



EuropaBio response to the Work Programme of the eHealth Stakeholder Group

EuropaBio welcomes the opportunity to shape the eHSG Work Programme 2020-2022, and is prepared to support and lead on eHSG topics, and work on the EEHRxF, where appropriate. Within the context of the wider digital transformation, we were encouraged by the first meeting and are ready to engage with our fellow stakeholders and colleagues to further the eHSG agenda.

In response to the first meeting of the stakeholder group held on the 13th of July 2020, and in addition to the Commission's proposals, we propose the following topics to be considered during the first mandate of the group:

- *Data governance*

EuropaBio believes that in order to properly facilitate a digital transformation, in eHealth and elsewhere, there are a number of data governance related issues which must be addressed with immediacy. Common standards for data collection, pooling and streamlining processes for data administration are imperative should Europe be able to take advantage of the technological advances available, including but not limited to AI, supercomputing, and quantum technologies. Scientific advancement, which could benefit from digitalisation of health related data, can suffer a lack of access to data for research. Removing the regulatory barriers to the voluntary sharing and reuse of citizens' data, for example, is something which must be considered thoroughly in the context of eHealth. Without an appropriate data governance structure in place Europe will not will not keep pace globally.

- *Public Trust and Data Ethics*

Advancement in relation to health related data is, understandably and correctly, a sensitive topic in the public domain. In order to build trust with EU citizens, it must become common understanding that data is used for scientific purposes. Engaging stakeholders in the context of the eHSG, particularly those who represent patients and civil society, with adherence to the RRI principles should be an objective of the platform. In order to inform the public of how research will benefit society, high-level stakeholders must be reflexive in their respective roles to ensure that a proactive, meaningful discussion on public trust in data can be had.

Related to this point, the eHSG should consider essential the need to engage with the creation of ethical, legal, and social guidelines in connection with the European Health Data Space. Progressing an eHealth and technologically-centric digital transformation presents an obvious windfall for patients and advancements in healthcare. However, there is a need to properly consider whether current frameworks, such as the Declaration of Helsinki which advocates on behalf of physical but not digital harms, adequately reflect the challenges which society may face

as a result of, what can be seen from the public eye, rapid uptake and operationalisation of digital tools.

- *eHealth Interoperability*

Within the wider context of the digital transformation eHealth related data must be interoperable, where appropriate, for use in the context of (virtual) clinical trials, as part of RWE/D, and with support for consolidating data from multiple sources. Ideally eHealth data should form part of one wider network of health related data (ideally within the European Health Data Space), which can be either cross-referenced pan-Europe in a care context, or anonymised and made available for research purposes. Ensuring that this is done within a strong data governance framework, can provide benefits to patients, industry, and regulators.

- *Artificial Intelligence / Machine Learning / wider technological advances in Health*

Provided the appropriate frameworks are in place, the relevance of eHealth in Europe can excel. Technologically and scientifically, the EU is ideally placed to implement breakthrough innovation within societally-calibrated programmes. Advances in AI / Machine Learning / algorithmic capabilities mean that not only can healthcare be supported, for example the use of AI to assist in diagnosis and prognosis decisions, but also go beyond that which is currently within the bounds of human research capacities, for example the application of machine learning / algorithms to omics data to identify patterns in genetic information that will inform gene and cell therapies. Automation and digitalisation go hand in hand; in essence when our capabilities in computing advance so too can our benefit from the amount of data which we can process. However, and as stated above, our ability to reap the benefit of these technologies relies solely on how accessible, and acceptable, use of European data is.

We believe the following three items should be given priority within the first year of the eHSG:

1. **Infrastructure and data sources** – in order to ensure eHealth and related cross-cutting aspects are realised, the EU must first ensure the right infrastructure for data is in place by investing resources in modernising / setting up where appropriate. Sources of data are essential, and furthermore, this data must be made interoperable in as wide a fashion as possible.
2. **Standardisation of Electronic Health Record Exchange format** – in order to facilitate the use of innovative technologies in healthcare, and complimentary to our first priority, the EEHRxF should be standardised. This is important to enable RWE use and data pooling, and in general presents benefits for all stakeholders, both public and private.
3. **Digital literacy and skills; citizens, public sector and health care sector employees** - there is a need for a gap / stakeholder analysis, followed-up with targets and objectives to address identified issues. Digital skills are dependent on how one uses or assesses a digital technology (eg regulators vs healthcare professionals vs citizens) and this study could provide insight to which skills are missing for a successful implementation of digital health strategies in Europe. The development of projects focused on improving digital skills provides a direct platform for

ensuring better public understanding of digitalisation, and related to this the trust and legitimacy needed for success of the overarching digital transformation.