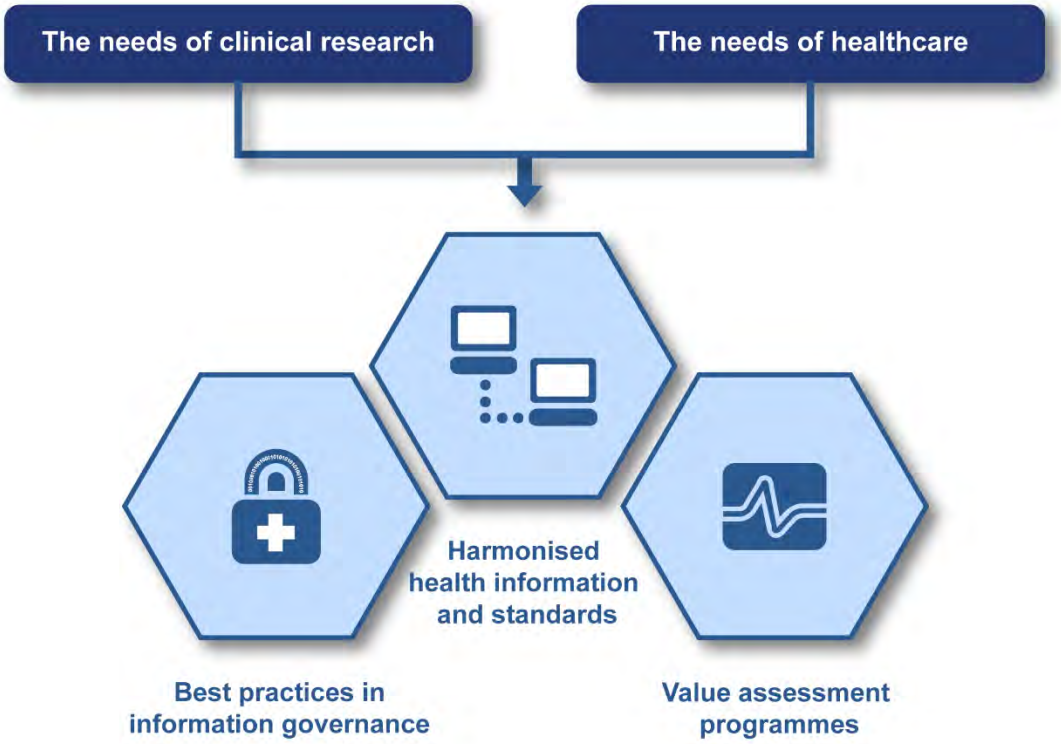
- AP-HP: Assistance Publique – Hôpitaux de Paris
  https://www.aphp.fr
- CORBEL: Coordinated Research Infrastructures Building Enduring Life-science Services
  http://www.corbel-project.eu
- ECRIN: European Clinical Research Infrastructure Network
  http://www.ecrin.org
- EFPIA: European Federation of Pharmaceutical Industries and Associations
  https://www.efpia.eu/
- EHR2EDC: From Electronic Health Records to Electronic Data Capture systems
  https://www.eithealth.eu/ehr2edc
- EHR4CR: Electronic Health Records for Clinical Research
  http://www.i-hd.eu/index.cfm/resources/ec-projects-results/ehr4cr/
- EMIF: European Medical Information Framework
  http://www.emif.eu
- EPF: European Patients' Forum
  http://www.eu-patient.eu
- ETRIKs: IMI funded project
  https://www.etriks.org/
- FAIR: Principles for Findable, Accessible, Interoperable, Reusable data
  https://www.force11.org/group/fairgroup/fairprinciples
- HOPE: The European Hospital & Healthcare Federation
  www.hope.be
- ICHOM: International Consortium for Health Outcomes Measurement
  http://www.ichom.org
- IMI: Innovative Medicines Initiative
  https://www.imi.europa.eu/
- RAMIT: Research in Advanced Medical Informatics and Telematics
  http://www.ramit.be
- SemanticHealthNet:
  Semantic Interoperability for Health Network
  http://www.i-hd.eu/index.cfm/resources/ec-projects/results/semantichealthnet/
- TRANSFoRm: Translational Research and Patient Safety in Europe
  http://www.i-hd.eu/index.cfm/resources/ec-projects-results/transform/

Appendix 5 Abbreviations

- CRO: Contract Research Organisation
- EHR: Electronic Health Record
- EU: European Union
- GDPR: European General Data Protection Regulation
- ICT: Information and Communications Technology
- NoE: Network of Excellence
- QS4RP: Quality Seal for clinical Platforms
- TF: Task Force
- UGent: Ghent University

The European Institute For Innovation Thr~ugh Health Data

Guiding and catalysing the best, most efficient and trustworthy uses of health data and interoperability, for optimising health and knowledge discovery



for Health ICT industry
Promotion of benefits from interoperable health and research solutions

for Patients
Seamlessly connected and informed healthcare professionals

for Healthcare professionals
Engagement in priority setting for future standards

for Standards developers
Evidence of value derived from interoperability standards adoption

for Scientific associations
Better quality health data for clinical and epidemiology research

for Pharma
Clinical research platform certification and governance

for Healthcare decision makers
Better evidence for policy, strategy and resource planning

for Health data brokers
More consistent clinical governance practices across Europe