European Association of Urology

Biomedical Alliance in Europe

EORTC European Organisation for Research and Treatment of Cancer
The future of cancer therapy

14 December 2021

EHDS: an opportunity to unleash the power of data?

The creation of a European Data Space (EHDS) is one of the key priorities of the Commission for the coming years. Through EHDS1 (for primary use) and EHDS2 (for secondary use) it has the potential to facilitate health data sharing with numerous benefits for health research, policy making and healthcare. The upcoming legislation has the unique opportunity to provide an aligned legal framework for secondary use of data for health research at European level.

The BioMed Alliance Taskforce on Health Data Sharing, in close cooperation with the European Association of Urology (EAU) and the European Organisation for Research and Treatment of Cancer (EORTC), has collected views and experiences of healthcare professionals and researchers on the foundations that the European Health Data Space must be built on to ensure health data becomes a powerful tool advancing European health research.

To ensure that the EHDS will unleash the power of data, the BioMed Alliance proposes key recommendations on data governance, the implementation of EHDS2 and the necessary skills and knowledge needed to facilitate participation.

Summary of the main recommendations:

1. We should use the EHDS legislation as an opportunity to **align different legislative approaches** with a clear and enabling EU legal framework which defines secondary use for all EU member states, enables research, and gives legal clarity on the framework which applies.
2. Researchers, healthcare professionals, medical societies and patients are important **stakeholders** which should be included as trusted partners to bring the EHDS to full success.
3. The **eHealth network and eHealth stakeholder network** should act as a catalyst for engagement and communication, but it needs increased resourcing, a clear strategy, broader membership and a more effective structure.
4. A **multi-stakeholder health data advisory and ethics committee** for the European health data space at EU level can play a key role in ensuring a European approach.
5. **Sector based guidance** must be developed for and with health researchers to provide legal clarity on how to process health data for research purposes without adding unnecessary layers of complexity.
6. The possibility of a European Health **data protection seal or certification** should be explored, and additional **standards/certification** for secondary use of health data need to be developed with different stakeholders, and these standards should be freely available.
7. **Targets and benchmarks for data interoperability** should be established.
8. We need to **incentivise adoption** to the EHDS and **build skills and capacity**, by funding digital health and digital literacy programs, creating training methodologies for continuous professional development and funding joint initiatives on standardisation and certification of healthcare professionals on data governance.

Data Governance: create a shared vision based on trust

Patient data governance is becoming more and more a top priority in the current health data age. If data is used responsibly, data becomes powerful.

In practice, there are many examples of secondary use of data in research aiming to:

- **Understand more about disease risks and causes**
- **Improve diagnosis**
- **Develop new treatments and prevent disease**
- **Plan health services and support clinical decision making**
- **Improve patient safety**
- **Evaluate policies**

Exchanging health data for the purposes envisaged by the EHDS will rely on trust of the patients and research community. Trustworthy data processing is reliant on a number of elements, such as transparency, good collaboration and communication, reliable data (quality, integrity, data protection), incentives for data sharing, and impact of the results of data usage on improvement of patient outcomes, reducing harms on patients and society, reducing costs on one hand and improving health systems efficiency on another hand.

Data governance requires an adequate balance. Data protection and privacy are considered universal rights of the individual. At the same time, one also needs to consider the right to transparency and the freedom of research, in particular with regard to anonymised data, and commercial interests such as protection of IP. In the field of health research, data subject rights largely overlap with the legitimate interests of the community of current and future patients who can benefit from data-based research.

Active participation of a broad range of stakeholders will be key in taking decisions around trustworthy data exchanges in the EU. Researchers, healthcare professionals, medical societies and patients are important stakeholders which need to be included as trusted partners.

A harmonised approach at the level of all EU Member States regarding data governance under EHDS would be tremendously important to streamline the process of data sharing and to facilitate cross-border research, to the benefit of all.

To achieve this, the EHDS must have a plan for continuous and vigorous engagement with a wide range of trusted stakeholders and citizens, and be willing to let them have a voice in the outcomes they consider most meaningful. It should also show in clear and concrete terms what it has achieved and be transparent about challenges. The EHDS needs to be firmly seated in a broad and strategic engagement process with EU citizens, and appropriately facilitate public understanding of sometimes

difficult and technical issues with the general public, patients, healthcare professionals, professional medical societies and researchers.

In short, the EHDS needs to create space for a broad conversation about the secondary use of data for research and what enormous benefits it will bring for European society to co-create a trustworthy environment. Due to the complexity of the legislative and policy landscape, any discussions or decisions in relation to the EHDS data governance need to be addressed in dialogue with the research community, authorities and regulatory bodies (of all competences: European Commission (DG-SANTE, DG-JUST), data protection authorities and EDPB, ethics committees) and other stakeholders, in particular data subjects, e.g., patients, medical societies, researchers and healthcare professionals.

Key considerations on Governance of EHDS2 on secondary use:

- Health and medical research rightly are highly regulated fields. There are a number of interacting, over-lapping pieces of legislation and policy that influence the health research space. This includes, but is not limited to, the EU Clinical Trials Regulation, Pharmaceutical Legislation, Medical Devices Regulations, ICH guidelines and ISO standards, General Data Protection Regulation, etc. This is combined with national provisions or legislation, policy, professional codes of conduct, and national guidelines of regulatory authorities. The complex environment can be overwhelming for researchers and clinicians and can lead to missed opportunities for research. Instead of adding to the complex legislative landscape, **the EHDS legislation is an opportunity to align these different legislative approaches with a clear and enabling, unique EU legal framework which defines secondary use for all EU member states, enables research, and gives legal clarity on the framework which applies.**
- **The eHealth network and the eHealth stakeholder group** could act as a catalyst for engagement and communication but it would need increased resourcing, clear strategy, broader membership, various sub working groups to look into specific areas and detailed overview/oversight on the other task forces or working groups/work packages of the same initiative (EHDS) but also of the other EU legal initiatives (cross-sectors: AI Act, Data Governance Act). Without a clear overview of the legal framework built or already applying to secondary use of data, including GDPR (which is also a cross-sectoral piece of law), there will continue to be loopholes and inconsistencies that will become bottlenecks and drawbacks in the EHDS (health sector specific).
- **Healthcare professionals and the medical research community have much to contribute to the EHDS, as well as being potential future users.** As the scope and objectives of the EHDS2 become clearer, the BioMed Alliance is willing to lend its expertise and advice to a complex landscape.
- We also note the **key role of ethics committees** in member states in interpreting ethical and data protection rights of patients for health researchers. They are usually the key ethical gateway for many health researchers in progressing with undertaking health research studies, and therefore they are a crucial stakeholder to be considered by the European Commission with respect to governance mechanisms of the EHDS.
- We believe a **multi-stakeholder health data advisory and ethics committee for the European Health Data Space at EU level will be necessary**. This committee needs to be fully and

adequately resourced and have the necessary expertise and skills to deliver appropriate guidance on health research and other secondary purposes. It should be a European one-stop-shop to implement the EU wide legislation on secondary use of health data. This body can define data governance procedures, data standards, guidance, and includes citizens, patients, healthcare professionals, researchers, data protection officers, members of ethics committees, data and IT specialists and regulators.

- The EHDS is an ambitious project with broad ranging implications for European society. It will require **substantial funding** to allow the wide engagement and decision-making process necessary.

Implementation: EHDS2 should act as a catalyser for the secondary use of data

Ensuring access, sharing and use of health data is a critical issue, and the intervention of the European Commission will be very timely. However, an aligned approach needs to be balanced with ensuring that it remains possible to continue data exchanges and studies which are currently possible.

One practical concern is that numerous EU member states have already enacted legislation on relevant derogations in the GDPR (Art 89 for example), which will not make the European Commission's task an easy one. The Commission will need to find an appropriate response at EU level; one that gives sufficient legal clarity across all EU member states, rather than an additional EU layer of administration on top of the diverse country level responses.

Key considerations on the implementation of EHDS2:

- Implementing the EHDS across the EU should be an **enabler/catalyser of secondary use of data** for essential research and should not come at the price of bringing in greater restrictions for necessary research.
- The Commission should conduct a full assessment to establish a **clear legal pathway for a harmonised approach** which will not add an additional layer of bureaucracy to national legislation on derogations and which will demonstrate where the gaps are at European level that need to be supported by the EHDS legislation on secondary uses.
- **Sector based guidance** for and with health researchers would be extremely helpful as long as it provides **legal clarity** on how to process health data for research purposes rather than adding layers of complexity. Any code of conduct on health research (Art 40 of GDPR) should be a bottom-up code initiated by the health research community and be helpful for the research community in providing them with legal clarity on how to process health data for research.
- Aligned with work on a code, the European Commission should also explore the **certification routes** available (under Article 42) for institutions conducting health research, and the possibility of a European **Health data protection seal or certification**. The European Commission can indeed encourage or even support the development of **standards and / or certification** on secondary use of health data and/or research using health data. These standards or certification should be developed involving patients, healthcare professionals

and academia as well as regulators, and should be freely available for use and implementation by all actors involved in research. Such initiatives can support trustworthy implementation.

- The EHDS can encourage and incentivise the principles of **FAIR data** (findable, accessible, interoperable, and reusable). As part of this, we recommend the establishment of **targets and benchmarks for data interoperability**[1]. Within this, the lack of standardisation and common taxonomy and fragmentation of data sets should be addressed with guidelines and European standards and processes.
- With the governance model well in place, there need to be **common, interoperable IT architectures** to facilitate secure data flows for clinical and research use across Europe which will need financing and incentivising through EU4Health and other EU funding programmes[2].

Incentivising adoption: build the necessary capacity/skills

Keeping practitioner skill set up to date presents an ever-increasing challenge. Indeed, the issue of training healthcare professionals has been at the forefront of the agenda for almost three decades. This agenda has in part been driven by the desire to introduce revolutionary and new technologies without risking patient safety. Training and raising awareness of clinicians are key elements that public, professional bodies/medical societies and governmental organizations are tackling to ensure doctors, surgeons and other healthcare professionals are adequately prepared for patient care. This training and capacity building will be essential for new digital tools such as AI.

The European Commission's Digital Education Action Plan foresees investments for boosting digital literacy across Europe. The EHDS will need to channel resources and investment from the broader programmes (Digital Europe, Horizon Europe, EU4Health etc.) to enhance digital skills for healthcare professionals, not only for advanced digital skills, but also for general digital literacy. For example, AI is more likely to be ethically and safely deployed if it is used by clinicians and citizens who are aware of the opportunities and limitations of data driven tools. The quality of data will also improve with a greater number of healthcare professionals aware of and using, the appropriate data governance standards. Members of the BioMed Alliance can play a role in communication to our broad networks across all EU member states. We can also deliver capacity building through our scientific content and education activities, but support and resources will be necessary to implement such awareness raising.

The EHDS should also have a strategic function of recommending the digital literacy programmes necessary for both healthcare practitioners and society, as well as advanced digital skills.

Key considerations on capacity building/skills relevant to EHDS:

- Specific **funding** will need to be available for digital health and digital literacy programmes to ensure healthcare professionals and patients can make full use of the EHDS.
- The development of robust **training methodologies for Continuing Professional Development** on new technologies such as the use of AI should be encouraged.

[1] For more information see European Cancer Organisation document 'Unlocking the Potential of Digitalisation in Cancer Care – No Stopping Us Now!'
[2] Also see BD4BO Recommendations on the EHDS

- Funding for joint initiatives on **standardisation and certification of healthcare professionals on data governance** would be very welcome.

The BioMed Alliance looks forward to following the development of EU Health Data Sharing Initiatives and is ready to provide additional feedback and assistance where necessary.