HIMSS

Mind the Gap in Digital Health: Trust

Digital Health Advisory Group for Europe (DHAGE) Report from Annual High-Level Meeting

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MINISTRY OF
SOCIAL AFFAIRS AND HEALTH
Finland

The Digital Health Advisory Group for Europe (DHAGE)

Meeting in June 2022, the High-Level Group continued to build on the outcomes of the previous meetings to focus on one of the core requirements for maintaining the drive towards digital transformation of health and care in Europe: **the need for trust.**

The Group looked at **how to earn, maintain and, if necessary, regain trust in digital health services in order to trigger long-term positive outcomes for the society as a whole.** Such trust is key to continuing to build on the digital health responses to the COVID-19 pandemic, that were discussed in 2020, and ensuring that digital health can help improve equitable access for all, as addressed in 2021.

Following the introductory panel presentations outlined below, the Group divided into three subgroups which looked at **the role of the proposed EHDS legislation in building and maintaining trust; the particular trust challenges in the use of digital therapeutics, and the importance of learning from failures in building trust.**

All three subgroups noted that **trust is multifaceted** and that it demands that the perspectives and needs of all stakeholders across the digital health ecosystem are considered - citizens, patients, healthcare professionals (HCPs), industry and policy makers. Each community must be engaged, heard, and nurtured, as losing the trust of one community could undermine trust for all.

HIMSS and the Finnish Ministry for Social Affairs and Health co-hosted the 4th annual Digital Health Advisory Group for Europe (DHAGE) High-Level Meeting. DHAGE is a thought leadership platform for key decision-makers in Europe to identify synergies and nurture collaborations on digital health policies. This year's meeting hosted over 30 participants from around Europe. In addition to the annual high-level meeting, the appointed Points of Contact from the participating ministries and organisations meet quarterly to advance the DHAGE agenda. The outcome of the high-level meeting is documented in the report that focuses on collaborative actions, policy recommendations, and suggestions for joint strategic initiatives.

01 All the trust we need

The Opening Panel:

- **Louisa Stüwe**, E-health Project Director, Ministry of Health and Prevention, "European ethical principles of digital health", France
- **Stein Olav Skrøvseth**, Director, Center for E-health Research – "EHDS, Trust among Member States", Norway
- **Ahmed El Saeed**, Innovation Scaling Lead, UN Global Pulse – "International Organisations as vehicles of trust", Finland
- **Paul Iske**, Chief Failure Officer, Institute of Brilliant Failures "What can we learn from brilliant failures?", Netherlands

The opening panel discussed ways of earning, maintaining and regaining trust in digital health innovation, with a particular focus on how the proposed European Health Data Space (EHDS) could nurture such trust. The panel also looked at the special needs for trust in data and its use that the EHDS brings. The opening panel highlighted four key issues:

European Union presidencies must keep trust high on their digital health agendas

Trust was the guiding principle for the agenda of French Presidency of the Council of the European Union in the domain of digital health. This bore fruit in the high-level conference of February 2022 on "Citizenship, Ethics, and Health Data" which endorsed sixteen core principles designed to create trust among citizens under the following four headings:

1. Placing digital health within a framework of humanist values
2. Enabling citizens manage their own health data digitally
3. Developing inclusive digital health
4. Implementing eco-friendly digital health

These principles must be continued not only in the work of the Czech Republic as they take on presidency of the Council of the European Union, but also in the ongoing work of the European institutions and other EU Presidencies going forward.

Citizens must be in the driving seat of the use of health data and included in its design.

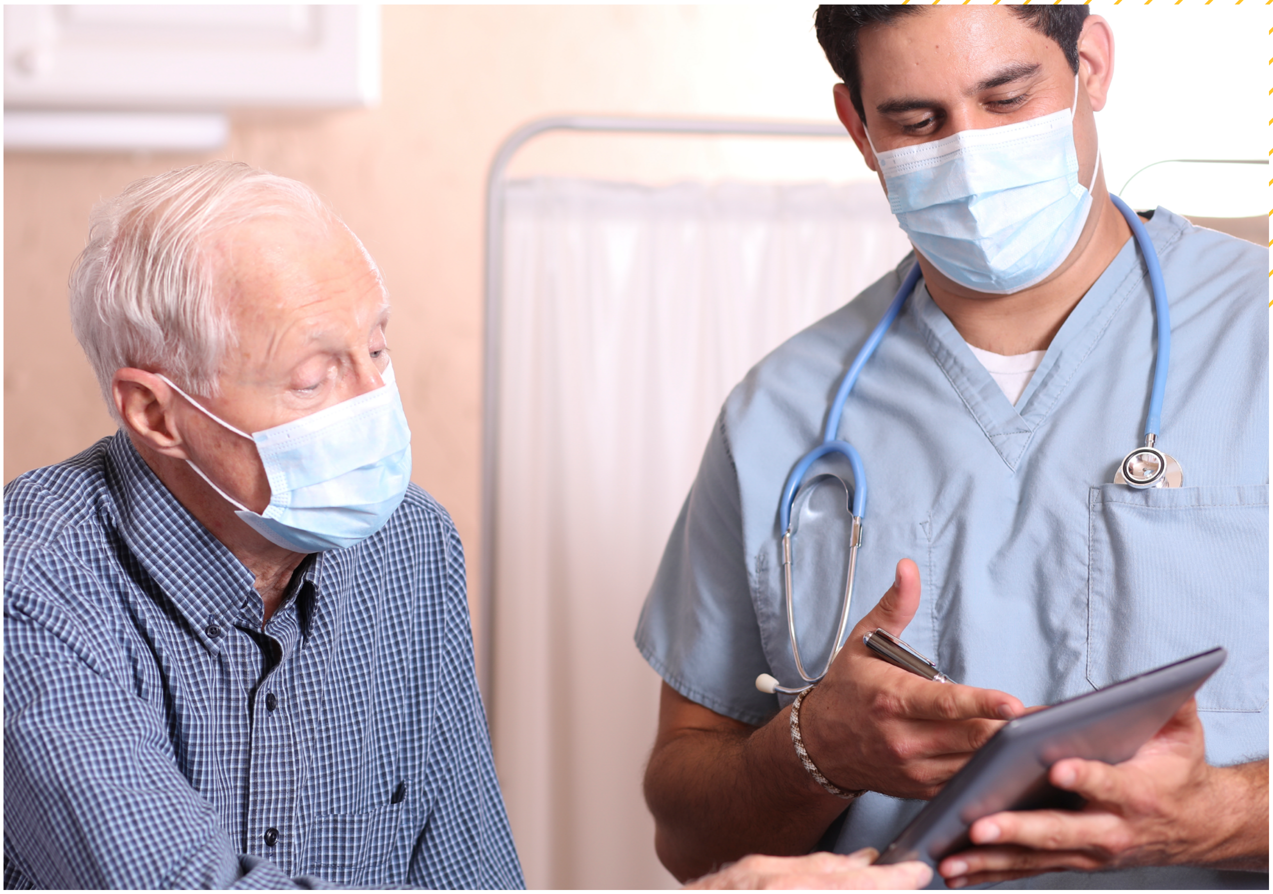
Citizens are key actors in digital health, whose trust must be actively developed through citizen-based, and where appropriate citizen-led, approaches.

Digital health solutions that are introduced from the bottom-up are much more likely to benefit from long term adoption than digital health solutions that are used in healthcare without the proper understanding and active consent of the citizens. In addition, innovations and strategies that are developed inclusively with a wide range of stakeholders from the early design stages onwards, are likely to be more successful and sustainable than non-inclusive ones, even if otherwise brilliantly designed.

To meet this need, design teams should always seek to develop dialogue with different levels of communities with different incentives – citizens, patients, informal careers, all levels of healthcare workers, administrators.

European Health Data Space must build on and actively foster trust

The much-needed European Health Data Space supports patients in exercising their data rights,



brings greater harmony to the rules on re-use of data across the EU and seeks to help patients and citizens better understand the impact of secondary usage of data. It also seeks to promote data altruism, through which citizens and patients can make their data available to the research community. These important objectives will be hard to meet if patients, healthcare professionals and researchers do not trust the bodies created by the EHDS, and trust that the rules developed to protect their rights will be properly upheld.

This demands not only that the means by which trust is earned are supported, but also that the actions and situations that may erode trust are understood and avoided. Building trust must also include transparency on mistakes and near-misses, so that these events can provide lessons for digital health users, providers, and policy makers.

Trust must be understood to be multifaceted

Trust is multifaceted and must be built on a number of levels — between governments, citizens and governments, citizens and healthcare, within healthcare between professionals, governments and the European Commission, and broadly among citizens.

To build high levels of trust, it is essential to continue working with data. We need to ensure that cyber security and a high level of trust in data handling and privacy remain a core focus. Ultimately, trust is key to accelerating the integration of digital health within mainstream health and care. In doing so, the needs of citizens should be at the forefront of any initiative to establish trust across the health ecosystem.

02 The Round Table Discussions

The Workshop hosted three closely interlinked Round Table discussions which addressed the following questions:

- What does trust mean within the context of the EHDS?
- How can we build trust in digital therapeutics?
- How can learning from failures support building trust?

What does trust mean within the context of the EHDS?

Moderator	Maria Hassel, Senior Advisor and International coordinator, Swedish eHealth Agency, Sweden
Facilitator	Tapani Piha, Special Adviser, Ministry of Social Affairs and Health, Finland

The Commission proposal for a regulation on the European Health Data Space of May 3, 2022 sets out the framework for health data exchange in the EU. It seeks to provide for rules, common standards and practices, infrastructures, and a governance framework for the primary and secondary use of electronic health data.

The proposal seeks to enhance security and trust in the technical framework for health data use, stating in Recital (61) that „Member States should work...with a view to achieving a high level of trust and security, enhancing continuity of healthcare and ensuring access to safe and high-quality healthcare.“

The EHDS will impact the health data landscape for decades. One important question is whether the EHDS will support or subvert trust at all levels. Will it create trust between stakeholders and across the member states? What are the pitfalls in the proposal and the potential for creating mistrust instead?

The proposal for a regulation on the European Health Data Space comes within a historic context. The EHDS's implementation is likely to take several years, and it will require considerable resources. But it is going to set the bar globally. The trust levels are influenced by history, and they vary from country to country. The one size fits all approach will yield, if at all, very limited results; therefore, local solutions for trust-building will be needed in the full implementation of the EHDS.

The EHDS has the potential to become a tool for building and earning trust. To avoid the unwanted outcome of creating mistrust instead, consideration must be taken on the perception of use, and the diversity of the local and cultural contexts across EU member states.

CHALLENGES

The Round Table discussed what needs to be done to ensure the EHDS can build trust at three levels:

- How can the Regulation best create trust between the European countries?
- What is the trust-building role of the Regulation for healthcare and research organisations?
- What is the role of an EU Regulation for citizens' trust towards national and EU exchanges of data?

While making few explicit references to trust, the EHDS legislation can build the means of achieving high levels of trust. The EHDS, once implemented, can be a tool for enhancing trust, by giving the citizens more power to control their health data, and by defining responsibilities of the member states to accommodate the rights of the citizens. In the process of implementing the EHDS, it will be vital to communicate the difference between the nature and purposes of primary and secondary uses of data, and the benefits of sharing data individually and collectively. To build trust in the EHDS among citizens targeted information campaigns must be developed to ensure that all types of citizens understand the objectives of the EHDS, the purposes to which shared data can be put, and the benefits that can arise for society when data is allowed to be used for research.

There is a rising concern that patients are unwilling to share their data if it is available for commercial purposes (e.g. to develop pharmaceuticals). The challenge is how to combat the distrust in science and public institutions that emerged during the COVID-19 pandemic.

Trust in the quality of the data in the EHDS must also be developed in the healthcare professional and research communities. The education of healthcare professionals and researchers traditionally leans towards collecting information when and where it is needed, often leading to unnecessary re-testing of patients, and eschewing the re-use of existing data for research.
To overcome this, trust in the quality of the data held in the EHDS must be carefully assured and demonstrated.

CALL FOR COLLABORATIVE ACTIONS on the EHDS

1. **Building trust is linked to giving citizens the right to access, share and manage their data.** The right way to build trust is to ensure that citizens have control over their data. Trust is something that is to be earned and the EHDS would enable that first step toward earning trust. It underlines the responsibility of all actors to accommodate that right.

2. **Ensure, across the EU, the integration of health and social care data,** making the pooling of health and social data possible (e.g. the Finlannish model). The health and social data are combined together in Finland. This has helped the country significantly enhance the secondary use of data and successfully pinpoints the benefits for society.

3. **Invest in education and communication campaigns** on why the secondary use of data benefits everyone. Bring examples of conveniences we currently enjoy thanks to secondary use of data (e.g, in other industries) that we take for granted or don't even think about.

   A good example of this is Estonia, which classifies data into three categories: primary, secondary, and cross-border. People have seen the benefit from health data exchange, e.g. ePrescription. The benefits of the secondary use of data are more obscure; education on the grassroots level is needed on how health research works and creates results.

4. **Target efforts in gaining trust among the healthcare providers** since they are the ones citizens often trust the most. If we gain their trust first, then we will be able to reach citizens.

Building Trust in Digital Therapeutics

Moderator	Nele Labi, Deputy State Secretary, Ministry of Social Affairs of Estonia, Estonia
Facilitator	Petra Wilson, Senior Advisor EU Policy, HIMSS, United Kingdom

Digital therapeutics are evidence-based medical treatments, which rely on new technologies and data. European countries pose different requirements for digital therapeutics and use different ways to prove their effectiveness. In Germany, a specific legislation called DiGA has been put in place. While various digital therapeutics tools have been developed, trust in digital therapeutics among the healthcare professionals who should prescribe them, the patients who should use them, and the public insurers who should reimburse them, remains low.

Health professionals, insurers and patient are unsure about the efficacy of these digital therapeutics tools and don't know how to evaluate the claims made by their developers. As a result, many have concerns about the privacy of the data generated by these digital therapeutics tools, and how such data may be used.

CHALLENGES

The Round Table discussed how digital therapeutics may effect trust in the wider digital health landscape:

- What kind of tools, channels or regulations are needed for building trust amongst clinicians and patients for using digital therapeutics?
- Can legislation like DIGA help to build trust? Or are mHealth validation tools more helpful to ensuring trust?
- Would labels or standards help to cultivate the burgeoning digital therapeutics landscape?

Digital therapeutics create challenges for building trust on many levels. Clinicians and patients need to trust that the services digital apps and devices deliver are safe, and that they can rely on the advice/or service these services provide. Alongside trust in the service, clinicians and patients also need to be able to trust that any shared data will be handled appropriately.

The transformative potential of digital technologies has only recently started to gain prominence in literature. However, even the most ardent proponents of the positive impact from innovations in areas like the Internet of Things, technology, digitalization, and robotics, acknowledge their reservations about the preparedness of governments to fully embrace the opportunities made available by the digital age. Health governance comes with the additional caveat that it is often characterised as being highly political and influenced by a plethora of stakeholders with contending interests and different levels of power.

On the other hand, businesses, not-for profit organisations, and citizens are becoming increasingly interconnected and, according to dominant thinking, tend to be more open to experiments with digital technologies and immersing themselves in a new tech-savvy world. This poses a challenge to the largely traditional and process heavy, hierarchical bureaucracies with internally siloed units, and demands a more agile and collaborative public service instead. As the divide between public service providers and service users becomes more apparent, a good governance model that shifts boundaries and taps into a more participatory learning and decision-making process is needed to stay in line with the expectations of citizens.

CALL FOR COLLABORATIVE ACTIONS

on digital therapeutics

1. **Implement understandable product descriptions and recognizable certifications uniformly throughout Europe** to encourage trust in, and use, of digital therapeutics.

2. To ensure trust in proper and appropriate data share and handling, **enable a simple and flexible consent process across the EU countries.**

3. **Ensure clinicians and other HCPs are able to trust that solutions are safe, effective and appropriate** by designing new targeted health technology assessment models for digital therapeutics.

4. **Design new models of service delivery** that integrate the appropriate use of digital therapeutics into workflows. Support this with targeted change management.

5. **Implement a reasonable timeframe for quality control and assessment measures.** The industry partners, many of whom are new entrants, need to be able to trust that the evaluation schemes for adoption of new technologies and their reimbursement are fair, easy to use and will allow them to bring a product to market in a reasonable time frame.

Building Trust through Learning from Failures

Table Chair	Helen Thomas, CEO of Digital Health Wales, United Kingdom
Facilitator	Prof Paul Iske, Chief Failures Officer, Institute of Brilliant Failures, Netherlands

Healthcare is facing drastic changes, with unprecedented digital transformation and change consisting of rapid innovation in the context of trial and error. New initiatives do not always go as planned, some initiatives are successful, and some fail. What is clear, is that every successful project has encountered challenges and failures along the way; innovation is the result of learning from what does not work, and the ability to learn with hindsight, as well as manage the failure in a constructive and trust inducing way.

Whenever there is a failure with data handling in healthcare there is a significant impact on the trust of citizens, patients and clinicians. The way in which we approach and manage failures can mold the way in which that failure is viewed in hindsight.

CHALLENGES

How can we use failures to demonstrate to the healthcare world that we have "learnt our lesson" and implemented remedies that strengthen the safety and security of data usage? The challenge lies in adequately managing and approaching failures in health data management so that they can be used to rebuild trust.

Trust is built on a relational model; a delicate balance between actors and stakeholders, which should be protected and nurtured through efficient communication, honesty and transparency. Communicating the risks of failure to citizens, and managing those risks competently, are methods to increase trust in the implementation of any project.

The overarching challenge for rebuilding trust following a failure is determining the many stakeholders in the trust equation. Patients, providers, clinicians, caregivers and information-sharing partners must all be included:

- Trust is damaged if stakeholders are not included, or goals of program are not clearly identified.
- Barriers to trust include real, or perceived, past experiences of governments underperforming.
- The media and social media coverage of a failure can have a tremendous impact on trust.
- Unrealistic expectations of the public or stakeholders can undermine trust-building efforts.
- Political and societal landscapes can limit the enabling environment for building trust.

Opportunities and facilitators of increased trust:

- Transparency on expected opportunities and challenges of implementing or using new technology.
- Clearly articulating the goals of a programme and creating a culture of constant learning and improvement via effective evaluation of achieving objectives, identifying roadblocks early, and implementing midterm solutions to mitigate risks.
- Identifying scalable and replicable solutions that allow for variation and flexibility to accommodate community experiences or concerns.
- Present the learning opportunity to empower all stakeholders. Answer "what's in it for me." for the community. When citizens understand the benefits and the risks, they will be much more tolerant of eventual issues within the initiative.
- Universality of trust is fine, but some solutions may need to be presented to specific communities.

CALL FOR COLLABORATIVE ACTIONS

on Failures

1. **Focus on informing and educating healthcare systems and stakeholders on how to address failures,** and creating a trusting environment where failure is recognized as a learning opportunity. Safety is unequivocally paramount, and it must be made clear that failure is not ERROR that harms patients. Redefining failure as a growth opportunity starts the conversation, allowing meaningful evaluation of the reasons for failure, and facilitates moving towards and building trust.

2. **There is an opportunity to reinforce trust** by highlighting lessons learnt through failures in healthcare, specifically in relation to digital health initiatives and creating a culture of learning and openness across Europe built on a foundation of psychological safety, where stakeholders feel supported and able to publicly demonstrate the reasons for the failure of the project, and subsequent learnings.

3. **Focus on co-collaboration and involvement of all stakeholders** in any initiative, while clearly informing them of the risks of failure, or challenges to the project, and how they are going to be mitigated.

4. **It is important to learn from lessons in all countries:** collect not only the good practices, but also the lessons learned from failures.

03 Key Conclusions of the Workshop

The DHAGE workshop considered seven essential ingredients to the development of strong common action to build trust:

- The participants noted the emphasis on citizen rights to control data will be important in building trust in the EHDS. But it demands a significant investment in communication and education to build and maintain the trust.

- For the clinicians and users, the infrastructure must be demonstrated to be safe and secure to ensure that they have trust to start using it—this demands that the objectives of technical interoperability as well as close policy collaboration are met.

- For the particular case of digital therapeutics it was noted that patient and clinicians need readily accessible, and understandable, certificates of conformity to be able to trust the digital therapeutics. Stakeholders need to know that these tools have been checked and approved by an organisation that they trust.

- Approval systems need to be trusted as transparent and fair to give the healthcare industry the certainty that the market they are entering has a level-playing field.

- The group also noted that digital therapeutics represent a change in care delivery models and the workforce needs to be able to trust that this will not disrupt or harm their ability to provide care—good change management is called for.

- The discussion on failures noted the need to develop a perception of failure as a growth opportunity that starts the conversation and can move toward trust.

- Reporting and learning from failures at local and international levels is key to building trust, but the system of doing so must itself be trustworthy. This demands transparency, clear goal identification and differentiated concepts of success for specific situations.

In review of the herewith-outlined success factors to building trust, three key conclusions have emerged:

- The development of the legislative framework of the EHDS must be supported by wider initiatives to help build and maintain trust in robust data governance and the quality of the data in the EHDS.
- Use international and European collaboration to ensure that the emerging digital therapeutics are accepted for use by professionals and bring true benefits for patients.
- Develop attitudes and environments which support the open discussion of failures so all stakeholders can trust that lessons will be learned from mistakes in an effort to avoid future failures.

04

Participating offices in the 2022 Workshop

- Danish Regions, Denmark
- Ministry of Social Affairs, Estonia
- Ministry of Social Affairs and Health, Finland
- Ministry of Foreign Affairs, Finland
- Ministry of Health and Prevention, France
- Ministry of Health, Israel
- Federal Ministry of Health, Germany
- Ministry of Health, Welfare and Sport, Netherlands
- Ministry of Foreign Affairs, Czech Republic
- Norwegian Centre for eHealth Research, Norway
- Swedish eHealth Agency, Sweden
- The Scottish Government, Scotland
- Business Finland
- SITRA, Finland
- NHS Digital, United Kingdom
- Digital Health and Care Wales, Wales
- Institute of Brilliant Failures, Netherlands
- RAND Europe/ Oxford University, United Kingdom
- United Nations
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