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Scaling up the availability and reusability of big health data

2021 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS

Round Table 4

Scaling up the availability and reusability of big health data.

Working groups based on Calls to Action on Health Data Ecosystems

This report presents the findings of a multi-stakeholder round table consultation focused on the actions that are needed at a European level, catalysed by the European Health Data Space, and actions required by other stakeholders across Europe, to help maximise the availability of high quality and interoperable health data on a large scale, to improve integrated patient care and for big data analysis across multiple heterogeneous sources irrespective of the European country in which the data reside.

This report is in the form of consensus papers from three Working Groups, which were scoped and convened by the Digital Health Society (DHS) and The European Institute for Innovation through Health Data (I~HD) neutrally and independently from the event sponsors Johnson & Johnson, Microsoft and MSD. A total of 41 participants contributed from EU and international institutions, national governments, industry, academia, hospital management, healthcare professionals, regulators and patient representatives. They were distributed evenly amongst the Working Groups.

CALLS TO ACTION

1. **Raise the digital literacy & skills of all stakeholders**
2. **Generate and value trustworthy Real World Evidence**
3. **Accelerate interoperability across Europe and globally**
4. **Demonstrate benefits to society from data access, use and reuse**
5. **Adopt a risk stratification approach**
6. **Build a trustworthy framework for data access and use**
7. **Adopt a transformational approach to health data**

These topics take a deeper dive on three of our 7 Calls to Action on Health Data Ecosystems, specifically:

- **Action 2: Generate and value trustworthy Real World Evidence**
- **Action 3: Accelerate interoperability across Europe and globally**
- **Action 7: Adopt a transformational approach to health data.**

Round Table 4 was held in October and November 2021. A Glossary is included in page 53.

We hope to take forward some of the topics in this report, and other topics arising from the Calls to Action, as future multi-stakeholder engagements during 2022.

WORKING GROUP 1

INTEROPER-ABILITY, STANDARDS ALIGNMENT AND ADOPTION

WORKING GROUP 2

DATA QUALITY, BENCHMARKING AND IMPROVEMENT

WORKING GROUP 3

DESIGNING HEALTH INFRA-STRUCTURE FOR LARGE SCALE DATA REUSE

Recommendations from the Working Groups

WORKING GROUP 1 INTEROPERABILITY, STANDARDS ALIGNMENT & ADOPTION

This Working Group examined the slow uptake of interoperability standards, and the lack of European cohesion around standards adoption across Europe. It targeted the actions that the European Commission and Member States could take, triggered by the momentum of the European Health Data Space, to align on standards, profiles, clinical models and priority data sets to focus efforts on standards adoption. This includes ensuring that systems are assessed for their demonstrated interoperability and the procurements require this. The main targeted calls to action are listed here and explained in the Working Group 1 report starting from page 12.

Accelerate the adoption of interoperability standards for health data communication and analysis

The European Commission and the European Parliament must require that all health data feeds into the European Health Data Space, to support cross-border care to individuals or for large scale data analysis, conform to a specified portfolio of international interoperability standards, profiles, clinical models, terminology value sets and interfaces, which should build on the European Electronic Health Record Exchange Format (EEHRxF).

The European Commission must negotiate with the relevant Standards Development Organisations (SDOs) to procure an open access licence to all of the standards included in the portfolio.

European Member States must specify a portfolio of interoperability standards for national eHealth and research infrastructures that aligns with the European standards portfolio, whilst accommodating national priorities and specificities.

Member States health policymakers must prioritise resource allocation to the procurement of electronic health systems in hospitals and primary care that have been certified to comply with its national standards portfolio.

The European Commission, European Member States and healthcare providers should collectively ensure that procurement officers for EHR systems and platforms are sufficiently educated about standards and interoperability, including what evidence of standards conformance they should require within tenders, to ensure that procurements result in genuinely interoperable and co-operating health ICT solutions.

Member States, health policymakers must ensure that the approval and reimbursement process for digital health tools (e.g. apps, wearable sensors) used by citizens under clinical supervision comply with relevant portions of the national standards portfolio.

The strategic governance of interoperability

The European Commission and the eHealth Network should consult stakeholders on high priority (high value / high unmet need / high volume / low complexity) health data sets to prioritise for pan-European interoperability standards adoption and information sharing. These could include the International Patient Summary, immunisation data, the core data sets enabling patient recruitment for clinical research, and rare disease diagnostic and clinical care data sets.

Stakeholders who utilise health data should collaborate on the benefits case for greater investments in standards adoption and interoperable interfaces, in the nominated priority areas.

eHealth Competence Centres of European Member States, working through the European Commission via the eHealth Network, should establish mechanisms for sharing their learning, approaches and benefits from scaling up standards adoption. This includes the sharing of methods, tools and developed semantic resources that connect structural standards and terminological standards (i.e. clinical models, EHR archetypes, FHIR profiles).

Member States must work towards the cross-country recognition of conformance testing and certification and approval of standards implementation by health ICT systems, platforms, mobile health apps and near patient devices to drive a strong and single European market for interoperable products

Enforcing the adoption of interoperability standards by health ICT developers

SDOs should proactively engage with clinical, clinical research, patient communities and innovators in awareness raising and co-developing educational resources regarding interoperability and standards.

Member States must cross-recognise certificates of conformity of interoperability. The assessment (and certification) must be coordinated across European countries, and assessment frameworks must be aligned across Member States.

Ensuring wider awareness and engagement

All stakeholders must collaborate to raise awareness within healthcare professional societies and patient organisations, and their members, about the benefits of creating more interoperable (i.e. structured, coded, complete, timely) records, of trusting the data professionals use from other sources and be more convinced about why their investment in creating better data brings societal value. This should be promoted through funded awareness-raising campaigns and demonstrators.

SDOs and profile developers must work together with clinical and patient communities in the development of interoperability specifications (e.g. clinical models, profiles) to ensure these have clinical validity and utility, such as effectiveness at the point of care (and to avoid fragmentation).

WORKING GROUP 2 DATA QUALITY, BENCHMARKING & IMPROVEMENT: MAKING THE TRANSITION FROM HEALTH DATA SILOS TO HEALTH DATA SPACES

This Working Group examined the importance of data quality and emphasised that key stakeholders, especially decision-makers and health system funders, need to prioritise investments as well as awareness raising and education about data quality so that quality is assured at source. They also considered the importance of standardising how data quality is assessed and reported, and the transparency of data quality metadata that should be promoted across the data sharing community. The main targeted calls to action are listed here and explained in the Working Group 2 report starting from page 27.

All Stakeholders must focus efforts on optimising data quality and re-usability at source, to optimise individual patient care and contribute to shared learning at all levels of the health system and health sciences.

Stakeholders across the health system, industry and innovators need to design new models for the data continuum from care to research and innovation, starting from properly articulating the value propositions, the needed investments, potential savings and the benefits to patients, professionals and health systems from better data, across the value chain.

Health Authorities and health care managers must view investments in data quality as part of their core strategy, create awareness and an understanding of how high quality and trustworthy data will impact all levels of care, including return on their investment.

Health data providers and potential users of health data need to collaborate on elaborating guidelines for trustworthiness of data shared for altruistic purposes, including obligations to share data that may be easily usable for research and innovation.

Health authorities and health care managers must use buying power to encourage the incorporation of tools supporting the capture of high-quality data and interaction with the users, aiming to optimise the collection of data against predefined quality specifications.

Health care decision makers should adopt a culture for going beyond just providing better care to leveraging new technologies that will consume high quality, trustworthy data to provide more intelligent care for their patients.

The European Commission and Member States, along with other stakeholders, should prioritise use cases to showcase shared data quality specifications, shared efforts for conformant data generation and shared benefits. The shared patient summary including a shared medication record should be considered as an example of a pragmatic use case with significant potential impact.

The European Commission should specify use cases for the European Health Data Space not only as an interoperability specification but also a data quality specification (data quality requirements), with data flows, intended data uses and standardised workflows for the generation of high quality, re-usable data sets.

All stakeholders should promote awareness of the importance of generating high and trustworthy data and promote a data quality culture as an integral part of contributing to and using the EHDS.

All stakeholders should agree on a Data Quality and Trust framework that includes

- Quality principles (dimensions of data quality)
- Process criteria for data provenance.
- Quality Information for the data consumer to assess the suitability of the data against the intended use.

All stakeholders should agree on core data quality metadata to be made available by the provider of shared data sets, at minimum:

- the data pipeline i.e., collection process, controls applied, any further processing such as mapping or transcoding;
- the original purpose for which the data was collected;
- who collected the data (i.e. patient, GP, hospital) and how was data extracted from which sources;
- internal quality assessment mechanisms and assessment reports.

The European Commission and Member States, along with other stakeholders, should enable the establishment of a chain of trust for data quality from the data source to the final receiver of value-added services and/or evidence fuelled by that data.

The European Commission and Member States, along with other stakeholders, should leverage citizen/patient agency to complement the validation of data in EHRs; co-ordinate concurrently policies and actions for data and digital health literacy for patients and professionals.

Policy makers must acknowledge the data quality imperative within the data ecosystem; they should further provide a practical concrete framework to operationalise data quality and data quality assessment and documentation.

The European Commission and Member States should provide incentives and assessment and certification frameworks for Digital Therapeutics and data collected from medical devices, as well as for EHR tools to facilitate collection of high-quality data.

WORKING GROUP 3 DESIGNING HEALTH INFRASTRUCTURES FOR LARGE SCALE DATA REUSE

This Working Group focused on the challenge of scaling up data infrastructures and data use, through and in addition to the European Health Data Space, alongside other data infrastructure initiatives such as GAIA-X, DARWIN EU and EHDEN. It also emphasised the importance of building on the successful EU Digital Covid Certificate. The main targeted calls to action are listed here and explained in the Working Group 3 report starting from page 41.

The European Commission should undertake and publish a survey of the data and infrastructure capability of Member States to inform policy and investment by the EC and Member States.

The European Commission should extend the EU Digital COVID Certificate into an EU Health Card in a staged process e.g., a) incorporate all routine vaccinations b) add e-Prescriptions and c) add summary care records.

The European Commission should incorporate into the EU Health Card the ability for citizens and patients to give informed consent to the access to and use of their health data and its portability into the EHDS and approved federated networks.

The European Commission and Member States should develop a clear communication campaign for citizens explaining the "jargon" e.g. federated networks so that they are able to understand the various components of the EHDS including the infrastructure concepts as well as what an EU health learning system is and what benefits it would bring citizens and patients.

The European Commission should undertake an EU wide survey to establish the extent of social care data today in Member States to inform future EU and Member State policy.

The European Commission, Innovative Medicines Initiative and the European Medicines Agency should together develop a communication plan and map to explain the roles of GAIA-X, DARWIN EU and EHDEN and how collaboration between them will be assured and duplication of effort and resources avoided.

The European Commission and Member States using EHDS should provide for a plan to create combined health and social care EHR.

The European Commission should undertake an audit of completed EU funded projects (including the Recovery and Resillience Facility and EU-4Health program) to determine what data sources could be made available (in compliance with GDPR and ethics) for the EHDS and all future funded projects should have a contractual condition to supply this data to the EHDS.

CALL TO ACTION 3

INTEROPERABILITY STANDARDS ALIGNMENT AND ADOPTION

WORKING GROUP 1

This Working Group examined the slow uptake of interoperability standards, and the lack of European cohesion around standards adoption across Europe. It targeted the actions that the European Commission and Member States could take, triggered by the momentum of the European Health Data Space, to align on standards, profiles, clinical models and priority data sets to focus efforts on standards adoption. This includes ensuring that systems are assessed for their demonstrated interoperability and the procurements require this.

Context

Interoperability of health data is required to support continuity and safety of health and care within and between countries, by connecting the data between electronic health record systems. Interoperability for patient care needs to include personally collected data, via apps and wearable and environmental sensors, which is currently a highly fragmented market. Interoperability is also needed when data are shared or when data are analysed through federated networks, to permit large scale insights for public health, health system strategy and research.

Despite the publication of health data interoperability standards, by several different Standards Development Organisations (SDOs) over some decades, their adoption into health ICT products, procurements and health infrastructures is proceeding slowly and in a fragmented way, using different standards combinations and therefore no European level coherence.

The creation of a European Health Data Space (EHDS) is one of the priorities of the Commission 2019-2025, including the health sector. A common European Health Data Space will promote better exchange and access to different types of health data (electronic health records, genomics data, data from patient registries etc.), not only to support healthcare delivery (so-called primary use of data) but also for health research and health policy making purposes (so-called secondary use of data). The EHDS is expected to be constructed as a combination of repositories that store public authority data from Member State agencies and link to existing and emerging data networks such as the European Reference Networks, the eHealth Digital Service Infrastructure and the European Medicines Agency DARWIN EU network. It will be built on transparent foundations that fully protect citizens' data and reinforce the portability of their health data, as stated in article 20 of the General Data Protection Regulation (GDPR).

The momentum to establish the EHDS is providing the opportunity for multi-stakeholder discourse and collaboration, within and across countries and across different stakeholder groups, to align efforts towards a convergence on interoperable and shareable health data at a European scale.

This paper examines why standards adoption has historically been slow and highlights actions that could now be taken to accelerate that adoption.

1 Target audience

- **All stakeholders who are involved in creating and using data:** patients and citizens, health and care professionals, public and industry research organisations, public health agencies and regulators who influence policymakers by their demands on how future healthcare should be envisioned

  » We would like to enable you with this paper to understand and assert your needs regarding future healthcare with high impact on short-term and long-term scale.

- **Health systems policymakers, payers and budget holders** who decide through their investments on the future healthcare infrastructure:

  » We would like to convince you that you need to use your levers to accelerate and target standardisation efforts, incentivising more connected care and allocate resources to standards and interoperability deployment.

- **Procurement officers** who drive the market and set by their requirements signals for companies if it is worthwhile investing in interconnectivity of health systems.

  » We would like you to be aware of the high importance for the future healthcare system that you make better informed and more specific demands for standardised and interoperable products and services, and prioritise budget allocation for more interoperable products.

- **The health ICT industry** which builds the technological basis for the future healthcare system.

  » We would like to convince you that it is important and also beneficial for your company to invest in standards adoption and in more collaborative systems.

2 Conditions to accelerate the creation and communication of inter-operable data across Europe

Proactive effort is urgently needed to accelerate the adoption of interoperability

Standards adoption is very slow, despite suitable standards for the representation and communication of clinical data now being decades old. There is limited policy, regionally, nationally or at EU level that specifies what standards are to be adopted within and between health systems, and limited sharing of assessment methods and compliance data.

Data needs to be seen by decision makers, and by many other stakeholders including patients, as an asset for collective computable analysis. Data should not primarily be stored and communicated as free text or PDFs, which have limited and/or less accurate computability. The electronic health record must not be regarded as a passive clinical documentation system, but a smart tool to collaborate with clinicians and patients to present trends and simulations, to offer alerts and care pathway guidance, safety warnings etc. These smart services require the data to be computable, and accurately understood by people and computers (i.e. full semantic interoperability).

Governments, academia and industry do not share a sense of urgency to have interoperable health solutions and interoperable health data now in place (e.g. for data transfer between EHR systems, between patient held apps and devices, between EHRs and apps, with social care systems).

There is a lack of visibility of the current interoperability landscape and of future needs in this space.

There are timely opportunities to promote proactive measures

Members of the European Parliament (MEPs) will in a few months receive and debate the proposals for the European Health Data Space (EHDS). We should use that opportunity to call for the enforcement of interoperability standards, including but not limited to the European Electronic Health Record Exchange Format (EEHRxF). We should also call at that moment for Member States to reinforce their commitment to standards adoption and the assessment of compliance within their countries, but coordinating across the Member States (MS) to ensure the ability to share and reuse (e.g. analyse) data across borders.

Our calls should align with the European Commission's (EC) Path to the Digital Decade, which includes a commitment for all citizens to have

access to their Electronic Health Record (EHR) by 2030. Member States will need national strategies to meet those targets and will need to engage with Standards Development Organisations (SDOs) to ensure any additional required standards are developed, and that all required standards are adopted.

Our calls to MEPs and Member States need to emanate from multiple stakeholders in an aligned way, to indicate the extent of support behind these calls to action.

The EHDS must act as a lever for wider standardisation

The data flowing into and out of the EHDS should require the use of interoperability standards to which data holders and users need to comply in order to be connected to the EHDS and have access to data for research.

It should be a requirement that public and private organisations show commitment to standards adoption themselves before they are permitted to access other data for research.

However, the connection rules for the EHDS must not compromise patient care if a health summary is required in urgent situations, and therefore needs to have some tolerance of the migration path towards standards adoption in the interests of patient safety.

Standards Development Organisations need more support

Interoperability standards should always be open access. This requires support for the sustainability business models of SDOs.

The productisation of standards as implementable and deployable components and solutions takes too long following their publication, and needs policy, governance, investment to accelerate wide scale interoperability within countries and at a European level.

SDOs need to be better resourced to follow up standards development and publication with adoption support to the ICT sector and to organisations and users that adopt interoperable solutions. They need to be able to offer a combination of education and professional guidance to these stakeholders, so developers can adopt and implement them more reliably, as well as themselves gaining in depth feedback from adoption experience. SDOs should be facilitated to work with these stakeholders in funded projects and programmes, to provide exemplars which cover the different stakeholder needs and the benefits to them of interoperable solutions.

SDOs, their end user communities and health ICT vendors must be supported (and funded) to work more closely together to ensure standards are well aligned to needs and are practical to adopt (especially, that multiple standards can be used together smoothly).

The voluntary nature of standards development brings some benefits in terms of commitment and neutrality that should not be lost.

Interoperability standards implementations (including the interoperability components within products) should more often be open access.

CALLS TO ACTION

Accelerate the adoption of interoperability standards for health data communication and analysis

1. The European Commission and the European Parliament must require that all health data feeds into the European Health Data Space, to support cross-border care to individuals or for large scale data analysis, conform to a specified portfolio of international interoperability standards, profiles, clinical models, terminology value sets and interfaces, which should build on the European Electronic Health Record Exchange Format (EEHRxF).

2. The European Commission must negotiate with the relevant Standards Development Organisations (SDOs) to procure an open access licence to all of the standards included in the portfolio.

3. European Member States must specify a portfolio of interoperability standards for national eHealth and research infrastructures that aligns with the European standards portfolio, whilst accommodating national priorities and specificities.

4. Member States health policymakers must prioritise resource allocation to the procurement of electronic health systems in hospitals and primary care that have been certified to comply with its national standards portfolio.

5. The European Commission, European Member States and healthcare providers should collectively ensure that procurement officers for EHR systems and platforms are sufficiently educated about standards and interoperability, including what evidence of standards conformance they should require within tenders, to ensure that procurements result in genuinely interoperable and co-operating health ICT solutions.

6. Member States, health policymakers must ensure that the approval and reimbursement process for digital health tools (e.g. apps, wearable sensors) used by citizens under clinical supervision comply with relevant portions of the national standards portfolio.

3 The strategic governance of interoperability

There is a need for top-down leadership and governance of accelerated standards adoption

There is little high-level governance within health systems to drive and prioritise the interoperability of health data and to oversee the adoption of standards within products and platforms used within health systems. However, there are a lot of stakeholders with different priorities and sometimes conflicting incentives within the health and data ecosystem, which limits the capacity for self-regulation and spontaneous maturation. Interoperability strategic governance is therefore required, specifying a feasible and prioritised standards adoption pathway, driving an accelerated adoption pathway through effective leadership and well-targeted incentives.

The drive to scale up interoperability needs to be accompanied by greater investment in workforce development: in how to handle health data originating from multiple sources, clarity about what it means if a clinician does not complete a data set (e.g. what does this mean for safety, liability and professional indemnity, for the reuse of that data by others).

Priority areas should be specified for focused multi-stakeholder efforts towards interoperability

Given the vast complexity of health and care data, and the present patchy extent of structured, coded data and interoperability standards adoption, it is recommended to focus acceleration efforts on high priority (high value, high volume, low complexity) health data sets. These should be selected with a legacy migration path and timeline to promote/enforce standards adoption.

Public and private organisations need to work together on data set and interoperability priorities, aligning the interests of healthcare, health policy and research. Regulatory agencies should also provide input (at a European level via EMA, HMA, ECDC, and at national levels).

The benefits case for greater investments in standards adoption and interoperable interfaces needs to be better articulated, to influence decision makers. This includes the potential for greater benefits from reusing more interoperable data.

We should prioritise health and health relevant data. (For example, this may be guided by the EFMI concept of "One Digital Health", and by the Social Determinants of Health). Health relevant data may include data collected outside of health systems, such as climate, pollution, traffic.

The International Patient Summary (IPS) is a practical and useful first target to champion global interoperability efforts, since this serves an important patient care need (within and between countries) and can generate a useful data resource for public health and research. It is a practical goal for wide scale adoption. If the IPS is well filled and the medication list is correct this can also be a very good vehicle to drive data quality assessment and improvement (by checking the internal validity of the IPS sections, such as highlighting medications without a corresponding diagnosis). Some extensions e.g. for nursing, for long term conditions, are also being explored, increasing its future utility. Parallel work on clinical trial eligibility criteria should be aligned with the current IPS to enable the data set to deliver greater clinical research utility, without extending it by much.

Immunisation data including vaccination coverage rates for all routine vaccines should be one of the high priorities, directed by the ECDC and building on COVID-19 experiences, as we lack a harmonised approach to data collection at a European level with publication on a regular basis. This is possible if there is the will politically (although ideally this needs to be global).

Rare diseases could be a useful priority because a multi-country scale is often needed and these can be high cost, high burden, conditions. They should be considered an important use case, as an area of significant unmet need which could be meaningfully addressed through greater interoperability of data. The number of patients with any given disease will, by definition, be small; however, the fact that there are over 6000 separate rare diseases means that the total number of people living with a rare disease is large (30 million across the EU). Patients with any single disease are geographically dispersed, which means that the ability to pool or otherwise federate data across borders is crucial to understand the cause, course and effects of disease, to predict outcomes, to establish 'what works' clinically, and to plan and deliver any kind of research. The rare disease field (and indeed paediatric research community, which shares many of the same challenges) has major unmet needs, which more interoperable data (of many kinds) would help to address (as presented in the Rare 2030 Foresight Study).

Reliable and interoperable data are needed for algorithms to function reliably and for explainable AI, which may be developed and used in the future for many different health and care scenarios.

Member States must collaborate at EU level on the development and selection of standards and profiles to promote

Standards decisions are usually made at regional or national levels but need increasingly to be harmonised across Europe (or even globally) by promoting alignment of those decisions, including priority setting to focus multi-stakeholder efforts.

Countries have varying levels of interoperability, and in different health data areas. Mechanisms for sharing their learning, approaches, and benefits need to be scaled up. This includes the sharing of methods, tools and developed semantic resources that connect structural standards and terminological standards (i.e. clinical models, EHR archetypes, FHIR profiles). These need to be developed top down and enforced, as today too much extension, profiling, customisation and localisation is in the hands of individual initiatives and developers.

Member States should consider more strongly promoting the 22 EC adopted IHE profiles.

Clinical structures like assessment scales, care pathways, algorithms, and visualisations also need greater interoperability in order to become more reusable. Computable guidelines will also drive the demand for interoperable and computable data.

How we exchange data and how we store (persist) data are BOTH important, to avoid costly data migrations.

European Member States should collectively target “a data layer for life”, using common data models and semantics.

(For example, openEHR supports FAIR principles and supports a “data for life” concept by storing data in structured and vendor neutral format). For cross border research, common data models (such as the OMOP common data model supported by the OHDSI community) could be promoted.

Medical devices additionally need CE marking and then to be adopted on the basis of clinical evidence. These assessment methods and the requirements for submitting clinical evidence need EU level alignment.

CALLS TO ACTION

The strategic governance of interoperability

7. **The European Commission and the eHealth Network should consult stakeholders on high priority (high value / high unmet need / high volume / low complexity) health data sets to prioritise for pan-European interoperability standards adoption and information sharing. These could include the International Patient Summary, immunisation data, the core data sets enabling patient recruitment for clinical research, and rare disease diagnostic and clinical care data sets.**

8. **Stakeholders who utilise health data should collaborate on the benefits case for greater investments in standards adoption and interoperable interfaces, in the nominated priority areas.**

9. **eHealth Competence Centres of European Member States, working through the European Commission via the eHealth Network, should establish mechanisms for sharing their learning, approaches and benefits from scaling up standards adoption. This includes the sharing of methods, tools and developed semantic resources that connect structural standards and terminological standards (i.e. clinical models, EHR archetypes, FHIR profiles).**

10. **Member States must work towards the cross-country recognition of conformance testing and certification and approval of standards implementation by health ICT systems, platforms, mobile health apps and near patient devices to drive a strong and single European market for interoperable products.**

4

Enforcing the adoption of interoperability standards by health ICT developers

The approach to health ICT procurement has to change

There is still vendor lock in. The power of vendors to dictate how data are represented and what can be exchanged by their systems remains too great. Legacy system dependence reinforces staying with the same vendor, procuring comprehensive single vendor solutions rather than best of breed modular solutions (which usually have to be interoperable to cooperate with other modular products). Clinicians and other stakeholders acknowledge the importance of interoperability, but procurement still uses models that allow lock in to sustain.

However, procurement is potentially a powerful change agent to drive the market towards the greater adoption of interoperability and standards. Procurement today seems disconnected from the ambition to make more computable use of (high quality) data and to share more data between systems, organisations, organisation types and countries. They do not focus sufficiently on ensuring the quality, value and reusability of the data captured by the systems being procured. This is mainly an organisational and health systems issue.

Procurers often lack sufficient knowledge of standards, which ones need to be used alongside others, and how to specify the interoperable capability they need (i.e. not just a checklist of standards). SDOs need to be involved (and resourced) to develop more procurement support so that their standards are specified correctly and precisely enough to deliver their intended value. Clinical and patient end users should also be involved since they know what interoperable capability they need. Such procurement support must carefully avoid introducing a bias towards particular vendors, but rather should help to ensure that an open market amongst standards-conformant products is stimulated. We should promote the wider use of the eHealth Network procurement guidelines.

Procurers also need to know what evidence of standards conformance they should require within tenders, so they can be confident of the compliance. This should build on IHE Connectathons and other existing health ICT quality labelling and certification programmes, preferably not introducing new bodies or assessment systems. EHR system upgrades should always have to include certified compliance to the EEHRxF.

The inclusion of standards has to be complemented by the implementation of open APIs so that inter-vendor co-operation is supported: services as well as data.

Health ICT companies must be directed to adopt the required standards

The health ICT marketplace is dysfunctional regarding interoperability and standards. There is a lack of a strong pushback from healthcare organisations, clinicians and regions when they do not find the interoperability they need within products they have purchased.

Healthcare providers should demand, from their EHR suppliers, explicit and independently verified interoperability against prescribed standards through procurement specifications and renewal contracts.

This situation is really critical but difficult to change overnight: a roadmap and timelines for the greater incorporation of standards must be set.

It must be recognised that some companies see interoperability and standards adoption as the business-relevant thing to do whereas others may not today be able to justify that commercial investment, especially if they have a rather local market and if the customer does not demand it. However, the majority of players in the health ICT market would welcome greater clarity about the positioning and priority of standards adoption, including a more specific standards and profiles portfolio.

We need a carrot and stick approach to address today's misaligned incentives towards interoperability. Developers would favour more guiding than binding measures, but it has to be recognised that interoperability guidelines alone have so far not proved effective. These must be reflected in procurement specifications.

Innovative disrupters can help to promote open data. Innovators (especially start ups) are often motivated to have an impact on healthcare, rather than solely make money, but this innovation space needs sustainability, and disruptive innovators that promote and provide open data need support to grow.

Standards mandates need to be aligned at a European level

There needs to be more concerted action across Europe so that cross-border information flows, with larger scale research and a digital market operational at the European level. Too many standards selections today are imposed at regional level, which leads to geographical fragmentation. The EC needs to be able to drive Member State endorsement of a single standards portfolio.

Agility is required when selecting standards and profiles portfolios, due to changing clinical and research data needs. One way to handle agility within a legislative framework would be to nominate a body to maintain a list of standards, profiles and clinical models. This body could ensure multi-stakeholder inclusion in its maintenance and update processes, whilst having enforcement powers.

Assessment of compliance of standards adoption must be harmonised across Europe

The implementation of standards needs to be formally assessed, as there is often too much room for developer interpretation about how to implement standards and especially multiple standards.

The assessment (certification of interoperability needs to be coordinated across European countries, and assessment frameworks must be aligned across Member States.

Certificates of conformity must be cross recognised by Member States to avoid duplication and variation in what compliance means. Compliance assessment has to be a continuous process due to product evolution and standards updates.

CALLS TO ACTION

Enforcing the adoption of interoperability standards by health ICT developers

11. **SDOs should proactively engage with clinical, clinical research, patient communities and innovators in awareness raising and co-developing educational resources regarding interoperability and standards.**

12. **Member States must cross-recognise certificates of conformity of interoperability. The assessment (and certification) must be coordinated across European countries, and assessment frameworks must be aligned across Member States.**

5 Engaging stakeholders

Ensuring clinical acceptance

Clinicians need to have reinforced to them the benefits of creating more interoperable (i.e. structured, coded, complete, timely) records, of trusting the data they use from other sources and be more convinced about why their investment in creating better data brings societal value. Many are nervous about data overload coming at them through having more connected systems. This means that they need better tools (EHR systems, screens and functions) to facilitate the capture of high quality and interoperable data, with the right metadata, without too much data entry effort. There is increasing awareness that we miss high quality user-friendly tools to prepare the data according to the right standards, metadata and provenance information.

Interoperability specifications (e.g. clinical models, profiles) must have clinical validity and utility, such as effectiveness at the point of care, which then means there must be clinical engagement – which has to be matched by clear and evidenced articulation of the clinical and patient benefits. Clinical validity, professional assurance and privacy are all important as well: we cannot look at interoperability in isolation.

Raising stakeholder awareness about the importance of standards and interoperable health data

There is a lack of awareness about why standards are important, including amongst clinicians, policymakers, healthcare organisations, pharma industry, registry custodians etc. Awareness includes how standards should be used: not only by developers but data creators and data users need to understand the standards that are inside the products that they use. This includes understanding about the difference between data models and terminology. Greater awareness may strengthen the sense of urgency amongst decision makers. We need a sense of adoption urgency within ICT companies as well.

We need to define a suitable curriculum for different stakeholder groups to grow this awareness and the relevant skills about interoperability standards, about creating and using interoperable data.

Data literate citizens should be encouraged to become more active in promoting standards adoption and interoperable data sharing.

Data harmonisation and mapping to common data models is also a skill needing greater awareness and training, including the handling of metadata, data quality and how semantic interoperability can be assured.

CALLS TO ACTION

Ensuring wider awareness and engagement

13. **All stakeholders must collaborate to raise awareness within healthcare professional societies and patient organisations, and their members, about the benefits of creating more interoperable (i.e. structured, coded, complete, timely) records, of trusting the data professionals use from other sources and be more convinced about why their investment in creating better data brings societal value. This should be promoted through funded awareness-raising campaigns and demonstrators.**

14. **SDOs and profile developers must work together with clinical and patient communities in the development of interoperability specifications (e.g. clinical models, profiles) to ensure these have clinical validity and utility, such as effectiveness at the point of care (and to avoid fragmentation).**

CALL TO ACTION 2

DATA QUALITY BENCHMARKING AND IMPROVEMENT

WORKING GROUP 2

This Working Group examined the importance of data quality and emphasised that key stakeholders, especially decision-makers and health system funders, need to prioritise investments as well as awareness raising and education about data quality so that quality is assured at source. They also considered the importance of standardising how data quality is assessed and reported, and the transparency of data quality metadata that should be promoted across the data sharing community.

Context

It is well recognised that health data is today of variable quality and origin. There are many uses of health data both at the level of care to individuals - such as sharing EHR data for continuity of care, the use of decision support and AI algorithms for better clinical decision making - and also for research uses that all need high-quality, trustworthy, health data. However, most of the actors that need to have access to better quality health data are not responsible for the quality of data capture, organisationally or financially, neither can they influence directly the quality of health data that they would use for their own clinical, research or digital service offering objectives. So, how can the multi-stakeholder value of health data be translated back into appropriately targeted incentives to improve the quality of that data?

Data quality is a universal requirement, whether from primary or secondary use; the difference between the two is more or less arbitrary, and the challenges identified in this report are applicable to both primary and secondary use of health data.

Data quality and trustworthiness will need to be contextualised and with the understanding that any federated data network within the EHDS will need to face and resolve its own data FAIRification issues. Working Group 2 of Roundtable 4 explored several challenges across the value chain from data generation to its use and re-use and identified a number of top-priority common challenges within the fast-developing data economy landscape that would benefit for collaborative action at European level, across four areas.

1 Balancing costs and benefits across the data value chain

The prevailing data collection culture for health professionals remains primarily for supporting own future clinical decisions. In the absence of investments in data quality, clinical staff engagement and a strong data sharing culture towards mutual benefits, the most common response to the demand for high quality data today is inevitably "We have what we have" leaving it to data consumers to deal with assessment and curation of the data before use. The costs, effort and time needed for this make this practice unsustainable and hence a virtuous cycle of more and better data for more benefits is not the norm today.

It is firstly important to highlight that "what we have" today is not necessarily poor or insufficient for patient care. In addition, person centred care has been in itself an incentive for data quality improvement. Indeed, as care is becoming more patient focused, shared and integrated, there is motivation to acquire a more complete view of the patient hence a motivation to collect more complete and more interoperable and re-usable data, for example when using clinical decision support, eventually stimulating data quality improvement and a quality culture. Therefore, shared care itself has spiralled a virtuous cycle effect for improving quality of hospital registries through direct benefits of integrated (summary) care records for professionals and patients.

Public authorities often stimulate such quality cultures through recognition or simply through benchmarking programs across providers and regions. These quality promoting strategies are voluntary and they rely on personal and corporate motivation. Data quality is today enforced through legislation when it is to be collected for regulatory purposes.

A similar virtuous cycle is more and more demonstrated from aggregating population data from shared summary records returning knowledge for improved care and smarter healthcare. There is increasing evidence that data value chains can start and terminate at the point of care, returning significant benefit to those that collected and shared data of appropriate quality and interoperability standards at the source. Added value for the data providers can be created through value added digital services and can be immediate, as for example on-line comparisons of patient data with population data, or can return benefit in the form of innovative medicines, devices, therapies or digital services through an innovation and market cycle.

We cannot however, claim today that we have the models we need for creating, delivering and capturing value from high quality and trustworthy data generated at the source.

There is suboptimal appreciation of the potential benefits by the health care providers decision makers and funders.

Data quality requires significant investment at the level of the health care provider while the benefits of this investment will not be immediate and they often may reach the organisation only indirectly, through health system benefits.

Hence, benefits need to be seen in a much broader perspective where data contributed from individual organisations, when aggregated, will generate value for health systems and will return to this organisation in the form of better policy, health system organisation, investments etc. The same goes for the health care professionals; the shorter the feedback loop is, the sooner a health care professional will try to improve his/her health care documentation quality and experiencing a return on investment.

Given that the quality efforts and costs are mainly borne by the health care providers, it is important that benefits are clearly articulated and the incentives for hospitals and health care professionals are sufficiently communicated and understood.

CALLS TO ACTION

15. **All Stakeholders: Notwithstanding the fact that data collection is and will remain context specific, efforts must focus on optimising data quality and re-usability at the source. This will not only optimise individual patient care, but will also contribute to shared learning at all levels of the health system and health sciences.**

16. **Stakeholders across the health system, industry and innovators need to design new models for the data continuum from care to research and innovation, starting from properly articulating the value propositions, the needed investments and potential savings and the benefits to patients, professionals and health systems across the value chain.**

17. **Health Authorities and health care managers need to also view investments in data quality as part of their core strategy, communicate and create awareness and an understanding of how high quality and trustworthy data will impact all levels of care, including return on their investment.**

18. **Health data providers and potential users of such data need to collaborate on elaborating guidelines for trustworthiness of data shared for altruistic purposes. The re-use of data for altruistic purposes entails also obligations to share data that may be easily usable for research and innovation.**

2 Tools and standards for data quality

The procurement of EHR systems has historically prioritised organisational efficiency and reimbursement, and - with some exceptions of countries where national hospital registries with high accuracy have been in place for a long time - only in recent years has also prioritised the capture of well-structured and coded health record information for continuity of care, care pathway tracking and decision support.

This means that a high proportion of clinicians today enter data in systems that are not well designed for patient centred record-keeping.

Furthermore, there are few feedback loops that take advantage of processable data to reinforce the value of high-quality data entry effort back to clinicians. Health care organisations therefore often lack the organisational, financial and workforce incentives to invest in data quality improvement.

Firstly, electronic health record systems, registries and other data carriers should incorporate supporting tools and intelligence to assist and assess data against pre-defined requirements and business rules; in the reverse direction, clinical decision support systems should encourage and enforce high quality data for them to work efficiently and provide better support for individual and collaborative patient care. Likewise, hospital management information systems need high quality data to enable learning from doing and continuous service improvement. It is therefore important that pressure is applied to vendors of systems to embed functionalities for following up on adherence to treatment guidelines and data quality enhancing capabilities into their systems.

While generic data quality programmes have been proposed and proven in practice, data quality requirements are context dependant and use case specific. Data quality specification should be therefore part of use cases dependant on health data and the actual implementation should be also assessed against this specification.

Data quality specification is also dependant on expectations of the end beneficiaries. Patients perceive data quality as being the data needed for them to receive the care they need. Health professionals on the other hand need to rely on trustworthy accurate and current data shared by other professionals.

The patient summary, containing both clinical data and a medication record, is an essential foundation for shared care and as such could be regarded as an opportunity and a common ground for sharing effort, investments on a common quality specification and uniform data collection with immediate return of benefits. An additional interesting aspect of this use case is that the medication summary, if more complete, can be used in cross reference as an additional quality verification of the data in the rest of the patient summary (for example, that each medication item has a corresponding diagnosis in the problem list).

The potential to capture high data quality at the source will also depend on standardised work-flows and a minimum level of awareness and workforce preparation. We proposed that we examine this area as an opportunity to make quick progress. If we were to take the example of European (international patient summaries) as an example use case:

Can quality requirements be specified for every use case? Who should assess quality and how? What metadata should be made available? By whom? In which format?

How could data be used and utilized to be able us to understand the situation and the outcomes/impact of an intervention better – to inspire to continued (and improved) data collection?

CALLS TO ACTION

19. **Health authorities and health care managers must use buying power to encourage the incorporation of tools supporting the capture of high-quality data and interaction with the users, aiming to optimise the collection of data against predefined quality specifications.**

20. **Health care decision makers should adopt a culture for going beyond just providing better care to leveraging new technologies that will consume high quality, trustworthy data to provide more intelligent care for their patients.**

21. **The European Commission and Member States, along with other stakeholders, should prioritise use cases to showcase shared data quality specifications, shared efforts for conformant data generation and shared benefits. The shared patient summary including a shared medication record should be considered as an example of a pragmatic use case with significant potential impact.**

22. **The European Commission should specify use cases for the European Health Data Space not only as an interoperability specification but also a data quality specification (data quality requirements), with data flows, intended data uses and standardised workflows for the generation of high quality, re-usable data sets.**

23. **All stakeholders should promote awareness of the importance of generating high and trustworthy data and promote a data quality culture as an integral part of contributing to and using the EHDS.**

3 Quality verification - Transparency

Responsibility and liability for products or services that rely on high quality data is eventually with the data user. It is possible to define, prospectively, data quality requirements for any given use case, plan an appropriate process for data collection and design the associated data quality verification tools and methods. However, this is not possible when data has been originally collected for another primary purpose, hence leaving it up to the data user to verify data suitability before using it. For example, research organisations may benchmark the quality of the data they are using, in order to give greater confidence in their insights; they may then use the data quality benchmarks that they derive to accompany the evidence that is published, and offered to decision-makers such as regulators, so that they can appropriately weigh the trustworthiness of the evidence they are presented with.

This establishes trust - in this case - between the provider of RWE and the user of such evidence.

Another important dimension of trust based on quality verification, is the powerful role of the data subject, the citizen/patient. Individuals, especially those that have acquired a good level of digital health literacy, are in an excellent position to review the data that has been collected for them by health professionals and hospitals and request rectification of inaccurate data. On the other hand, equipping the health systems and the citizens with infrastructures and tools to access their own data, in itself acts as a substantial transparency data quality transparency mechanism, creating incentives for accountability for complete and accurate data in patient records.

4 A Way Forward

Given the diversity of health systems across Europe and the worldwide, and the number of possible uses of data, the question of pursuing harmonisation of data quality standards that could then be applied by data providers is currently out of consideration. What can, however, be realistically standardised, as demonstrated recently by the mutual recognition of COVID 19 vaccination certificates, are quality principles (dimensions of data quality) and process criteria for data provenance. An example of how these may be operationalised in a data provider's environment is provided in Annex I. What is in addition needed is a transparency framework allowing the data consumer to assess the suitability of the data against the intended use.

While it is the stakeholder community that has the collective knowledge, experience and drive to create such frameworks and guidelines, securing conditions for high quality, trustworthy data would also require top-down initiatives and enabling actions. At EU level, there is a role for the eHN to adopt guidelines focusing on the elements described above and ensure that the current and future priority cross-border use cases do encapsulate also quality requirements and specifications. The EC can promote this endeavour by encouraging the application of the guidelines by the MS through the open co-ordination mechanisms and support stakeholder communities create the required knowledge base.

CALLS TO ACTION

24. All stakeholders should agree on a Data Quality and Trust framework that includes

- **Quality principles (dimensions of data quality)**
- **Process criteria for data provenance.**
- **Quality Information for the data consumer to assess the suitability of the data against the intended use.**

25. All stakeholders should agree on core data quality metadata to be made available by the provider of shared data sets, at minimum:

- **the data pipeline i.e., collection process, controls applied, any further processing such as mapping or transcoding;**
- **the original purpose for which the data was collected;**
- **who collected the data (i.e. patient, GP, hospital) and how was data extracted from which sources;**
- **internal quality assessment mechanisms and assessment reports.**

Besides these direct interventions, additional policies, being in part adopted policies and under implementation for digital health and data literacy, DTx quality certification, health care providers and health professional engagement are all important to complement the data quality and trustworthiness framework.

CALLS TO ACTION

26. **The European Commission and Member States, along with other stakeholders, should enable the establishment of a chain of trust for data quality from the data source to the final receiver of value-added services and/or evidence fuelled by that data.**

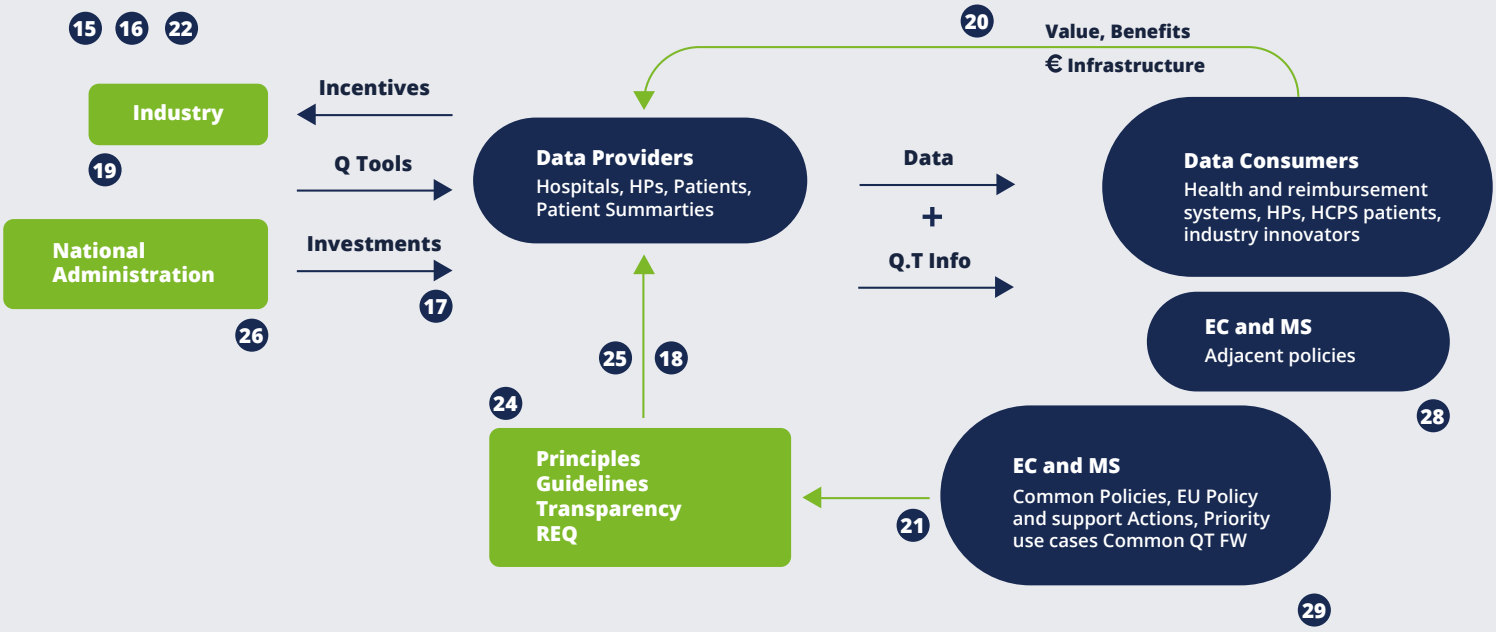
27. **The European Commission and Member States, along with other stakeholders, should leverage citizen/patient agency to complement the validation of data in EHRs; co-ordinate concurrently policies and actions for data and digital health literacy for patients and professionals.**

28. **Policy makers must acknowledge the data quality imperative within the data ecosystem; they should further provide a practical concrete framework to operationalise data quality and data quality assessment and documentation.**

29. **The European Commission and Member States should provide incentives and assessment and certification frameworks for Digital Therapeutics and data collected from medical devices, as well as for EHR tools to facilitate collection of high-quality data.**

FIGURE 1

Articulation of Recommendations



The numbers shown represent the Call to Action that describes that process.

ANNEX 1

Data Quality Principles: An example of implementation

Principle	Considerations for good governing health system policy
Accuracy – Data should reflect the event as it actually happened (2)	**There is a well-defined and adopted set of principles/ use cases that guides the ecosystem on what constitutes accurate data.** **There is widespread adoption of stakeholder-accepted data accuracy standards to improve the quality of health data across the ecosystem; for example, the work that the Duke-Margolis Center for Health Policy is doing on RWE quality (1)** **Measures are in place to ensure that data can be verified back to original source datasets to guarantee that data representation reflects the true state of its source information (provenance).** **If data are transformed in some way, ensure that the transformed data is accurate. A simplistic example would be converting the units used for a lab testing value in one data model to the units used in a different data mode.**
Consistency – Refers to a data value in one data set being consistent with values in another, and over time (e.g. a patient's unique identifier is represented in consistent format across datasets)	**Ensure standardization of collection methodologies for healthcare data to improve the consistency of data. Ideally, physicians should be collecting the same data in the same way to maintain data consistency (i.e. no differences between hospitals/medical jurisdictions).** **The use of common data models across the ecosystem is increased, to ensure consistency across health data sets.** **Alignment exists on standard models for new data types, to drive data consistency from the outset. (Examples of new data types include: imaging, genomics, IoT, digital biomarkers, socio-economic status, etc.)** **Technologies are adopted across the ecosystem that automatically improve consistency, such as by auto-populating data from master datasets, or evaluating consistency across data sets, highlighting/flagging discrepancies at point of collection, storage, transfer and analysis. For example, flagging out of range values.**

(1) *Duke Margolis Center for Health Policy. Determining Real-World Data's Fitness for Use and the Role of Reliability* https://healthpolicy.duke.edu/publications/determining-real-world-datas-fitness-use-and-role-reliability

(2) *WHO Improving Data Quality: A guide for developing countries* https://apps.who.int/iris/bitstream/handle/10665/206974/9290610506_eng.pdf?sequence=1&isAllowed=y

(3) *Quality Dimensions, Core Values for OECD Statistics and Procedures for Planning and Evaluating Statistical Activities. STD/QFS(2011)1.* https://www.oecd.org/sdd/21687665.pdf

Principle	Considerations for good governing health system policy
Completeness – All data required for this specific purpose should be present and the medical/health record should contain all pertinent documents with complete and appropriate documentation (2)	**A defined and adopted set of principles / use cases is created to provide guidance to the ecosystem on what constitutes complete data.** **Appropriate governance/measures are in place to track and understand levels of completeness in data sets.** **A minimum dataset should be defined for specific purposes.** **Incentivise RWD capture that balances healthcare provider concerns with efforts to improve data quality, and allow for flexibility.**
Timeliness – Information should be documented as an event occurs, treatment is performed, or results noted (2)	**Considerations for good governing health system policy:** **Clinical data/information is timestamped appropriately as an event occurs, treatment is performed or results noted resulting in a clear understanding across the ecosystem of a dataset's value.** **Creation of defined time intervals to ensure that data is kept up-to-date; these intervals will be dependent upon need/data type. For example, data should be refreshed and checked on a regular recurring basis.** **There is a recognition across the ecosystem, for the need to have access to up-to-date or near real-time data, where patient outcomes and treatment decisions rely on this.** **Appropriate analytics should be in place to translate data into actionable evidence in a timely fashion.**
Accessibility – Data are available to authorized persons when and where needed. (2) The value of quality data will be lost if it isn't accessible for specific purposes.	**Measures are in place to control access to data, in order to ensure that appropriate (vetted) users have access to the correct data.**
Interoperability – Patients/other users of data can interpret and properly use/analyse the data to glean value from it (3)	**Considerations for good governing health system policy:** **Governance plans for data are thorough and transparent** **Guidance is in place to ensure adequate definitions of variables are clearly described** **Limitations to both data and subsequent analysis of those data are identified and discussed in a transparent fashion**

CALL TO ACTION 7

DESIGNING HEALTH INFRASTRUCTURES FOR LARGE SCALE DATA REUSE

WORKING GROUP 3

This Working Group focused on the challenge of scaling up data infrastructures and data use, through and in addition to the European Health Data Space, alongside other data infrastructure initiatives such as GAIA-X, DARWIN EU and EHDEN. It also emphasised the importance of building on the successful European Digital Certificate for COVID-19 vaccinations.

1 The need for clinical use

Can we envisage an EU-wide clinical network architecture (interoperable, common security architecture, underlying data structures, CDMs, etc.)?

We agreed unanimously yes that an EU-wide clinical network architecture was possible and increasingly clinicians and citizens are likely to demand it.

Challenges identified in discussions:

At a national level for example Sweden has 21 autonomous regions responsible for health and 290 autonomous municipalities and this fragmentation in infrastructure such as EHR systems will be applicable in other Member States

27 Member States which are very heterogeneous where healthcare is a Member State competency (and the challenge is seen in the variations in interpretation and implementation of GDPR)

Repetition by systems of questions to patients, clinical history and tests and when you really need access to information it is not possible

Many patients do not really care about an EU-wide clinical network. They are focussed on more practical and personal things like waiting times for their treatment, seeing the right clinician and getting a good outcome

Political will, leadership and political barriers

Not all Member States have EHRs and levels of investment vary widely; How do we influence the needed investments?

Access to records/data even within Member States is not universal;

The lack of commonly used data bases structure in the same area

Availability of records/ data in different languages

The variation in data capability (infrastructure, capture and quality) between Member States and how do we reduce this variation? How does solidarity work in this context?

Leave no one behind/ digital exclusion

How might these variations in data capability be reduced?

- Understanding what the variations in data capability are would be an important first step: there have been EFPIA publications on this subject e.g. https://www.efpia.eu/media/412192/efpia-on-co-data-landscape-1-report.pdf. The concept of strategies for particular health areas (cancer, dementia) is also applicable for health data – health data strategies/support for developing them would be a useful policy tool, and there are exemplars already from e.g. UK;
- Harmonising registries;
- Improving the quality of data capture at source and post capture (a topic of Working Group 2). The greater the use that is made of health data by the source organisations the more likely they are to make improvements to the quality of that data;
- Increasing the digitalisation of health by wider adoption of existing EU initiatives including the EEHRxF (European Electronic Health Record Exchange Format), MyHealth@EU and expanding the EU Digital COVID Certificate.

Patient/Consumer Perspectives

- Patients want access to their records/data across borders for safe treatments (e.g. working in one Member State but a national of another Member State). Ability to access complete EHR intra Member State and across Member States;
- Political leadership and initiative needed to bring about change;
- Seamless patient and clinician experience accessing data in EHRs anywhere within a Member State and between Member States;
- A holistic approach to the delivery of digital health care services;
- Want a portability system to access health data; The EU Digital COVID Certificate for the first time ever has created the portability system which is universally accepted and trusted;
- Both clinicians and patients want a seamless experience whatever platform /interface is used for remote consultations and which link to the EHR;
- Access to other health data for example to benchmark outcomes;
- Patients have their own electronic wallet with all their records which they are able to show any third parties on a need to know basis.

Opportunities

At least two distinct types of training for staff and patients to know how to access records/data already available within and across Member States and "so understand what is in it for me" – this is training focussed on national systems so will vary from country to country. Wider digital skills and literacy training;

Case Studies detailing how cross border health services work today including data flows using Member States that have to rely on treatments in other neighbouring Member States e.g. Luxembourg and using expert patients;

The Pandemic exposed the lack of digital and data preparedness globally of health systems (including in Europe Member States and EU) and presents a once in a lifetime and time limited chance (before the pandemic ends and we return to business as usual ways to work) to capitalise on;

- The patient awareness of the need for health data for treatment, research and public health purposes;
- The acceptance of patients sharing their data (vaccination information) in the EU Digital COVID Certificate (App) which could be extended in steps such as all vaccinations, existing EU eprescriptions and summary care records then any EHR information to create a "Health Card" for all EU citizens. Key to this is the patient is able to see and give informed consent to the data being shared;
- The speed with which Member States moved to introduce regulations for the EU Digital Covid Certificate and allow portability of health data never seen before demonstrating the art of the possible;
- The uses cases for the EU Digital COVID Certificate such as plane travel, access to entertainment venues and restaurants where data is accessed that is hosted by third party apps;

- ID has shifted from central to decentral using certain developed privacy standards;
- The rapid responses of governments to the pandemic has also exposed the lack of response to public health endemics over many years: e.g. dementia. A good message might be ensuring the rapid advances in the context of COVID also benefit other (often overlooked) health areas.
- "Chain of care" to mitigate digital exclusion e.g. parents take responsibility for children and children take responsibility for infirm parents. So a Health Card needs to give consents for access by the Chain of Care and in so doing drive inclusion not digital exclusion. However, we must not make the assumption that the so called "hard to reach" groups can only be managed via "easier to reach" relatives and supporters. This is why digital education and skills training is still important. A combination of approaches are needed to mitigate digital exclusion which must be inclusive and increase equity.
- Both TEHDAS Joint Action and EHDS itself are important in seizing the opportunities identified in this section;
- FINDATA and France's Health Data Hub provide real practical learning for the EC and other Member States including the one stop shop for consumers of health data and other Member States provide learning opportunities such as Estonia but these are in the minority of Member States;

What are the key drivers to facilitate change from today to this vision tomorrow?

- **Political will, leadership and actions;**
- **Investment by Member States, EU and industry.**
- **Digital Europe Programme €7.6Billion fund which health is able to bid for.**
- **The role of the eHealth Network to help coordinate the actions of the EC and Member States.**
- **EU Recovery & Resilience Funds where a total of €12 Billion is available for Member States together with the Multi Annual Financial Framework which both provide funding for health digitalisation.**
- **It is important to understand that the consumers of health data divide into at least 4 categories, patients, clinical and care staff, and researchers, and the health system itself (funder and commissioner of services) who have distinct needs and requirements. The data capture systems need to support these different intended uses.**
- **Regulation by Member States and EU should be used as both a carrot and stick.**

- **There was agreement that the approach should involve both carrots and sticks not one or the other to achieve optimal results. What are the possible carrots and sticks?**

  » Tangible carrots: national or EU legislation may also mean access to support for developing and implementing strategies. This support could take many forms; financial, guidelines, access to infrastructures or existing tools to improve health systems efficiency and coordination between member states.

  » The European Commission should for EU projects mandate the use of standards in project specifications to improve infrastructure systems and Member States should do likewise for national and regional procurements.

  » Incentives need to be designed to include SMEs.

  » Intangible carrots: greater digital or health literacy, greater engagement of citizens in managing their own health & care; new ways to communicate health information and messages to citizens & patients.

  » Sticks: fines for lack of compliance; inability to participate in EU initiatives, projects and access funding/support if not in compliance.

- **Involve and attract major companies as they have material resources and aligned interests.**

How best to encourage the infrastructure today/status quo to integrate with the vision?

- **Capitalise on the EU Digital COVID Certificate benefits of sharing health data across borders and have a campaign explaining how it works including the suggested case studies above and expert patients to champion the benefits;**
- **Encourage them to imagine the huge potential of having access to the current pool of existing data to which only a very fragmented access exists today.**

CALLS TO ACTION

30. **The European Commission should undertake and publish a survey of the data and infrastructure capability of Member States to inform policy and investment by the EC and Member States.**

31. **The European Commission should extend the EU Digital COVID Certificate into an EU Health Card in a staged process e.g., a) incorporate routine vaccinations b) add e-Prescriptions and c) add summary care records.**

2 The need for research use

Can we envisage an EU-wide research network architecture (interoperable, common security architecture, underlying data structures, CDMs, etc.)?

- **A unanimous yes.**
- **Not an option but a necessity. For example, diseases (especially rare diseases) that know no borders.**
- **EU has an ocean of data, is information poor and a desert of analysis.**
- **There are incipient EC financed projects that produce results. Horizon Europe financing programmes would support proposals in that direction.**

What are the key drivers to facilitate change from today to this vision tomorrow?

- Need to change the language typically used in the public discussions. It is not about "data sharing". The data stays behind fire walls with analysis being undertaken on it in the cloud. It can be more about data visiting, or remote analysis, via networks, but centralised approaches will also likely remain. We need to explain the technologies now being used for analysis to increase trust and confidence.
- Opportunity to broaden the discussions from just data sharing to include analysis sharing.

What practical ideas and suggestions do we have to create this switch?

- It is not a choice between data sharing and analysis sharing as both probably have a role to play and which is more appropriate is likely to be a decision on a case by case basis e.g. public/citizen trust and confidence maybe higher when analysis is shared with industry rather than the actual data itself.
- Terminology is important and the need for consistent and clear language will be important. Jargon such as federated distributed databases need to be clearly explained to the citizens.

- Patient and citizen consent for access to data and avoiding consent fatigue are important. Architecture systems must make the consenting process as clear and simple as possible (as well as having the necessary security and safeguards). The EU Digital Covid Certificate which involved both EU technical standards and national and wider international portability reciprocity provides not only lessons learned but an approach which can be replicated for other use cases.
- Analysis comes from researchers, policymakers and - particularly for health data from Health Care Professionals (HCPs). Accordingly use HCPs and put them in the driving seat for communications; HCPs are viewed as trusted and unbiased providers of analysis. Analysis sharing is also likely to resonate more with citizens/patients; messages could focus on what data tells us (benefits to citizens/patients), rather than what data is, how it is shared in a trustworthy way, etc.
- Clear, simple articulated benefits for patients, clinical/care staff, citizens and health systems (quality and efficiency)

How best to encourage the infrastructure today/status quo to integrate with the vision?

- The "Health Card" could incorporate a simple user-friendly modern mechanism for informed patient and citizen consent which could accelerate consent and research especially for those health systems that do have such consent mechanics in their health systems today. This would ensure also that the Health Card is integrated in both primary use (treating patients) and secondary use (research).
- The Health Card and integrated modern consent mechanism should be linked to the federated networks to accelerate access and use of the data inside those federated networks;
- The Health Card with consent capability offers the EC a solidarity win for Members States and for the EHDS.

CALLS TO ACTION

32. **The European Commission should incorporate into the EU Health Card the ability for citizens and patients to give informed consent to the access to and use of their health data and link to the EHDS and approved federated networks.**

33. **The European Commission and Member States should develop a clear communication campaign for citizens explaining the "jargon" e.g. federated networks so that they are able to understand the various components of the EHDS including the infrastructure concepts including what an EU health learning system is and what benefits it would bring citizens and patients.**

3 Convergence

Should we be reconciling both clinical and research networks into a single EU learning healthcare system?

- **Does having EHDS1 for primary use and EHDS2 for secondary uses risk reinforcing silos between research and clinical practice?**

- **Unanimous support for a single EU health learning system but a recognition that this may take time and need a staged process reflecting the different likely regulatory requirements of treatment from research;**

- **Should EHDS drive strategic collaborations between EHDS 1 and EHDS2 (and if so what might this look like?) or create just one network?**

» Whilst primary and secondary uses involved different institutions with different purposes there is a substantial connection and interplay between them e.g. the relationship between teaching hospitals and the linked University (including Academic Health Sciences Centres);

» It is important that EHDS1 and EHDS2 are designed for strong collaborations with common standards and full interoperability.

- **Should EHDS ensure strategic collaborations between GAIA-X, EHDEN and DARWIN EU and if so how?**

» DARWIN EU is a federated network being created by the European Medicines Agency to provide data and analysis for regulatory purposes. EHDEN is a public private partnership set up by the IMI (Innovative Medicines Initiative) programme involving 43 countries to create open science networks .EHDEN is based on accepting diversity of systems and living with that and this approach should be followed. GAIA-X is a network across all industry sectors, driving standards adoption, MS exemplar projects and architectural developments across the EU.

» It is important that the data inside these federated projects and initiatives are not siloed and that the data can be access for analysis with necessary safeguards by researchers. It is important that interactions between disease specific conditions are possible (whether bilaterally or unilaterally)

Please see the following links:

DARWIN EU: https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu

EHDEN: https://ehden.eu

GAIA-X: https://www.gaia-x.eu/

» In creating these data networks it is important to understand each disease condition has specific types of data and that common data models do not always have these variables of interest. There is very little data on the provision of social care (on care providers, care givers and the burden on care givers). This is part of the Real World Evidence and lived experience of patients. Given the policy recognition for integrated health and care services EHRs should cover both health and social care to provide a complete data picture for and of citizens.

» To maximise the lessons of the pandemic opportunity it is important that the strategic infrastructure initiatives are coordinated and collaboration mandated by the EC in future funding specifications and the EHDS legislation

What are the parallels and redundancies we see between clinical and research to realise this overall vision?

Clinical decision-making is based on experience and the medical science in terms of how best to manage care and treat patients and populations.

There needs to be a feedback loop between clinical generation and use of data, and the ability to inform relevant research that improves insights, understanding and real world outcomes

EHDS1 and EHDS2 will likely require differing technical architecture and governance aspects, but they should not be separate in terms of supporting the feedback loop

What points would optimise development, implementation and maintenance – how do we ensure 'buy in' from all key stakeholders for the coming decades?

A complex balancing act is required to ensure that the incentives for digitalisation and infrastructure does not increase the health inequalities and in turn reduces not increases the digital divide. This requires both a top down and bottom up approach to planning and implementation and different styles of engagement and focus.

Case Studies demonstrating the benefits of convergence examples currently happening and dissemination of these case studies to all stakeholders to drive support for the convergence.

Use the existing EU initiatives with eprescription and summary care records to scale into wider use cases with a road map to full integration of cross border data enabled health services

Important to understand what data needs to be shared or is being shared (UK Patient View) to ensure informed consent is possible.

CALLS TO ACTION

34. **The European Commission should undertake an EU wide survey to establish the extent of social care data today in Member States to inform future EU and Member State policy.**

35. **The European Commission, Innovative Medicines Initiative and the European Medicines Agency should together develop a communication plan and map to explain the roles of GAIA-X, DARWIN EU and EHDEN and how collaboration between them will be assured and duplication of effort and resources avoided.**

36. **The European Commission and Member States using EHDS should provide for a plan to create combined health and social care EHR.**

37. **The European Commission should undertake an audit of completed EU funded projects to determine what data sources could be made available (in compliance with GDPR and ethics) for the EHDS and all future funded projects should have a contractual condition to supply this data to the EHDS.**

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Glossary

API	Application Programme Interface
DARWIN EU	Data Analysis and Real World Interrogation Network
DTx	Digital Therapeutics
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEHRxF	European Electronic Health Record Format
EFMI	European Federation for Medical Informatics
EFPIA	European Federation of Pharmaceutical Industries & Associations
EHDEN	European Health Data Evidence Network
eHN	eHealth Network
EHDS	European Health Data Space
EHR	Electronic Health Record
EMA	European Medicines Agency
FHIR	Fast Healthcare Interoperable Resources
GAIA-X	A federated data infrastructure ecosystem set up by the German and French Ministries of Economic Affairs.
GDPR	General Data Protection Regulation
HCP	Health Care Professionals
HMA	Heads of Medicines Agencies
ICT	Information and Communications Technology
IHE	Integrating the Healthcare Enterprise
IPS	International Patient Summary
MS	Member States
OHDSI	Observational Health Data Science and Informatics
OMOP	Observational Medical Outcomes Partnership
TEHDAS	Towards European Health Data Space – EU Joint Action
SDOs	Standards Development Organisations

Common basis for health data access across Europe

2021 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS

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