Learning Health Systems

COMMENTARY

The European Institute for Innovation through Health Data

D. Kalra[1] | V. Stroetmann[2] | M. Sundgren[3] | D. Dupont[4] | I. Schlünder[5] | G. Thienpont[6] | P. Coorevits[1] | G. De Moor[1]

[1] Department of Public Health, Unit of Medical Informatics and Statistics, Ghent University, Gent, Belgium

[2] Empirica Gesellschaft für Kommunikations- und Technologieforschung mbH, Bonn, Germany

[3] AstraZeneca, Mölndal, Sweden

[4] Data Mining International, Geneva, Switzerland

[5] Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V., Berlin, Germany

[6] RAMIT, Research in Advanced Medical Informatics and Telematics (vzw - asbl), Ghent University Hospital, Gent, Belgium

Correspondence
D. Kalra, Department of Public Health, Unit of Medical Informatics and Statistics, Ghent University, Universitair ziekenhuis Gent, 5K3, De Pintelaan 185, 9000 Gent, Belgium.
Email: dipak.kalra@i-hd.eu

Abstract

The European Institute for Innovation through Health Data (*i~HD*, www.i-hd.eu) has been formed as one of the key sustainable entities arising from the Electronic Health Records for Clinical Research (IMI-JU-115189) and SemanticHealthNet (FP7-288408) projects, in collaboration with several other European projects and initiatives supported by the European Commission. *i~HD* is a European not-for-profit body, registered in Belgium through Royal Assent. *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 will specifically address obstacles and opportunities to using health data by collating, developing, and promoting best practices in information governance and in semantic interoperability. It will help to sustain and propagate the results of health information and communication technology (ICT) research that enables better use of health data, assessing and optimizing their novel value wherever possible. *i~HD* has been formed after wide consultation and engagement of many stakeholders to develop methods, solutions, and services that can help to maximize the value obtained by all stakeholders from health data. It will support innovations in health maintenance, health care delivery, and knowledge discovery while ensuring compliance with all legal prerequisites, especially regarding the insurance of patient's privacy protection. It is bringing multiple stakeholder groups together so as to ensure that future solutions serve their collective needs and can be readily adopted affordably and at scale.

1 | MOTIVATION: SCALING UP THE ACCEPTABLE ACCESS, INTEGRATION, AND USE OF HEALTH DATA

There are common needs spanning clinical research and health care, at European, national, and local levels, for accessing, combining, and using high-quality health data on a large scale while complying with data and patient privacy protection legislation (Figure 1).

1.1 | Clinical research needs

Around half of clinical trials fail to meet their recruitment targets.[1] Obstacles to conducting clinical trials today include high cost, lengthy time frames, administrative barriers, and delays in study execution.[2] These include assessing and optimizing the feasibility of clinical trial protocols and identifying suitable patients for recruitment in clinical trials. A third of (costly) clinical trial protocol amendments are

avoidable.[3] Regulators, health technology assessors, and payers require greater evidence of the effectiveness of innovative medicines and their safety once licensed and will require even more fine-grained evidence as adaptive licensing extends across Europe including in real-world settings.[4] Routinely collected data from electronic health records (EHRs), sometimes known as real-world data, therefore, now needs to be better harnessed to gather such evidence: to enhance and speed up drug development, increase efficiency, and generate added value for clinical trial sponsors, health systems, and patients.[5]

1.2 | Health care needs

Health data are captured today at a variable quality and are not collected or stored consistently, and the adoption of interoperability standards is far from ideal. At the level of the individual patient, guideline and decision support systems, notification and alerting components, and analytic tools need to process integrated health data drawn from

Clinical Research needs

Optimise clinical research processes
- achieve faster and more accurate patient identification
- identify sites that have access to the most suitable patients
- reduce protocol amendments

Enhance access to Real World Data
- study the use of new medicines in real populations
- conduct comparative effectiveness studies
- monitor long-term safety
- gather evidence for adaptive licensing

Healthcare needs

Improve quality and safety of care
- enhance care co-ordination
- increase adherence to clinical evidence
- reduce medical errors and treatment delays

Support patients in self-care and health maintenance

Improve efficiency of care
- optimise care pathways to improve outcomes
- collate evidence for public health strategy and decision-making

The European Institute For Innovation Thr~ugh Health Data

Harmonised health information and standards

Best practices in information governance

Solutions for better quality health data, and legitimate uses of health data

Quality assessments, certification and audit

Intelligence derived from health data e.g. research, outcomes
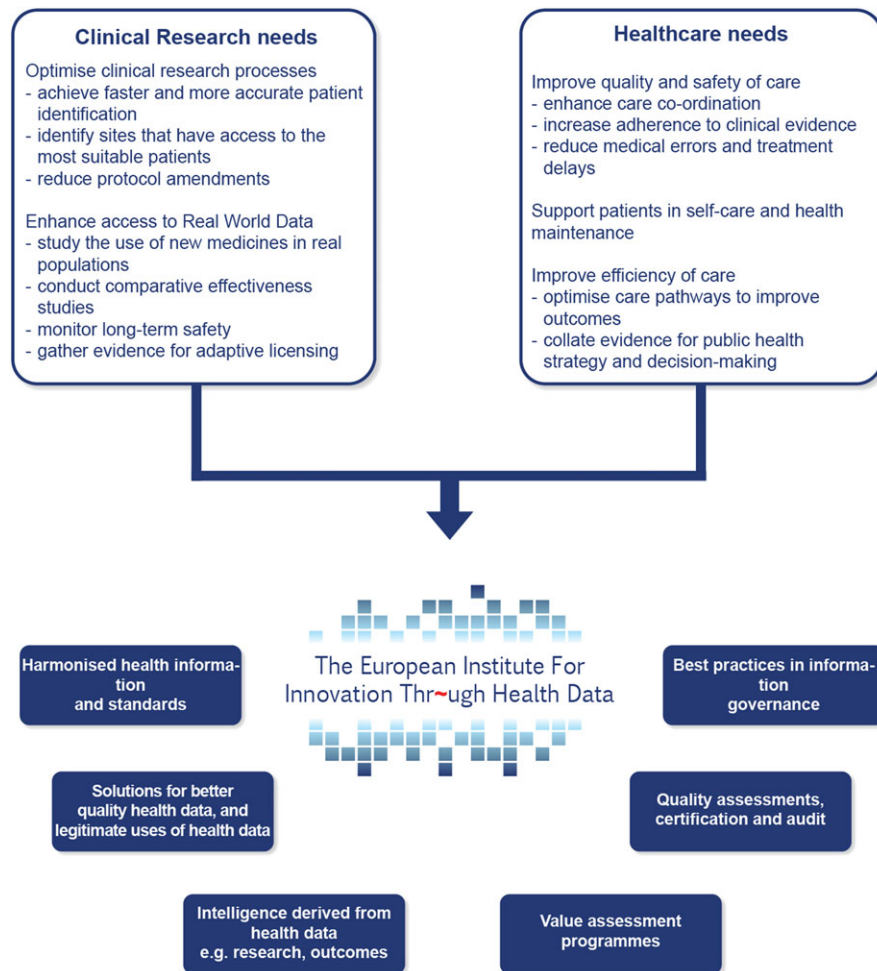
Value assessment programmes

FIGURE 1 *i*~HD has been formed in response to a convergence of clinical research and health care needs

multiple EHR systems in a consistent manner. Health services, insurers, and public health bodies also need fine-grained activity and outcome data to inform service planning, commissioning, and prevention/wellness programs. Electronic health records and personal health records need to be able to share information and care pathways so as to empower patients to manage more of their own care and to play a stronger role in decision making.

Some of the major challenges faced across the research to health care spectrum (ie, the learning health systems spectrum) relating to enabling best learning use of health data are as follows: (1) information governance, privacy protection, and ethics and (2) the quality and interoperability (especially semantic interoperability) of health data. A further challenge is the present day limited availability of evidence that investments in health information and communication technology (ICT; especially large-scale investments such as national programs) actually deliver significant benefits from more and more computable health data. This relative lack of evidence (which may be in part because the evidence from each ICT "intervention" is hard to isolate and be directly attributable and in part because most programs invest little in evaluation) hampers the construction of convincing business models and plans to scale up the adoption of eHealth solutions and to sustain them.

The data processed in health care are very sensitive data, which imply a high risk for a patient's privacy. Therefore, the success of innovation in this field is highly dependent on the ability to gain and maintain patient trust. A major prerequisite in this regard is that any electronic

system is built on high data protection standards, which are fully compliant with the respective legal framework. Therefore, information governance is a core part of the activities of European Institute for Innovation through Health Data (*i*~HD), because it ensures the implementation of the legal requirements at all stages. In addition, it makes the measures taken transparent for ethics committees and patients and thus serves the goal of adequate communication with all stakeholders.

2 | THE OBJECTIVES OF *i*~HD

The *i*~HD has been formed as one of the key sustainable entities arising from the Electronic Health Records for Clinical Research (EHR4CR[6]) and SemanticHealthNet[7] projects, in collaboration with several other European projects and initiatives supported by the European Commission.*

The following objectives are reflected within the Articles of Association that define *i*~HD.

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.

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*These projects include PARENT, TRANSFoRm, EMIF, SALUS, EXPAND, Trillium Bridge, ASSESS CT, and VALUeHEALTH.

Championing harmonized 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 health care 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 as follows: 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 organizational processes relating to the use of health data. Such audits may, for example, relate to the governance of the capture, usage, and communication (sharing) of health data, or to the quality of health data at a given site such as a hospital.

Building synergy and consensus: acting as a focal point bringing stakeholders together to share experiences, agree common priorities, and approaches for maximizing the benefits of good quality and interoperable health data and the trustworthy reuse of health data. *i~HD* is working toward convergence and cross-fertilization between: health care providers, patients and families, health ministries and insurers, EHR system vendors and standards development organizations, pharma, and the clinical research community, national, and multinational decision makers.

3 | MISSION AND SCOPE OF *i~HD*

i~HD has been established in recognition of the need to sustain and propagate the results of research projects, to tackle areas of challenge in the successful scaling up of innovations drawing on health data. It is specifically addressing obstacles and opportunities in making greater use of health data, such as collating and promoting best practices in information governance and in semantic interoperability. Most importantly, *i~HD* brings multiple stakeholder groups together so as to ensure that future solutions serve their collective needs and add tangible value and can be readily adopted affordably and at scale, in a way that is socially acceptable.

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, toward achieving best practices and sustainable integrated person-centered health care, to optimize health and wellness in Europe, and beyond. It aims to guide and catalyze the best, most efficient, and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery.

Examples of knowledge discovery in this context include the use of health data to derive local knowledge (for example, to determine quality of care or to monitor the adoption of a care pathway) or generalizable knowledge that supports optimizing care effectiveness, safety and equity, developing or evaluating new health care services and products (such as medicines and devices), epidemiological and observational research, and the conduct of prospective research such as using health data to identify patients to participate in research studies. All of these are essential ingredients of a learning health system.

There are other organizations, active at a European level, making contributions in this general direction. The eHealth Network[8] brings together health ministries and other high-level eHealth decision makers across Europe to agree on common areas of strategy and standardization in the field of eHealth. The European Institute for Health Records (EuroRec[9]) promotes the high-quality use of EHR systems and provides quality labeling and certification services for this. Integrating the Healthcare Enterprise[10] defines interoperability profiles for user-driven use cases and provides testing and certification services for this. CEN TC/251[11] is increasingly acting as a European forum for many other standards development organizations at a European level. The European Clinical Research Infrastructure Network[12] assures the quality of clinical research organizations. Many health care professions and specialties have European associations that agree on good practices and develop guidelines and audit data sets to promote best practices for their specific domains. There are specialist associations catering for particular stakeholder groups such as the European Federation of Pharmaceutical Industries and Associations[13] and umbrella organizations for patient associations. However, none are working across the rich range of domains and stakeholders who need to be involved in cocreating the solutions to complex problems (such as advanced technological platforms) centering on the use of health data. Although *i~HD* is constituted as a European entity, its mission, the challenges that it is addressing, and the approaches it is developing and promoting all have global applicability, and it is therefore seeking to collaborate with other organizations internationally to enable these issues to be tackled coherently on a global level.

i~HD has been established, after an extensive consultation and engagement process involving many stakeholders, to fill a recognized gap: to develop and maintain methods, solutions, and services that can help to maximize the value generated for all stakeholders from optimizing the use of health data and to support innovations in health maintenance and health care delivery and in knowledge discovery. It wishes to work with the above groups, and others not mentioned here, to complement— not duplicate—their activities and to address issues that remain outstanding and are of importance to be resolved. While having a clear initial work plan focused on enabling the trustworthy reuse of health data for research and promoting better semantic interoperability of health data, *i~HD* is seeking to respond in an agile and coherent way to new needs and opportunities that can enable its stakeholder members, health systems, and society as a whole to maximize the value derived from health data.

i~HD is a European not-for-profit body, registered in Belgium through Royal Assent. It is governed by its member stakeholders, public and private, through elected board and officers. Each of the main

categories of stakeholder has an allocation of seats on the board, which they will elect or re-elect annually through a general assembly. The board will determine the strategy of the institute, appoint its executive officers, and approve its annual budget. The institute is being financed by a mixture of membership subscriptions, fees from providing services such as certification and accreditation, specific project grants, and other income from education, training, and expert advisory roles.

4 | PROMOTING AND ENABLING THE TRUSTWORTHY REUSE OF HEALTH DATA FOR RESEARCH

European projects, future call topics for Horizon 2020 proposals, national research infrastructure programs, and real-world studies to assess the effectiveness, safety, and cost-effectiveness of innovative medicines in routine medical practice, including large observational studies funded by pharmaceutical industry, all point to the growing interest among many stakeholders to collaborate and tackle on a large scale access to high-quality, integrated, and appropriately protected health data to conduct research.

Concerns about the protection of privacy when health data are integrated or shared, even for direct patient care as well as for aggregated data purposes, limit the extent to which even the data we have today can be combined, aggregated, and analyzed appropriately. However, a number of European initiatives are making progress in addressing these issues and are generating solutions for the reuse of health data for research that are ready to be adopted, at scale.

Electronic Health Records for Clinical Research has developed an innovative technological platform that can connect securely to the data within multiple hospital EHR systems and clinical data warehouses across Europe, to enable a trial sponsor to predict the number of eligible patients for a candidate clinical trial protocol, to assess its feasibility, and to locate the most relevant hospital sites, all contributing to enhance and improve the efficiency of existing clinical research processes.[5,14,15] Applications for internal use are offered to connected hospitals to assist them to efficiently identify and contact the patients who may be eligible for particular clinical trials. Contrary to other initiatives, EHR4CR designed a solution that is compliant to European Union legislation and respects the position of hospital and patients. One of the key aspects is that patient-level data never leave the connected hospitals. The platform and services are now being launched by the first commercial service provider, Custodix,[16] ready for Europe-wide deployment and use.[17]

The European Medical Information Framework (EMIF) is creating an environment that allows the efficient research reuse of existing health data repositories such as cohort studies and bio-banks, as well as EHRs. The EMIF Platform will allow authorized access to multiple, diverse data sources, at present spanning primary and secondary care data from nearly 48 million subjects in 7 European countries. The EMIF Platform will integrate data cohorts and conduct data source profiling, allowing researchers to browse metadata, providing them with a single point of access for searching aggregated data across different sources and countries, and enabling them to answer specific research questions on identifying and validating novel biomarkers.

The TRANSFoRm project has developed a research data architecture to implement the learning health system in general practice, using outcomes data to develop new evidence that can be delivered back as computable rules, to improve clinical decision making.[18] TRANSFoRm has specified a strong separation between zones for clinical use and research use, and the provision of pseudoidentification and linkage services managed within a trusted "middle" zone.[19]

For all of these projects, it has been important to establish information governance, privacy protection, and information security measures that enable their large-scale reuse of health data in full compliance with the applicable legislation, and in a way that is socially acceptable. Each project, and others in this field, has developed methods and instruments that contribute to overall trust in the research reuse environment, but there is a need for a consolidation of these approaches and for a single source to publish and maintain harmonized best practices. i~HD is specifically supporting the development, harmonization, promotion, and sustainability of these best practices in the reuse of health data for research. Its experts have started working on an overarching set of high-level principles and standard operating rules that bring together these project results, combining them with other relevant instruments developed within the informatics and bioinformatics communities. An important governance starting point is the recently published Innovative Medicines Initiative[20] Code of Practice on secondary use of medical data in European scientific research projects (Figure 2).[21]

With an initial focus on EHR4CR, which is to go live in early 2016, i~HD is ensuring that all parties involved in the EHR4CR ecosystem operate in full compliance with all applicable requirements and policies, by certifying the ICT systems, overseeing their operation, auditing the information flows, and establishing good practices in information
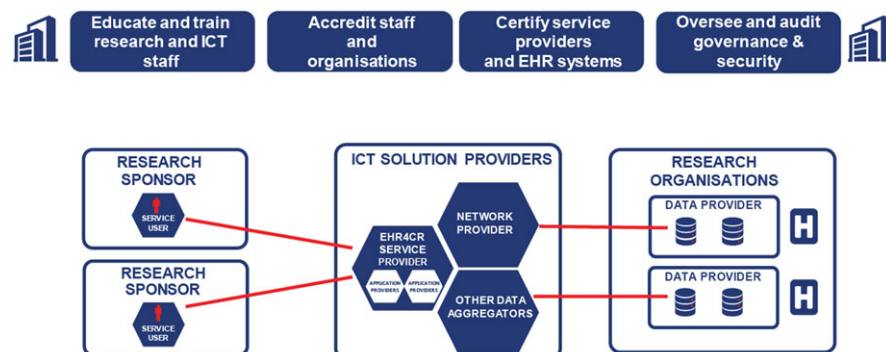

FIGURE 2 The services provided by i~HD to facilitate the trustworthy reuse of health data for research. ICT, information and communication technology
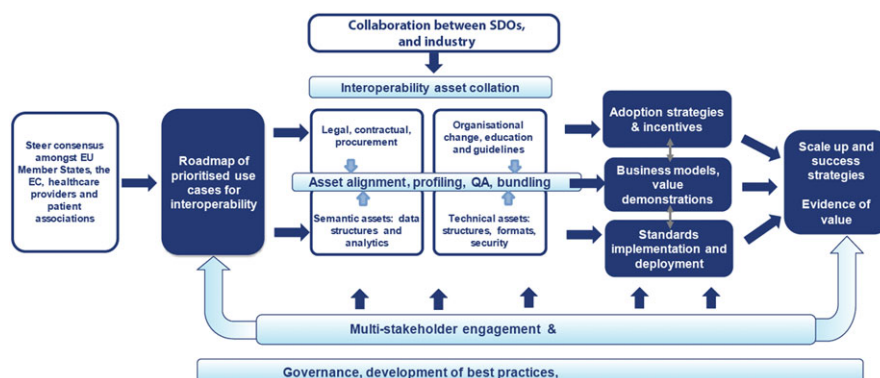
FIGURE 3 The activities needed to scale up semantic interoperability and the adoption of standards (EC = European Commission, SDO = Standards Development Organization)

governance for all service providers, hospitals, and research sponsors. i~HD has no legal or assigned mandate to apply such governance, to require compliance with audit, or to apply sanctions, but in view of the importance of this issue, the participating pharma companies have all agreed to abide by such measures and agreed that they may be included as stipulations within contracts that they are signing for use of the platform. Participating hospitals have likewise agreed to comply with these measures. It is developing and promoting best practices for the wider use of EHRs for research, including engagement with patient associations, privacy protection agencies, and regulatory authorities to ensure the solution is well accepted by all of them and generates benefits. The activities i~HD will embark upon during 2016 to promote this trustworthy research ecosystem are listed in Box 1.

5 | FOSTERING AND COORDINATING AN ECOSYSTEM FAVORING STANDARDS ADOPTION AND INTEROPERABLE SOLUTIONS

Health data are captured today at a variable quality and are not collected or stored consistently in the EHR systems of different vendors, and standards adoption is far from ideal. There are many organizations, initiatives, and research projects tackling different aspects of this interoperability challenge. However, research results have not proved easy to sustain and are therefore frequently reinvented by successor projects rather than enriched. Initiatives are often driven by individual stakeholder groups in isolation, such as health informatics standards bodies developing isolated standards. Health professional bodies develop guidelines in a narrative form without specifying how conforming health records should be structured. Performance targets are set for health care providers that require the specific collection of reporting data that is not related to the data that needs to be collected to support patient care.

Semantic interoperability, which is about ensuring that the meaning of clinical data can be correctly interpreted when it is shared between EHR system from different applications within and cross-border, is a priority area for i~HD. Its members are already working with many European projects and key stakeholders to define the top priorities and the good practices for developing and implementing semantic interoperability standards, for example, to enable safe and efficient continuity of care between professionals looking after a patient with a long-term condition, who may be employed in different organizations and working on different sites. Examples of projects whose results

have already contributed to i~HD's support for semantic interoperability include SemanticHealthNet, which has defined good practices in multistakeholder engagement in the definition of semantic interoperability needs and assets,[22,23] and EXPAND, which has developed a set of quality label descriptors for interoperability assets (Figure 3).[‡]

i~HD will promote the importance of interoperability, in particular establishing strong links with standards development organizations and industry to promote the adoption of standards. It will help to bring together the patients and clinicians who create and use most health information with other critical stakeholders such as the health ICT industry, standards developers, clinical research communities, and health care funders, to cocreate the most relevant future standards and champion their adoption. This work will take into account of and align as closely as possible with, the eHealth European Interoperability Framework[24] and with the recently published Interoperability Roadmap by the US Health and Human Services Office of the National Coordinator for Health Information Technology.[25] The activities that i~HD will embark upon during 2016 to promote better semantic interoperability are listed in Box 2.

i~HD is keen to promote the engagement and empowerment of patients in health decision making and in illness self-management, and for all citizens to have access to information about their health status so as to make informed choices that promote wellness and prevent disease. Semantic interoperability, including the ability to communicate health information effectively and meaningfully to patients, is critical to enabling well-informed coproduction of health and decision making.

6 | DEMONSTRATING VALUE FROM THE USE OF HEALTH DATA

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

There are many perverse incentives not to adopt standards, many of which are locked into antiquated models of health care reimbursement, antiquated models of procurement, and antiquated supplier relationships with customers. Standards bodies publish standards, as

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[‡]These EXPAND results are not yet published.

BOX 1. Planned activities for 2016 to promote a trustworthy ecosystem for reusing health data for research.

Best practices in information governance

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

Certification of health research platforms, services, and tools

- develop and deliver, primarily in partnership with EuroRec, quality labeling criteria, a test plan and certification process for platforms, services, and tools supporting the reuse of health data for research, with an initial focus on certifying conformance to the EHR4CR specifications;
- maintain and publish the specifications of services and interfaces for clinical research platforms and tools, to which conformance can be tested.

Accreditation of clinical research staff

- develop and promote, primarily in partnership with UKCHIP[†] and ECRIN, a code of practice for staff using health data for research, and provide an accreditation process to recognize the necessary skills in clinical research staff.

Governance oversight of clinical research platform service providers

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

Network of excellence for research through health data

- foster and coordinate a multistakeholder community involving those who collect, integrate, manage, and analyze health data for research, so as to cocreate and promote good practices, identify challenges needing new research and innovations, grow the evidence for measures that scale up and speed up the adoption of innovations, and deliver education and provide accreditation.

BOX 2. Planned activities for 2016 to promote better semantic interoperability between EHR systems.

Fostering the codesign of semantic interoperability assets by clinicians, patients, and research

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

Quality labeled public directory of interoperability assets

- publish an online register to act as a central reference point to discover which interoperability assets may be used, together, to tackle a particular use case;
- develop and maintain a set of services that can support research and development projects and other initiatives to mature their novel interoperability assets to the level at which they can be published and reused by others;
- facilitate convergence and reuse of existing assets, in preference to reinvention.

Semantic harmonization services

- maintain a list of data items and mappings across terminology systems, to support the harmonization of data and queries in support of clinical research, especially clinical trial feasibility and patient recruitment, and patient summaries to support continuity of care across Europe;
- maintain the service specification of a central semantic broker to support the construction of local mappings between the data dictionary of a hospital or general practice EHR system and a centralized representation.

Semantic interoperability evidence base

- collate and synthesize worldwide experience and learning of success strategies for scaling up semantic interoperability, of demonstrating value and deriving benefits from sharing and analyzing semantically interoperable health information.

SemanticHEALTH Alliance

- hosts and coordinates a network of stakeholder communities that collaborate to enable the development and successful adoption of relevant and usable semantic interoperability standards.

individual assets, but we lack a multistandard neutral organization to oversee and promote the assessment of value of standards as a whole, and to highlight targeted use cases where standards can play an important enabling role.

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

There is a need to better harness the best available evidence so as to guide and optimize future strategic investments, to promote and direct standards adoption, and thereby to accelerate the delivery of benefits, particularly those relevant in the context of learning health systems.

[†]The UK Council for Health Informatics Professionals. http://www.ukchip.org

*i~*HD will engage in initiatives to capture the experience, learning, success strategies, and warnings from across large-scale pilots and large-scale deployments of eHealth and of the reuse of health data for research. It will collect and synthesize evidence frameworks (existing systematic reviews, best practice guidelines, well-regarded case study reports, and data collection templates) and develop standards adoption guidelines, illustrated with successful case studies. *i~*HD will also actively promote the assessment of evidence of benefits compared with current standards, as these emerge to help stimulate the market for good-quality health ICT products, for their successful use, and of the value to all of collecting and using good-quality health data.

7 | CONCLUSION

More and more health data are being collected across care organizations, and increasingly by patients directly, providing formidable new opportunities for learning health system environments. Nonetheless, there is limited capability for these data to be brought together and interpreted collectively to enable better patient care, organizational learning, or research. The most important obstacles to making better use of health data are well known and include the following: the weak incentives for busy clinicians to capture high-quality health data; a marketplace for health ICT products that does not favor well the adoption of interoperability standards; a current generation of standards that are still poorly matched to the semantic interoperability needs of clinicians, patients, public health, and research; the challenges of legitimately reusing health data for research while protecting patient privacy; the tendency for projects and initiatives to reinvent approaches to the representation and protection of health data; and the overall limited evidence base to confirm that all of this effort to improve the quantity and quality and interoperability of health data will actually deliver significant benefits.

*i~*HD (www.i-hd-eu) has been formed so as to provide a point of consolidation of best practices in emerging solutions to these issues, and to help to develop new practices and strategies where there are gaps. It will work with many existing organizations in eHealth and clinical research, initially in Europe, but always to focus on the delivery of concrete solutions and the support of a multistakeholder ecosystem favoring better learning from health data.

*i~*HD was formally launched through an inaugural conference in Paris, on March 10, 2016. This was attended by over 200 clinicians, health care providers, and researchers from across Europe, as well as representatives of the pharma industry, patient associations, health professional associations, the health ICT industry, and standards bodies. The event showcased the issues and approaches discussed in this paper and presented the specific activities that *i~*HD intends to pursue, as indicated in Boxes 1 and 2 above.

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