The European Institute For
Innovation Thr~ugh Health Data

i~HD ANNUAL REPORT 2019

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You can also consult this annual report on our website:
https://www.i-hd.eu/index.cfm/about/i-hd-annual-report-2019/

The importance of health data continues to grow. More and more stakeholders recognise that we must all make better use of high-quality health data, in trustworthy ways. Health data has the potential to catalyse solutions for the urgent need to improve the quality of health, care pathways and services, advance research more rapidly and effectively. Moreover, health information can help to engage patients in self-care and shared decision-making.

This is the foundation on which i~HD was created and strengthens the case for the activities we have prioritised scaling up over the past year. During 2019 we have been increasingly active in synthesising the emerging good practices in **reusing health data in GDPR compliant ways**. We are supporting innovative European health-promoting projects funded by the IMI Innovative Medicines Initiative, Horizon 2020 and EIT Health through guidance and codes of practice for sharing and using health data for research and value-based care. We also deliver GDPR education through tutorials and workshop events for the health data industry. We have advanced our work on **data quality assessment** and begun to develop Data Quality Seals. We are promoting the adoption of interoperability standards, targeting this towards high-value data that deliver benefit to care and research, providing practical focal points around which stakeholders can engage to accelerate **interoperability standards adoption**.

An important part of what we do is to **bring diverse health data stakeholders together** to hear and learn from each other. We strive to create together the momentum to drive initiatives and co-create solutions that enable us all to improve the data we collect and our capability to combine and share that health data for societal good. We held our main annual conference "Joining the Dots" in Brussels in November 2019, as a partnership with several European projects, bringing them together and "Joining the Dots" between them along several vital lines such as high value data sets, multi-morbidity, patient empowerment, privacy protection and federated research infrastructures. We also ran streams in other major European conferences and gave presentations in many others.

We are delighted to announce that **the i~HD team has grown** over the past year, with new staff working in the Gent office and additional experts around Europe contributing to our fields of activity. We have been fortunate in winning a significantly increased grant income from diverse research and industry sources, and also **grown our membership**. We are especially pleased to welcome MedTech Europe, which broadens our industry sector representation. We have strengthened our collaboration with the European Patients' Forum and the European Multiple Sclerosis Platform, enriching our much-valued patient inputs.

We have expanded considerably during 2019, and have recognised that it is important to better formalise our internal organisational quality processes. We have sharpened our vision and mission, which you can read on the next page, and we are in the process of drafting new internal policies and protocols so that we can **apply next year as an ISO certification body**. This will give added weight to the Quality Seals we have developed in the past and others that are in the pipeline. Our website will soon have a new look too!

So, we have started 2020 with a stronger in-house team and a fantastic network of European experts, a large portfolio of projects, a healthy income stream and an ambition to have even greater impact within our multi-stakeholder community on the success factors for scaling up innovation through health data.

Professor Dipak Kalra
President

Geert Thienpont
Managing Director

ABOUT i~HD

i~HD is an international not-for-profit organisation created in 2016.

Mission & Vision

We strive for a world in which multiple stakeholders collaborate in the trustworthy use of high quality health data to continuously improve care and accelerate research.

We promote, develop and share good practices, tools and quality assessments to maximise community value from health data for innovations in health, care and research.

Fields of Activity

We focus on the following fields of activity:

A. Quality and interoperability of health data
B. Quality seals and assessments of EHR systems and clinical research systems
C. Trustworthy data protection and governance
D. Community building to develop and share innovations using health data

Members and Collaborators

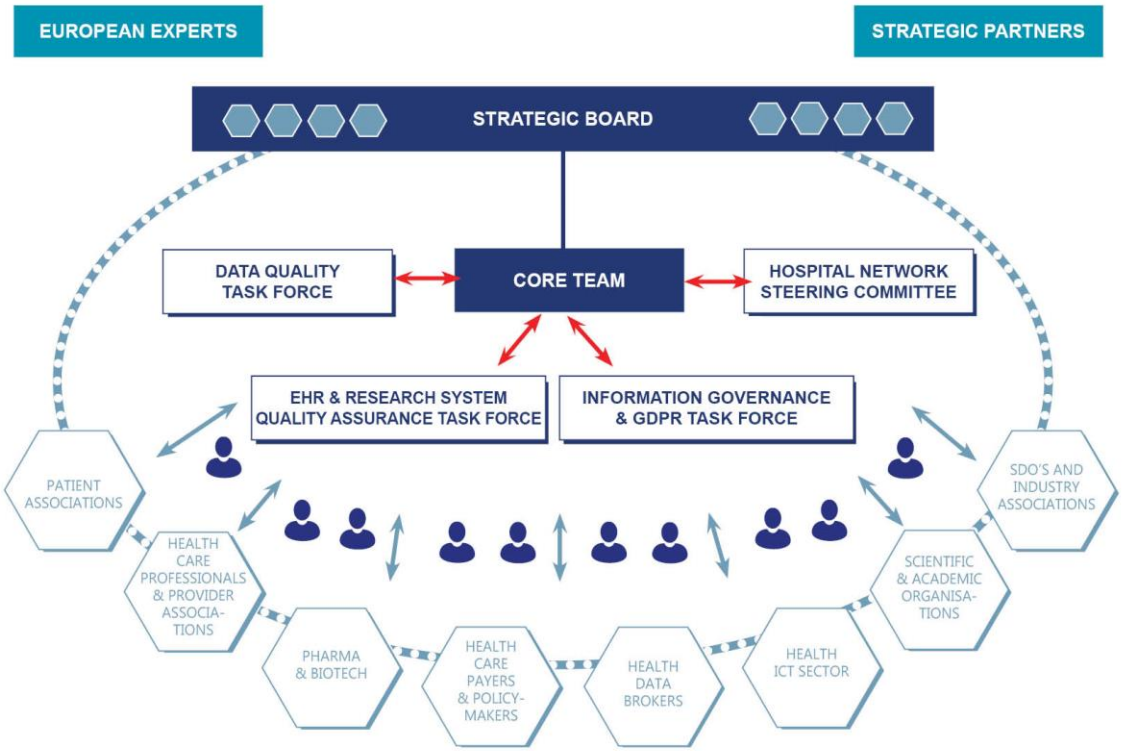
i~HD members and collaborators include pharma, MedTech, the health ICT sector, healthcare providers, academic organisations, patient organisations, healthcare payers and standards development organisations. We work across these stakeholders through R&D, education and events to promote collaboration in realising the value to all in society from the better uses of health data. i~HD has staff with experience of leading or being a partner in over 100 European projects and in developing international standards.

Uniqueness

What makes us special:

- We have one focal point: health data
- We are neutral
- We unite the community of health data stakeholders
- We are European, and beyond
- We are not for profit
- We have created a network of world-leading experts
- We have the expertise to identify the most important barriers to scaling up our learning of health data
- We focus on developing and promoting practical solutions

Community



The i~HD core team is surrounded by European thought leaders in each field of expertise, working together in task forces and committees. This means that we constantly stay at the top through monitoring emerging legislation, research and development.

The European Institute For Innovation Thr~ugh Health Data

FIELDS OF ACTIVITY

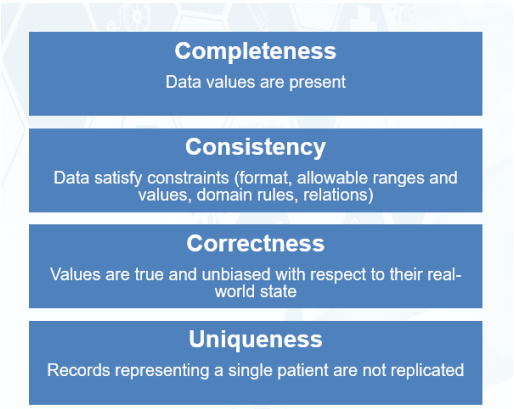
Quality and Interoperability of Health Data

The importance of the quality of health data is being recognised by more and more stakeholders each year, as we scale up the many ways in which health data provides us with vital knowledge to improve healthcare and accelerate research. Artificial intelligence is the latest topic on which it is recognised, finally, that AI algorithms will only be safe if the machine learning systems are fed with high quality data. We have been involved in events where we have promoted the importance of data quality for trustworthy AI, for clinical research and for redesigning care pathways for patients.

In collaboration with Juan M. Garcia-Gomez, Carlos Sáez and Marta Durá Hernández of the University of Valencia, one of our strategic partners, we have continued to advance our experience and rule base for data quality assessments during 2019.

For instance, through the EHR2EDC project (Electronic Health Records to Electronic Data Capture) we have worked with European hospitals and pharma industry colleagues to determine key variables that are most relevant to include in oncology clinical trials, building on the previously defined EHR2EDC dataset that is generic across disease area clinical trials. We have begun developing the data quality rules for this oncology data set, which we will finetune and pilot test during 2020.

Further, through a project sponsored directly by EFPIA, we are developing a methodology to assess data quality to provide evidence of heart failure outcomes, in order to assess the extent to which European hospitals are ready to implement value-based healthcare. We will define the data quality rules and perform pilot assessments at a number of European hospitals during 2020. For these pilot assessments, we will focus on the following four data quality criteria: completeness, consistency, correctness and uniqueness.



We have configured our methodology to tailor quality assessments to the hospitals' needs.

In general, we have configured our general Data Quality service methodology and the workflow through which we engage with hospitals and potentially other data sources to tailor a quality assessment to their needs. This optimized data quality service is currently being promoted to hospitals.

Although we recognise that the year 2020 is being significantly disrupted by the COVID-19 pandemic, we are optimistic that later in the year we will be able to undertake some of these intended data quality assessments at hospital sites, to help them improve data quality, grow our own experience and add to our library of data quality rules.

We are in parallel continuing to promote the importance of data quality for a number of different scenarios, such as the forthcoming common European Health Data Space.

Quality seals and assessment of EHR Systems and Clinical Research Systems

The i~HD Quality Seals and our assessment of EHR systems and clinical research systems have been developed and deployed to provide health care and research organisations with an independent and rigorous assessment of the security, integrity and accuracy of their installed systems or systems they intend to purchase. A successful result following our audit is recognized with a quality label with regards to robust capabilities in data protection, data management, data privacy and GDPR compliance. This label, awarded by i~HD, is an objective way for system vendors to showcase the quality and reliability of their systems, creating trust with potential purchasers and overcoming possible barriers to engage with business partners, authorities and private stakeholder groups.

In order to obtain this quality label, an in-depth, well-considered and tailored assessment must be undertaken. The foundations of each assessment are based on a body of quality criteria curated and validated over years of field experience and involvement in both commercial and European research projects.

Today's quality is tomorrow's innovation

Ever since the beginning of our organization back in 2016, we applied our Quality Seal for EHR systems and clinical research systems in several EU funded R&D projects. As a strategic partner with RAMIT (Research in Advanced Medical Informatics & Telematics) our expertise and knowledge regarding system testing has been recognised through the LABEL.BE project. This is a project coordinated by the Federal eHealth Platform (Belgium) with regards to certification of primary care software.

Also, the landscape of digital health is continuously changing and innovating:

- The increasing business and performance criticality of reliable health data
- The introduction of the General Data Protection Rules (GDPR)
- The rapid evolution of e-health and m-health
- The digital acceleration fuelled by innovations such as Artificial Intelligence

This not only creates opportunities but also challenges for our Quality Seal and assessment for EHR systems and clinical research systems. Our founding experts have

Example of an in-depth testing process

In the first phase of one of our available testing scenarios we submit the organisation to a pre-assessment. During this phase we determine the suitability of the system and the developing organization for the quality label. Based on the pre-assessment results, the team develops a series of scenario-based tests.

The second part (requiring an onsite visit) involves a series of tests and assessments on the software systems, as well as interviews with key members of the staff and an examination of internal policies and protocols. One or more in-depth scenarios are developed which our assessment team will further specify according to the client's organisation and the responses that were provided during the pre-assessment.

Once the onsite assessments have been completed, our assessment team members will each independently score the responses and reconcile their results with each other, at which point a recommendation can be made as to whether the seal and/or improvement process is designated.

nearly 15 years of EHR system quality labelling experience. Our team has grown considerably in 2019, so has the expertise we can rely on. Our aim and promise towards our members and stakeholders is to keep system quality standards one of our priorities in order to be the catalyst of innovation through health data.

Trustworthy Data Protection and Governance

Following the implementation of the European General Data Protection Regulation (GDPR) in 2018, i~HD experts have played important roles within Europe exploring the interpretation challenges and Member State implementations regarding the application of the GDPR to the research re-use of health data. There are many challenges in getting this right, including the correct choice of legal basis, the appropriate positioning of informed consent amongst those legal bases, and how the role of data controllers, joint controllers and data processes should be assigned. Other challenges include determining the adequacy of safeguards relating to pseudonymised data, and the acceptability of different anonymisation techniques. Our experts have been involved, sometimes as speakers, in European workshops and think tanks, taking a deep dive into these topics. The research re-use of health data is a recognised grey area of GDPR interpretation in which good practices are slowly emerging in parallel to Member State interpretations.

We have been fortunate to be a partner in several initiatives and projects across Europe that have involved us in developing good practices and education for different stakeholder groups and consortia. These have sought to reuse data from electronic health record systems, disease registries, rare disease bio-banks and patient generated data sources for various areas clinical research. Our experts have been involved in analysing the information flows, information processing needs, supporting the conduct of data protection impact assessments, advising on the wording of informed consent forms and transparency notices, guiding on data protection measures within research platform innovations and on appropriate audit arrangements.

On the basis of this experience members of the i~HD Information Governance and GDPR Task Force have developed a tutorial package specifically focusing on GDPR compliance when reusing data for research. The GDPR tutorial i~HD developed for UCB in 2019 is an example of a tailored workshop for the pharmaceutical industry. The tutorial was developed to help understand and handle the challenges of processing different kinds of personal health data safely and securely. The focus was on a practical approach that explored in detail the protection of data about many individuals gathered from multiple platforms to support different kinds of health research and innovation

Under the guidance of Nathan Lea (i~HD Information Governance & GDPR Task Force Leader) and supported by field experts Mariana Rissetto (Department of Innovation and Digitalisation in Law at the University of Vienna), Petra Wilson (Health Connect Partners and i~HD), Ruben Roex (research group Law & Technology at the University of Ghent) and Brendan Barnes (EFPIA), our i~HD Task Force focused on topics as:

- Real-World Evidence
- The regulatory framework
- Accountability, security and breach management
- Extra-EU transfers and operations

- Data protection impact assessments
- Case studies developed by i~HD taskforce jointly with UCB

A customised tutorial package for research active hospitals has also been developed.

Accurate accountability and a customized approach are the main keys to tackle GDPR.

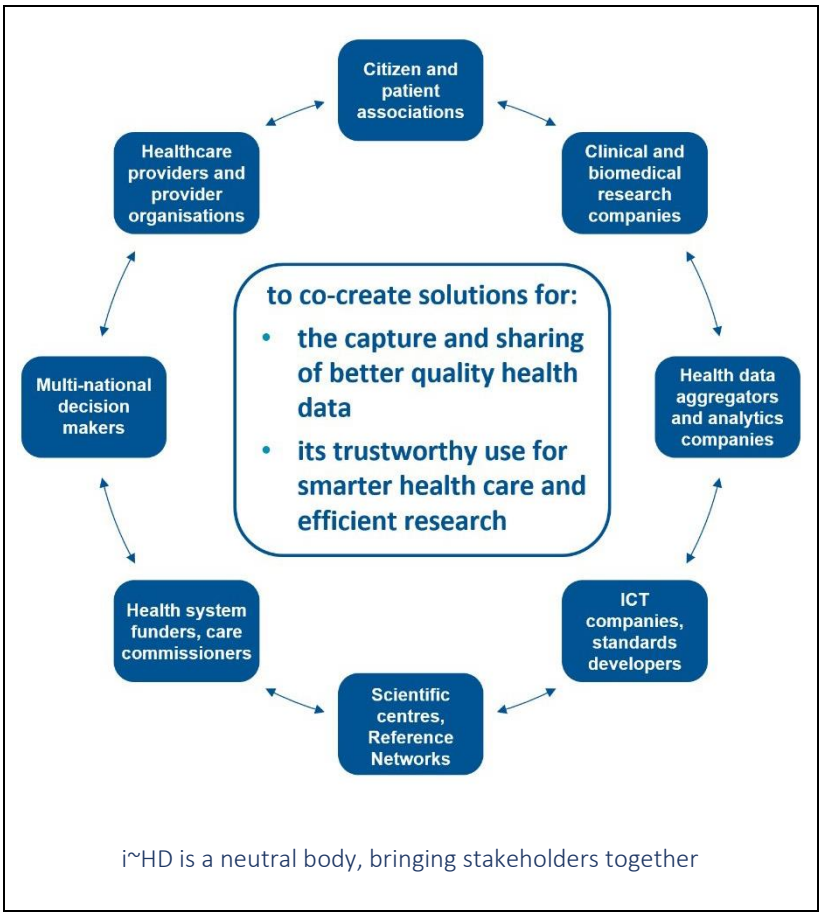
We are gradually evolving our portfolio of instruments through these opportunities. We have agreement from all of those project coordinators that we can snowball our learning from project to project, building up better solutions and seeding consistency across Europe in how these challenges are tackled.

We have more projects starting in 2020 and will therefore be able to scale up our initiatives in data protection, data sharing, codes of practice and the collation of GDPR compliance measures adopted across the research and learning health ecosystems.

Community Building to Develop and Share Innovations using Health Data

The health data community needs to become smarter at learning from digital health information: we need to better understand how we can improve the quality and safety of care, better empower patients, develop smarter software and algorithms, accelerate the development of medicines and medical devices.

The large-scale data needed to address these many different knowledge needs comes from multiple sources.



i~HD is a neutral body, bringing stakeholders together

Foster the co-creation of solutions and building trust through better understanding

Hence, scaling up this 'Learning Health System' is only possible when all stakeholders cooperate. We therefore foster the co-creation of solutions by bringing stakeholders together, building trust through a better understanding of the roles and potential contributions of different stakeholders to the health data and learning ecosystem.

In 2019, i~HD ran streams within large-scale conferences in Finland, Sweden and Belgium. We also held our own multi-stakeholder event, Joining the Dots, in late 2019. These are described later in this report.

We were also present at other multi-stakeholder events through the projects we are involved in, which themselves often have large networks. Of particular note, we have been a collaborator in engagement activities through Data Saves Lives, at an EFPIA patient organisation think tank, an Oncology Data Summit and a dedicated Data Saves Lives community event on the societal acceptance of using health data.

We are part of an EFPIA think tank on the future of value-based care, through which our collaborative project on heart failure outcomes data has arisen. We were invited to a workshop on the value of diagnostic information hosted by MedTech Europe, and to present on good practices in the data sharing at the launch meeting of the Multiple Sclerosis Data Alliance, at the Charcot Foundation annual meeting in Italy. We also presented to a national patient and professional association annual meeting in Ireland.

Our messages always strongly emphasise the importance of making greater but always trustworthy use of health data across the learning health spectrum from care to research. We stress the vital importance of engaging patients more, both as data providers and as decision makers about their own health trajectories. We promote the importance of research and the essential need for larger scale data access in order to enable that research to be more personalised and more effective.

In progressing our multi-stakeholder mission, we are grateful to many colleagues across these different stakeholder groups who have supported us, joined forces with us within our events, co-created solutions and have been our champions.

COLLABORATIVE PROJECTS

Value Based Health Care

In order to explore to what extent current systems can deliver the data that would be needed for a more outcomes-based care model, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has launched a project together with i~HD to perform an assessment of how a selected sample of European hospitals collect data on Heart Failure outcomes.

Heart failure is a chronic condition with dramatic consequences for people's quality of life that is estimated to affect more than 10 million people in the EU, also leading to around 2% of all healthcare expenditure. Collecting meaningful data on the health status of heart failure patients is an important step to ensure better quality care, and as a result better quality of life, for these patients. The project will continue to run through 2020-21.

How ready are European hospitals to evidence their outcomes?

Our role is to reflect wide-ranging background expertise about many of the challenges that lie in scaling up value-based healthcare, but with a special emphasis on clinical engagement issues and on the availability of relevant health data to provide evidence of clinical outcomes achieved by healthcare providers. i~HD will assess the readiness of 10 example hospital EHRs to measure health outcomes.

The benchmark for the exercise is ICHOM's standard set for Heart Failure, which represents a global standard for the data that ideally should be collected, including patient-reported outcomes. The objective is to explore how much of the ICHOM standard set is routinely collected today in a sample of hospitals, and draw conclusions on what the gaps are and how they could be addressed.

How to address the gaps to accelerate a transition towards an outcomes and value based focus

A reference group with representatives of patients, clinical experts, hospital management and industry experts is providing advice to the project, including on the scope and deliverables, selection of hospitals and what data items to focus on.

Supported by:

efpia
European Federation of Pharmaceutical Industries and Associations

Data Saves Lives

i~HD is a partner in an initiative led by the European Patients' Forum to convey to the public how health data can contribute to gaining insights that lead to improvements in the quality and safety of healthcare, and can accelerate research leading to novel treatments, medical devices and software such as artificial intelligence.

Objective: convey to the public how health data can contribute to gaining insights

The initiative is joint sponsored by EFPIA, EIT Health and MedTech Europe. The role of i~HD is to create content for the web portal and other dissemination materials that explain health data, how it is used, the benefits that arise from its use and how the data and the rights of patients and citizens are protected during this use. Our work included the collection of case studies that illustrate ways in which large-scale health data use has led to health system improvements. We also helped shape and structure the website. We contributed to multi-stakeholder engagement events as well.

The Data Saves Lives campaign and website was launched on 12 November 2019 and obtained a lot of visibility.

Coordinated by:

Supported by

Multiple Sclerosis Data Alliance

The Multiple Sclerosis Data Alliance (MSDA) is a global multi-stakeholder collaboration that was launched in 2019. It is working to accelerate research insights for innovative care and treatments for people with Multiple Sclerosis (MS).

Scaling-up real-world MS data is necessary to transform the care of people with MS and MSDA envisions a patient-centric data ecosystem in which all stakeholders contribute and use big data to co-create the innovations needed to advance timely treatment and care of people with MS.

The MSDA Toolbox aims to reduce the time needed to find and assess data registries and cohorts, building a data source catalogue and tools that can help a potential research user to understand the kind of data that is inside any data source before formalising a research data access request.

The MSDA Academy focuses on awareness raising, community building and education, providing education to the MS professional, research and patient communities on topics relating to good practices in the use and sharing of data.

We help shape the MSDA Academy workshops and the information governance approach

i~HD is a partner in this consortium, which is being funded mainly by pharma industry sponsorship. We lead a work package on MSDA Academy workshops, and lead work on information governance (including GDPR compliance, and data sharing agreements).

EUROPEAN R&D PROJECTS

These Projects are (partially) funded by the European Commission via different programmes.

Four new European R&D Projects

i~HD was a partner in seven ongoing European R&D projects. We proudly started work on four new European projects in 2019, i.e. Helical, EU-Pearl, UNICOM and mHealth Hub, while the kick-off meeting of ADLIFE (Personalized Care for Patients with Advanced Chronic Diseases) will take place in January 2020.

- **EHR2EDC** - Connecting EHR and EDC systems for more efficient clinical trials
- **Conception** - Real world evidence on safe, effective medicines use in pregnancy and lactation
- **Helical** - Advancing research on rare vasculitis *NEW!*
- **EU-Pearl** - Patient-centric clinical trial platform *NEW!*
- **UNICOM** - Up-scaling the global univocal identification of medicines *NEW!*
- **mHealth Hub** – European MHealth Innovation and Knowledge Hub *NEW!*
- **Conect 4 Children** - Harmonising clinical trials in children across Europe

Research Proposals

i~HD is also involved in new research proposals. Two of these, in the IMI programme, have been successfully shortlisted and we are therefore very hopeful that they will be awarded and start in late 2020: on the establishment of a network of health outcome observatories across Europe, and on novel ways of delivering personalised electronic prescription information to patients. We are also participating in research proposals in Horizon 2020.

Ongoing European R&D Projects

EHR2EDC - Connecting EHR and EDC systems for more efficient clinical trials

Health and EFPIA pharma companies. This project is developing solutions to enable routinely collected hospital EHR data to be directly reused within the conduct of clinical trials, if trial subjects have given their consent for this. The project is designing and implementing a platform to enable the reuse of EHR data within a trial, which has been piloted in four European hospitals. i~HD leads a work package on governance, especially compliance with the GDPR, and has developed a code of practice covering this aspect of EHR reuse. i~HD also leads the task 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 is developing 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. During 2020 the project will enrich the data set to be communicated between EHR and EDC systems in the domains of cardiovascular medicine and oncology. Follow on grant applications are being submitted to EIT Health for 2021.

Consortium partners: EIT Health, Assistance Publique - Hôpitaux de Paris, Custodix, Hospital 12 de Octubre, Hannover Medical School, ICON, i~HD, Inserm, IRST, AstraZeneca, Janssen, Sanofi, UCB

Supported by:

ConcePTION - Real world evidence on safe, effective medicines use in pregnancy and lactation

Conception is developing an ecosystem for generating and disseminating real world evidence on the use of medicines in pregnancy and during breastfeeding, the effectiveness and safety of these medicines. The evidence will be generated through a network of women's health databases held by consortium partners and third parties, and published for access by women, healthcare providers and other decision makers including medicines regulators. This will be achieved by generating, cataloguing, linking, collecting and analysing data from pharmacovigilance, modelling, routine healthcare, pregnant women and their children through a large network. i~HD is a partner and leads a work package on multi-stakeholder engagement and consensus building on the acceptance of real-world evidence, in particular interacting with medicines regulators such as EMA. It also leads a task on information governance and GDPR compliance. The ConcePTION project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Consortium partners: Novartis, UMC Utrecht, Ulster University, Uppsala Universitet, BBMRI-ERIC, Alma Mater Studiorum Università Di Bologna, i~HD, KU Leuven, Medicines & Healthcare products Regulatory Agency, Netherlands Pharmacovigilance Centre Lareb, Ars Toscana, Karolinska Institutet, The Newcastle Upon Tyne Hospitals, University of Kwazulu-Natal, University of Oslo, St George's University of London, Eurohealth, UMCG, Orcion, Inserm, BioNotus, Hôpitaux de Toulouse, Università Degli Studi di Ferrara, Prifysgol Abertawe Swansea University, Université de Genève, EFCCP, The Synergist, Entis, The University of Manchester, Region Stockholm, Elevate, Finnish Institute for Health and Welfare, IFC, FISABIO, Ttopstart,

European Medicines Agency, RIVM, Janssen, Sanofi, Takeda, GSK, Lilly, Pfizer, Bristol-Myers Squibb Company, Merck, Novo Nordisk, UCB, Abbvie, Ellegaard, Covance, Teva

https://www.imi-conception.eu/

Supported by:

Helical - Advancing research on rare vasculitis

Health data LInkage for ClinicAL benefit is a training network comprising 17 academic and 9 non-academic/industry partners for early stage researchers in the field of Healthcare Data Linkage in the GDPR era. HELICAL will link research datasets with longitudinal healthcare records, based on a robust ethical foundation required for linkage studies using near-patient data, to address key experimental questions, using autoimmune vasculitis as a paradigm. Fifteen PhD studentships will be funded through this network. i~HD will host one fully funded PhD to conduct research to work for 3 years into the implications of GDPR for biomedical research using personal and genetic data, the role of consent in rare disease research and the appropriate safeguards for the pseudonymisation of genetic data. This project is funded through the European Union's Horizon 2020 research and innovation programme (Marie Skłodowska-Curie grant).

Consortium partners: Adapt Centre, IBM, Trinity College Dublin, University of Glasgow, Kantonsspital St. Gallen, ISGlobal Barcelona, Instituto de Parasitología y Biomedicina "López - Neyra", Consejo Superior de Investigaciones Científicas, University of Leeds, Anaxomics, IDIBAPS, Medizinische Universität Wien, TissueGnostics, KTH Royal Institute of Technology, Firalis, i~HD

http://helical-itn.eu/

Supported by:

EU-Pearl - Patient-centric clinical trial platform

EU-PEARL has the ambition of transforming the current approach of conducting single-compound clinical trials into the use of cross-company Integrated Research Platforms (IRPs), taking into consideration both patients' interests and the opportunities from novel molecules for addressing medical needs. Patient-centric data and knowledge sharing have the potential to accelerate the development of new treatments and reduce the operational costs of clinical trials. EU-PEARL will improve clinical effectiveness, patients' satisfaction and societal access to timely and affordable medicines, and it will shape the clinical trials of the future. This will change the industry paradigm from competition to cooperation in four disease areas and provide the framework for designing IRPs in other disease areas. EU-PEARL will create a reusable, accessible and sustainable modular IRP for the design and execution of patient-centric, cross-company IRP in any disease area with unmet needs. This will take into account the appropriate regulatory, ethical, legal, statistical and data utilisation requirements. The IRP design will deliver trial-ready IRP networks in the four disease areas of Major Depressive Disorder, Tuberculosis, Non-Alcoholic Steatohepatitis and Neurofibromatosis. EU-PEARL receives funding from the Innovative Medicines Initiative 2 Joint Undertaking. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

i~HD leads the main governance work package of the project, and so will play a leading role in ensuring the project meets its objectives. It has specific responsibilities in information governance and GDPR compliance, interoperability and data quality, platform certification, and contributes to other sustainability actions.

Consortium partners: Fundació Hospital Universitari Vall d'Hebrón – Institut de Recerca, EATRIS ERIC, SYNAPSE Research Management Partners SL, Medizinische Universität Wien, Katholieke Universiteit Leuven, King's College London, Universita Vita-Salute San Raffaele, Erasmus Universitair Medisch Centrum Rotterdam, Ludwig-Maximilians-Universitaet München, Charité - Universitaetsmedizin Berlin, Assistance Publique - Hôpitaux de Paris, Custodix, i~HD, Berry Consultants, ECRIN European Clinical Research Infrastructure Network, European Patients' Forum, University of Newcastle upon Tyne, EUROSCAN International Network, Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, The Chancellor, Masters and Scholars of the University of Oxford, Università degli Studi di Milano, DocuMental OÜ, The University of Manchester, Janssen Pharmaceutica, Novartis Pharma, Allergan, AstraZeneca, Novo Nordisk, Otsuka Novel Products, Pfizer, Sanofi-Aventis Research & Development, Institut de Recherches Internationales Servier, Teva Pharmaceutical Industries, Children's Tumor Foundation, SpringWorks Therapeutics, Global Alliance for TB Drug Development

http://eu-pearl.eu/

Supported by:

UNICOM - Up-scaling the global univocal identification of medicines

This innovation action will give a powerful impulse to implementation of ISO IDMP (ID of Medicinal Products) standards in EU Member States drug databases, supporting safe cross-border ePrescription/ eDispensation and effective pharmacovigilance. Once EU-interoperable data on medicines taken by patients become available, further benefits will accrue through better health data for improved clinical decision support, patient empowerment, public health and clinical research. New opportunities will arise for pharma industry, software developers, SMEs providing smart apps and others, thereby fostering their innovation capacity and competitiveness.

The project ambition centres on conversion of key regulatory and clinical processes to use IDMP. These information value chains must be converted over their full length from data input to data repositories to data usage. The project will mainly focus on the implementation of EU and national SPOR (substances, products, organisations, referentials) data bases, including establishing an EU Substance Reference System (EU-SRS). Such information is fundamental to cross-border ePrescription where safe dispensation may require reliable identification of substances in available products. 19 countries are represented, including 26 national Drug and eHealth Agencies. Stakeholders are involved through their associations. This project is funded through the European Union's Horizon 2020 research and innovation programme.

i~HD leads work packages on the delivery of enhanced medicines information to patients, pharmacists and clinicians, its use in pharmacovigilance and in personalised medicine, and the incorporation of IDMP medicines identification standards into healthcare provider and pharmacy systems including decision support.

Consortium partners: AEMPS, AFMPS, AGES, ARIA, BFARM, BIDMC, CGB, COCIR, Datawizard, EESAM, EHTEL, ELGA, EMPIRICA, FIMEA, FOUND, GNOMON, HALMED, HL7, HPRA, Croation Health Insurance Fund, IDIKA, IDMP1, IEDOH, i~HD, IHE Europe, ILIM, INDRA, INFARMED, KELA, MHRA, NICTIZ, NOMA, REGLOMB, SAS, SEMPA, SPMS, VIDAL, ZINDEX

https://unicom-project.eu

Supported by:

mHealth Hub - EUROPEAN MHEALTH INNOVATION AND KNOWLEDGE HUB

m Health Hub is a project funded by the EC through the WHO and ITU. Its goal is to develop a web platform of knowledge to enable mHealth to be more widely and successfully deployed in national and regional level health services, and for mHealth to deliver large scale benefits. The platform aims to become the focal point for expertise on mHealth in the EU, identifying and highlighting trends and gaps in policies, standards, regulations, etc. and best practices and barriers to the creation of consistent mHealth

infrastructure and strategy. i~HD is responsible for threads of work relating to stakeholder engagement, contributing to the structure and content of mHealth knowledge frameworks and for charting the innovation landscape of mHealth.

Consortium partners: Campania Region, Ehtel, Empirica, Ericsson Nikola Tesla D.D., Foundation Tallinn Science Park Tehnopol – Connected Health Cluster, European Society of Cardiology (ESC), Health Care Centre Zagreb, Hl7 International Foundation, i~HD, International Telecommunication Union (ITU), Junta de Andalucia, Mdog, Spanish Ministry of Health, Osakidetza (Basque Health Service), PCHA, Promis, Jämtland Härjedalen Region, SPMS, University of Agder, University of Applied Sciences Technikum Wien, WHO

http://mhealth-hub.org

Supported by:

Conect 4 Children – Harmonising clinical trials in children across Europe

The conect4children (collaborative network for European clinical trials for children (c4c)) consortium aims to enhance the competitiveness of Europe, as a critical region for developing medicines for children. This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking. The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

i~HD plays an advisory role as a third party in this IMI project, providing expertise in semantic interoperability and the development of a standardised paediatric data dictionary.

Consortium partners: Fondazione PENTA Onlus, The University of Liverpool, Ospedale Pediatrico Bambino Gesù, EURORDIS–Rare Diseases Europe, European Cystic Fibrosis Society, Radboud University Medical Centre, Swiss Clinical Trial Organisation, Associação para Investigação e Desenvolvimento da Faculdade de Medicina, Istituto Giannina Gaslini, University College London, The European Society for Paediatric Oncology (SIOP Europe), University of Tartu, Okids, Newcastle University, Universiteit Gent, Universitaetsklinikum Heidelberg, Aristotelio Panepistimio Thessalonikis, Instytut "Pomnik-Centrum Zdrowia Dziecka", Helse Bergen HF*Haukeland University Hospital, ECNP, Robert Bosch Gesellschaft für medizinische Forschung, University College Cork, Karolinska Institutet, Fundació Sant Joan de Deu, Servizo Galego de Saude, Gyermekgyógyászati Klinikai Vizsgálói Hálózat, Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, ECRIN European Clinical Research Infrastructure Network, The Hospital District of Helsinki and Uusimaa, Institut National de la Santé et de la Recherche Médicale, Helios Dr. Horst Schmidt Kliniken Wiesbaden, ARSENAL.IT-Centro Veneto Ricerca e Innovazione per la Sanità Digitale, Univerzita Karlova, Janssen Pharmaceutica, Bayer, Sanofi-Aventis Research & Development, Eli Lilly, UCB Biopharma,

Novartis Pharma, Institut de Recherches Internationales Servier, GlaxoSmithKline Research and Development, Pfizer

https://conect4children.org/

Supported by:

ADLIFE - Personalized Care for Patients with Advanced Chronic Diseases

Due to population ageing and advances in medical science, people with chronic diseases – including advanced severe life-threatening chronic diseases - live longer. Challenges are how to sustain quality independent living for the patient; support caregivers facing an increasing burden; create sustainable healthcare and social care systems with limited resources. ADLIFE aims to provide a solution for the integration of therapies and approaches targeting early detection and assessment of deterioration, advanced and well-coordinated care planning and integrated supportive care to enhance quality of life, reduce suffering and accelerate recovery for these patients and their families. It will deploy developed and validated personalised digital solutions for integrated supportive care based on H2020 projects C3-Cloud and Power2DM, previously tested in two health systems. The ADLIFE Toolbox solutions include: a Personalised Care Plan Management Platform, Clinical Decision Support Services; Interoperability Solutions and Patient Empowerment Platform with Just-In Time Adaptive Intervention Delivery Engine.

The ADLIFE Project has received funding from the European Union under the Horizon 2020 Programme, and started on 1 January 2020. i~HD will be a partner and lead work on data management and GDPR compliance, the communication of the project results to patients, the public and to healthcare systems, and contributes to the business plans for sustainability.

Consortium partners: Asociación Centro de Excelencia Internacional en Investigación sobre Cronicidad (KRONIKGUNE), University of Strathclyde, The University of Warwick, Odense University Hospital, Falkiewicz Specialist Hospital, OptiMedis, Region Jämtland Härjedalen, Assuta Ashdod Hospital, Software Research & Development Consultancy (SRDC), EVERIS, i~HD, Osakidetza, Maccabi Healthcare Services

www.adlifeproject.com

Supported by:

Trillium II

i~HD has been a partner in this Horizon 2020 Co-ordination and Support Action which ran from January 2017 to June 2019. Trillium II has co-ordinated and supported efforts towards an interoperable international patient summary. The consortium comprised EU and US partners. i~HD led a work package to promote successful patient summary adoption, focusing on a strategy for identifying success factors including education for a range of stakeholders, those who will implement or use patient summaries, or those who will benefit from access to aggregated patient summary information. An additional goal was to promote the social value of international patient summary standards. This work package produced its deliverables at the end of 2018, on the potential contribution of the international patient summary in disaster response situations, to improve child immunisation rates, as well as for emergency care in emergency departments, on the critical success factors for adoption, and on the educational requirements for patients and healthcare professionals to make best use of patient summaries.

Consortium partners: MedCom, HL7 International Foundation, CEN/Stichting Nederlands Normalisatie-Instituut, Integrating The Healthcare Enterprise, i~HD, Empirica, Gnomon Informatics, Reseau Phast Association, SRDC, Offis, Lombardia Informatica, Terveyden Ja Hyvinvoinnin Laitos, Agence e-Santé, Fundacio Ticsalut Social, SPMS, ECH Alliance, Advanced Digital Innovation, Reliant Medical Group, Lantana Consulting Group, Healthcare Services Platform Consortium, Prosocial Applications, Healtheway, inc. DBA The Sequoia Project, Kaiser Foundation Hospitals

https://trillium2.eu/

Supported by:

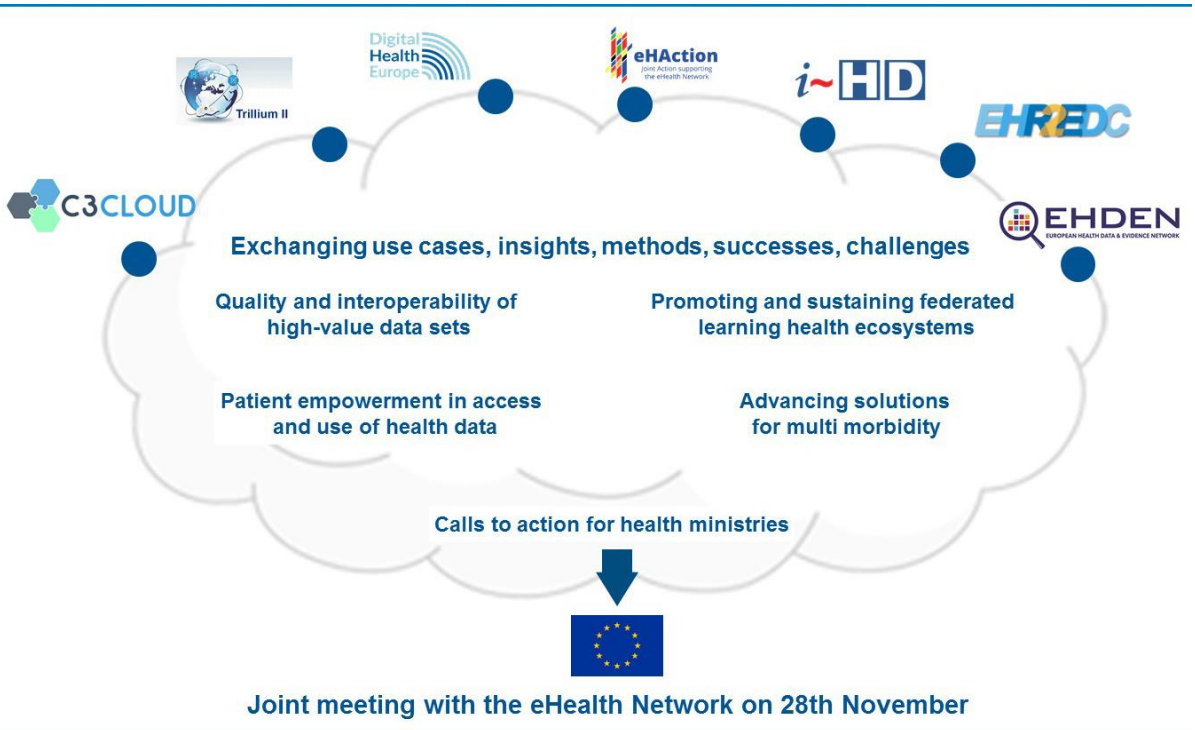
CONFERENCES

We had the pleasure to host our annual conference 'Joining the Dots' in Brussels at the end of November 2019 with the support of leading European initiatives. It soon turned out that the conference topics were highly relevant and that we had created a very exciting programme that was attractive to all of our stakeholder groups. The overwhelming response forced us to adjust and readjust some of our initial plans. We left no stone unturned to accept as many registrations as possible, including live stream, extra speakers, and some changes to the programme.

Furthermore, we ran dedicated tracks in conferences in Finland, Sweden and Belgium. Our presence at EAHM was special as it was organised in Ghent, hometown of our European office, and proved a very valuable network event. Several European conferences invited i~HD team members to present their expertise at a European level.

Annual Conference 2019: Joining the Dots Conference

Ensuring better data for person-centred health and care,
optimised research and Learning Health Systems
Brussels, 27 and 28 November 2019



Strength lies in numbers. That is why we wanted to make a powerful impact by joining the dots between all those striving for a better use of data to optimise person-centred health and research.

Objective: Contribute to key recommendations and future strategies for Europe

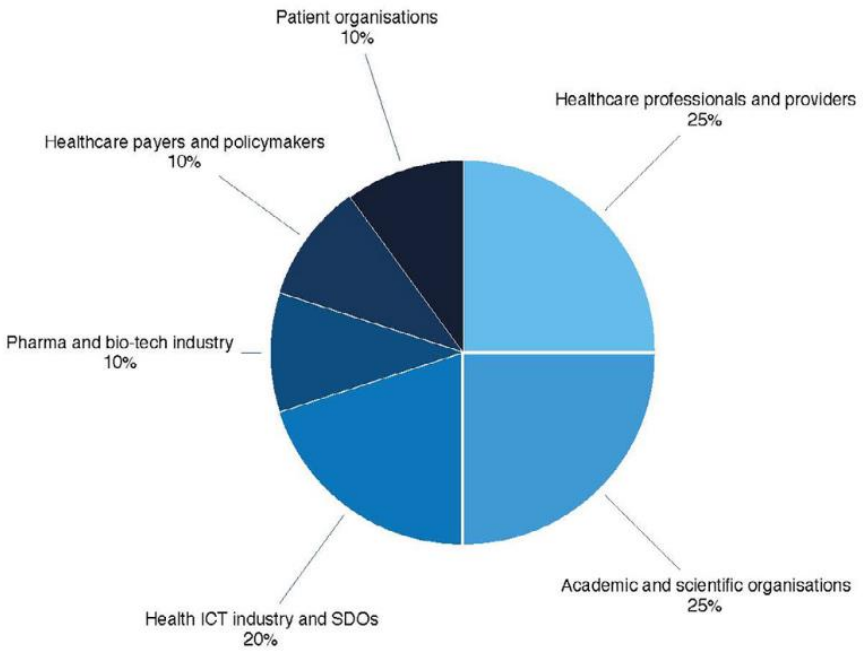
The tangible goal we wanted to achieve thanks to each attendee's input: finalise a list of forceful calls to action for European Health Ministries to be presented to the nearby eHealth Network meeting during the second day of our conference. You can consult our recommendations on our website.

With the support of leading European initiatives

In order to guide the discussion sessions, i-HD brought together leading European projects that have tackled some major health data challenges. Attendees participated in three of the six sessions. These sessions were led by European thought leaders who exchanged use cases, insights, success and challenges. DigitalHealthEurope contributed multi-stakeholder expertise to help shape actionable policy recommendations.

The final session on Thursday 28th focussed on how EHR systems can be adapted to guide clinicians and patients to manage multimorbidity, starting with lunch-time demonstrations of C3-Cloud project's clinician and patient solutions.

Attendance



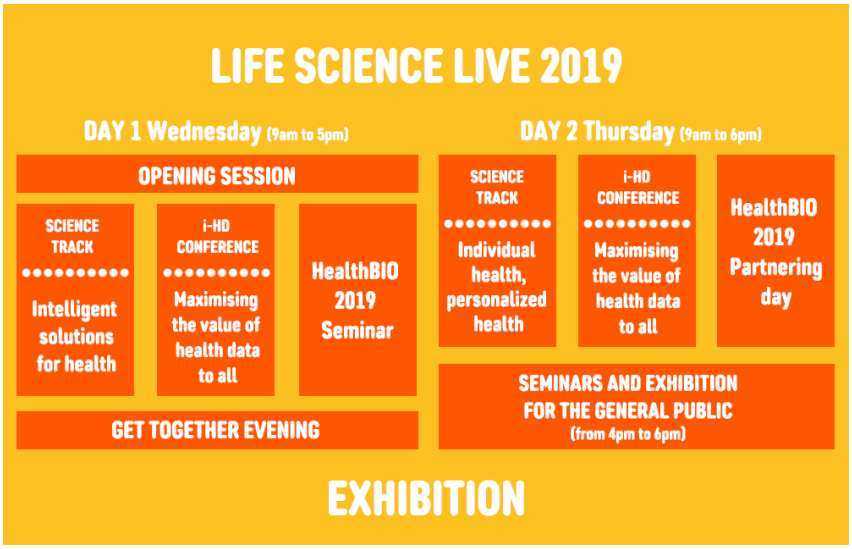
153 attendees	22 nationalities	13 sessions

Scientific Tracks at major European Conferences

i~HD was invited to organise a scientific track at some major European conferences, notably in Turku (Finland), Gothenburg (Sweden) and Ghent (Belgium).

LIFE SCIENCE LIVE, 15 & 16 May 2019, Turku (Finland)

Life Science Live was a new international event for professionals in the fields of pharmaceuticals and healthcare, which i~HD co-organised. The science content at Life Science Live was coordinated by the University of Turku, Åbo Akademi University, Turku University of Applied Sciences and Turku Science Park Ltd (HealthTurku). The HealthBio event by Turku Science Park Ltd. was organized simultaneously.



President Dipak Kalra gave one of the opening keynote talks at the conference. Furthermore, we were in charge of a scientific track on "**Maximising the value of health data to all**", which consisted of three half-day sessions:

- The value of health data for Learning Health Systems
- How hospitals can measure and improve EHR data quality
- Complying with the GDPR when reusing EHR data in care and research

Our track featured, amongst others, speakers such as Thomas Allvin (EFPIA), Jusso Blomster (Turku University Hospital), Bart Vannieuwenhuyse (Janssen), Pieter Van Galen (i~HD), Pascal Coorevits (i~HD and Ghent University), Frank Staelens (OLV Hospital Aalst), Saara Malkamaki (Sitra Finland), Filip De Meyer (University Hospital Ghent), Dipak Kalra (i~HD), Nadir Ammour (Sanofi R&D), Nigel Hughes (Janssen Pharm R&D), Catherine Chronaki (HL7 Foundation), Olivier Zobell (Jülich, Germany), Jari Forström (Turku University Hospital and Abomics Ltd) and Petri Virolainen (Turku University Hospital).

VITALIS, 21 – 23 May 2019, Gothenburg (Sweden)

i~HD was invited to organise a half-day conference stream on demonstrating **how electronic health records can successfully be used for research**. Our session conveyed to delegates that there are important opportunities to conduct academic and industry research using routinely collected data. It also highlighted the importance of good information governance and of good data quality. The session was closed with a panel discussion.

Presenters in the i~HD track were Dipak Kalra (i~HD), Filip De Meyer (University Hospital of Ghent), Ole Fröbert (Örebro University), Pascal Coorevits (i~HD and Ghent University) and Mats Sundgren (AstraZeneca).

EAHM, 11 – 14 September 2019, Ghent (Belgium)

The 2019 edition of the EAHM Congress (European Association of Hospital Managers) took place in Gent. It was very much an interactive happening with visits to six hospitals complementing the presentations on offer at the main conference site of the prestigious Ghelamco Arena. The umbrella theme was labelled as 'sharing innovative healthcare strategies'. i~HD was present with a session on the reuse of Electronic Health Records for Learning Health Systems.

The gathering of more than 450 European hospital managers gave us the opportunity to capture their viewpoints on health data and gain insight in the latest uses of data. Throughout the presentations and personal conversations, big data turned out to be a key success factor for innovation.

Given the medical, operational and strategic decision-supporting uses of data, the apparent lack of initiatives in the field of data quality reinforces our stand that more attention to the quality of data is pivotal for the delivery of even safer and more effective patient care.

I~HD session: The reuse of electronic health records for Learning Health Systems

Dipak Kalra (i~HD), Pascal Coorevits (i~HD and University of Ghent), Bart Vannieuwenhuyse (Janssen) and Brecht Claerhout (TriNetX) jointly guided the very interactive session.

The speakers responded to questions hospital managers struggle with in their daily experience. The topics that were cited include how to motivate people, both the general public as well as clinicians, to share data. To have a sustained effect, the best approach is to demonstrate the value of data analysis by means of real life examples and benefits and to show how we can turn data into insights, smarter behaviour and better outcomes.

Turn validated data into insights to improve your organisation and create value for patient and organisation

The general public are still unsure about the safety of their personal health data, so we need to insist that GDPR is effective and that the protection of the public's data is guaranteed.

The participants concluded that we are at a crucial intersection in our ecosystem where individualised data meets big data, which requires a major paradigm shift.

Speaker Appearances

Members of the i~HD team also appeared as speaker at other conferences.

DATE	EVENT	LOCATION	SPEAKER	TOPIC
25/12/2019	HOPES 1st International "Better data, best health" conference	Barcelona, Spain	Pascal Coorevits	i~HD : changes in the move toward quality and certifications
4/2/2019	CARE4 Congress	Leuven, Belgium	Pascal Coorevits	Quality of mobile applications
19/2/2019	EFGCP Annual Conference	Brussels, Belgium	Dipak Kalra	The role of RWD in evidence generation
21/2/2019	2nd Annual Big Data & Analytics in Healthcare Forum	London, UK	Dipak Kalra	Scaling up the use of big health data
27/2/2019	EAPM Conference	Brussels, Belgium	Dipak Kalra	The importance of EHRs for precision medicine
13/3/2019	Pistoia Alliance conference	London, UK	Dipak Kalra	The quality and governance of health data
18/3/2019	SCRS European Site Solutions Summit	London, UK	Nathan Lea	Panel discussion: The Future of Clinical Research - focus on regulatory issues
19/3/2019	Health Summit Lisbon	Lisbon, Portugal	Dipak Kalra	Learning Health Systems
9/4/2019	EFMI Special Topic Conference	Hannover, Germany	Dipak Kalra	Reusing health data for research
15/5/2019	Life Science Live conference	Turku, Finland	Dipak Kalra	Learning Health Systems
15/5/2019	Life Science Live conference	Turku, Finland	Pieter van Galen	Getting the best value from health data: the patient perspective
15/5/2019	Life Science Live conference	Turku, Finland	Pascal Coorevits	Essential enablers for scaling up the value of health data: Measuring and improving data quality in hospitals
15/5/2019	Life Science Live conference	Turku, Finland	Filip De Meyer	Essential enablers for scaling up the value of health data: Complying with the

				GDPR when reusing real world data for research
23/5/2019	Vitalis Conference	Gothenburg, Sweden	Dipak Kalra	Reusing health data for research
23/5/2019	Vitalis Conference	Gothenburg, Sweden	Pascal Coorevits	Assessing the data quality of hospital EHRs
23/5/2019	Vitalis Conference	Gothenburg, Sweden	Filip De Meyer	Establishing a trustworthy data reuse framework
28/5/2019	Flemish Parliament launch of Health Innovation Business Models	Brussels, Belgium	Dipak Kalra	Success factors for innovative health ICT business models
4/6/2019	UCL Event on Artificial Intelligence, Privacy and Big Tech	London, UK	Nathan Lea	Panel Discussion with Věra Jourová, EU Commissioner for Justice, Consumers and Gender Equality
5/6/2019	EFPIA Patient Think Tank	Brussels, Belgium	Dipak Kalra	Data Saves Lives
18/6/2019	EFPIA Oncology Data Summit	Brussels, Belgium	Dipak Kalra	Data Saves Lives
27/6/2019	Health Horizons Conference	Cambridge, UK	Dipak Kalra	Making better use of RWD
3/7/2019	Privacy Laws & Business Annual Conference	Cambridge, UK	Peter Singleton	Anonymisation
19/7/2019	Mobilising Computable Biomedical Resources	Washington DC, USA	Dipak Kalra	Trustworthy knowledge resources
29/8/2019	Global Summit on Circulatory Health	Paris, France	Dipak Kalra	Assuring the trustworthiness of AI
13/9/2019	EAHM Congress	Gent, Belgium	Dipak Kalra	The reuse and governance of health data
13/9/2019	EAHM Congress	Gent, Belgium	Pascal Coorevits	Assessing the data quality of hospital EHRs
16/9/2019	BMS workshop	Brussels, Belgium	Dipak Kalra	The reuse and governance of health data
25/9/2019	Pharmaceutical IT & Data Congress and Artificial Intelligence in Drug Development	London, UK	Nathan Lea	The Role Of Information Systems In Supporting Healthcare Delivery And Empowering Patients, In The Age Of Information And Big Data
7/10/2019	IPPOSI AGM	Dublin, Ireland	Dipak Kalra	The reuse of health data
24/10/2019	MedTech Europe workshop	Brussels, Belgium	Dipak Kalra	Contributions on evidencing the value of medical technology
13/11/2019	EPF Congress	Brussels, Belgium	Dipak Kalra	Citizen empowerment through health data
14/11/2019	Data Analytics for Pharma Development Forum	Munich, Germany	Nathan Lea	The challenges surrounding data security following the arrival of GDPR
19/11/2019	Medica 2019 conference	Düsseldorf, Germany	Dipak Kalra	Responding to the German Medical Informatics programme
19/11/2019	Data Protection in Health Research Workshop	Brussels, Belgium	Peter Singleton	Secondary Use and Data Sharing
20/11/2019	ECF Conference	Baveno, Italy	Dipak Kalra	Governance of data sharing
3/12/2019	EIT Health session	Paris, France	Dipak Kalra	Speaker on EHR2EDC
4/12/2019	BioData World Congress	Basel, Switzerland	Juan M. Garcia-Gomez & Geert Byttebier	Advances in Data Quality Assessments of GP and hospital EHRs for Clinical Research
11/12/2019	Digital Health Society Summit	Helsinki, Finland	Dipak Kalra	Opportunities from Big Health Data

i~HD TEAM

19 team members	30 Task Force members

Given the rise of our activities in 2018 and our further growth ambitions, the i~HD team has more than doubled over 2019. We are happy to have attracted the specialised profiles in each field of expertise to support the initiatives, strategies and services we are developing.

Dipak Kalra,
President

Geert Thienpont,
Managing Director

Hannelore Aerts,
Data Quality Programme Manager

Geert Byttebier,
Liaison Manager

Pascal Coorevits,
Lead for Data, System Quality and Certification,
EuroRec Representative,
Ghent University

Jos Devlies,
Senior Research Consultant

Tom de Vree,
System Quality Programme Manager

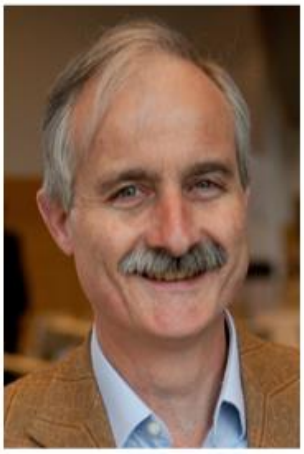
Veerle De Wispelaere,
Communications Manager

Julie James,
Senior Researcher

Nathan Lea, Data Officer & Leader of the Information Governance & GDPR Task Force

Christophe Maes,
Business Developer Benelux

Rahil Qamar Siddiqui,
Senior Researcher



Peter Singleton, Senior Researcher and member of the Information Governance & GDPR Task Force

Miriam Sturkenboom,
Senior Researcher

Bob Vander Stichele,
Senior Research Coordinator

Pieter Van Galen,
Patient Representative

Martine Vannevel,
Administrative Officer

Petra Wilson,
Senior Researcher

Karl Wouters,
Communications Adviser