Facilitating health research and protecting citizens' rights: Life science research infrastructures and patient advocates joint reply to the "Legislative framework for the governance of common European data spaces"

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Introduction

The unbreakable symbiosis between data, health and research & why listen to European research infrastructures.

In today's world, healthcare and research are inextricably linked. The Scientific Panel for Health (SPH) in its recommendations on "Building the future of health research"[1] declared up front that "Health, healthcare and health research form a unique and interdependent ecosystem". The collection and sharing of health data underpin this new research-care continuum. Technological and scientific development, for example, in sequencing, biobanking, ground-breaking imaging technologies, preclinical and translational research (e.g. using patient-derived models), artificial intelligence, as well as innovative clinical trial models have brought researchers closer to the delivery of care and clinicians closer to research, not only in clinical settings, but also in people's daily lives.

COVID-19 made it clear that healthcare and research are two sides of the same coin. The pandemic accelerated the implementation of mHealth and eHealth solutions that have been developing for years (although seldomly implemented coherently at national levels); it highlighted global research networks and their impact on public health; it raised the profile of large multinational corporations in the field of digital health and health research to non-experts and stressed the importance of health literacy and self-disease management.

The global pandemic also raised the importance and relevance of European Life Sciences Research Infrastructures (LS RIs https://lifescience-ri.eu/home.html) as powerful connectors between research and public health. RIs are placed at the intersection of public health and research: as large intergovernmental organisations, we were specifically created to interconnect scientific communities from both academia and industry across key areas for the development of future research and its implementation for public benefit. RIs provide researchers with reliable platforms to consolidate collaboration among national research infrastructures and facilitate access to knowledge, key resources, and generate high quality data and reproducible results. LS RIs work closely with patients and citizens. Some of Europe's largest and most active patients' associations have been involved over the years in our debate on health data and contributed to this document.

In relation to the sharing of health research data, **RIs have already proven themselves as a sizeable positive force towards increased interoperability of data**, a crucial element that links each research stage and therefore each RI on the continuum. Virtually all European RIs, in particular LS RIs, abide to FAIR principles, essential to extract the most value from data and extended to FAIR-health. LS RIs are also involved in key EU initiatives and projects, such as CORBEL and EOSC-life that use synergies across RIs and enable joint services.

Each RI brings a specific added value to the healthcare-research continuum. Here are few examples of the latest achievements of the LS RIs in support of COVID-19 research. They show the undeniable role RIs have to connect public health professionals, academic and

[1] https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/building_the_future_of_health_research_sph_22052018_final.pdf

industry researchers, patients, policymakers, and governmental decision makers, to discuss the crucial issues related to sensitive data used for research purposes:

- BBMRI-ERIC (www.bbmri-eric.eu) brings together over 600 biobanks across Europe, many of which are directly involved in the daily management of the SARS-CoV-2 COVID-19 samples and associated data (https://www.bbmri-eric.eu/covid-19/).
- EU-OPENSCREEN ERIC (www.eu-openscreen.eu) supports Sars-CoV-2 research by prioritizing user access to its core services and technologies while partner sites are identifying new lead molecules from a repurposing library.
- Instruct-ERIC (instruct-eric.eu) has provided priority support for COVID-19 research by identifying candidate molecules for vaccine and therapy targets and providing assurance data for reagents used in virus and antibody testing methods.
- ECRIN (www.ecrin.org) supports multinational, multi-arm COVID-19 clinical trials designed to rapidly test various therapeutic or preventive options, including vaccine trials.
- EATRIS (https://eatris.eu/insights/eatris-covid-19/), through its COVID-19 research task force brings the necessary expertise and facilities to advance the development of innovative therapeutic and prophylactic products closer to the patients.
- ELIXIR provides hundreds of databases, tools, interoperability resources and computing facilities to users across the globe, including a dedicated set of services for COVID-19 research (https://elixir-europe.org/services/covid-19) and a list of national activities being taken in each member country (https://elixir-europe.org/services/covid-19/what-we-are-doing).
- Euro-BioImaging ERIC (https://www.eurobioimaging.eu/content/Covid19) provides fast track, open access to 40+ advanced imaging technologies, training and image data services (BioImage Archive) in biological and biomedical imaging, to support researchers in their fight against the pandemic.

LS RI – via their national member institutes – provide a unique vehicle for alignment and adoption of common standards and regulatory frameworks in European organisations. Each RI serves a large pool of users, and in the case of distributed RIs (with multiple chapter/nodes in Member States) and are therefore harmonisation forces, capable of spreading best practices, standards, success stories and expertise across countries.
Furthermore, RIs are historically highly connected to international fora and initiatives on research data (e.g. CoData, RDA, Go-FAIR, WDS…).

It is because of the structural overlap between healthcare and research, that we are aware of the very complex regulatory framework in which health research is performed: topic-specific regulations such as the Clinical Trials Regulation 536/2014 and the Cross-Border Healthcare Directive 2011/24 live side to side with other key general norms, like the General Data Protection Regulation 679/2016. Now more than ever, healthcare professionals and researchers, regulators, policymakers, and practitioners need to coordinate within such a complex regulatory framework to meet the needs of society and to facilitate health research to the benefit of the patients. Any future regulatory solutions must fully involve RIs and other key stakeholders (RIs, patients and civil society in particular), to draw from their experience and solve the current idiosyncrasies.

Through the years, LS RIs provided their expertise to EU policymakers both proactively and reactively, responding to public consultations and other engagement opportunities. However, the emergence of several cross-sectorial, pan-European initiatives on health research require a stronger, more structured and transparent dialogue between research infrastructures and EU decision makers. **The development and success of the 1 Million Genome Initiative, the Horizon Europe Mission on Cancer, the Health Data Space, the European Open Science Cloud, just to mention a few, will all depend on the appropriate integration and involvement of European LS RIs.**

Do not reinvent the wheel

Europe health data space must rely on existing infrastructures

The impact assessment correctly identifies problems hindering the creation of a single European market for data. In particular, LS RIs recognise the largely untapped potential of consented data made available by individuals for the common good (problem "ii" in the impact assessment). To better analyse this issue, it is necessary to involve the stakeholders collecting and sharing sensitive health data to ensure that key issues identified in the impact assessment will be resolved, and the full potential unlocked in the future.
Consequently, LS RIs understand the general objectives of the initiative and believes that any meaningful progress in the direction of a European Health Data Space needs to build and connect to the achievements and future objectives of European LS RIs, in order to avoid duplications, and to ensure long term sustainability.

The impact assessment raises important aspects, **yet it does not weigh sufficiently on the specificities of health and health research data, and the peculiar issues with data privacy, sharing, and interoperability linked to sensitive data.** By focusing mostly on the economic and single market impact of the new initiative, the impact assessment misses out on crucial ethical, legal and societal issues (ELSI) such as stigmatisation or discrimination. By its very nature, health research data requires a high level of technical and organisational safeguards, as well as professional expertise and care to be handled correctly while still allowing the data to be used to its full potential for the public benefit. While we share the broad objective of the initiative, we remain conscious that the right balance needs to be struck to enable the EEA whilst protecting the integrity, dignity of its citizens, especially of vulnerable populations. Consequently, we believe that the inextricable link between health care and health research can be developed safely only with the full engagement of those players (research infrastructures, patients and healthcare professionals) in the development and implementation process. We are strongly convinced that health data-collection and its use for research should be driven towards better public health, disease prevention as well as treatment and patient-centred care, benefitting people's health and wellbeing.

There are concerns regarding the broad horizontal approach of the Commission concerning the policy options. The establishment of new, horizontal frameworks/structural enablers (as described in the impact assessment) risks to duplicate/conflict with existing initiatives. The main objectives of the policy options do not seem to take into due consideration the role of LS RIs as existing enablers in the field of health research data, with the risk of creating duplications and confusion, when coordination, collaboration and interoperability are needed. All new thematic European data spaces must be established based on existing infrastructures and exploit already developed models for joint service provided by the existing RIs (as developed in, e.g. CORBEL), which will accelerate development of concerted operation of the LS-RIs (for example, through joint Service Level Agreements).Research infrastructures already facilitate access to health research data, and have a crucial harmonisation and standardisation role within the scientific and health research community. EU funded cluster projects such as CORBEL or EOSC-life are already developing new tools and structures to better implement and interconnect existing RIs solutions including to facilitate the access to health research data.

At the micro/individual level, the new generations of young European researchers within life sciences and health care must be able to acquire all the necessary skills to perform the reality of interconnected, data-driven health research continuum. Collaborative means between the Union and the Member States, similar to the success story of the ERASMUS+ programme, could be developed to enable the RIs to become broad-based training platforms to support the skillsets and technological expertise of young European researchers. In this way, effective training within life sciences and health

care will be achieved through the existing LS-RIs that will create the necessary conditions to attract data and talent.

Conclusions

Whereas the initiative for more clarity in European data spaces is highly welcome, its success will depend on how well it can integrate and interconnect the expertise, tools, research infrastructures and networks already in place. As regards the life sciences, the LS RIs should be involved in the design and implementation of any new pan-coordination initiative impacting the sharing of health (research) data. LS RIs should be included in the conceptualisation and creation of such bodies as key founding partners, not only in the strategic/tactical discussions over the implementation of new European data spaces, but also in the implementation of the very infrastructures foreseen in the impact assessment. This measure will prevent setting up parallel structures and avoid reinventing the wheel.

Finally, other programmes mentioned in the impact assessment might not be best suited to consider the specificities of health research. The Connecting Europe Facility simply did not focus on health data projects (other than eHealth implementation), therefore did not develop sufficient expertise and understanding of health data issues. The Digital Europe Programme is geared up towards developing technological leadership in key sectors, like AI, that can have a huge impact on health research. However, the orientation document focuses on the economic and technology aspects, without a clear understanding of the underlying ELSI issues with the implementation AI in health research. Involving LS RIs, with their vast experience and understanding of EU-funded R&I projects, can help to bridge the CEF and DEP to Horizon Europe, the EU4Health programme and other funding instruments that can leverage the impact on the ground of enhanced coordination on health research data sharing.

Involving LS RIs early on can guarantee long-term sustainability of the policy options mentioned in the impact assessment. LS RIs are intergovernmental organisations, with secure, long term budgets that sustain the core activities of RIs. Instead of kickstarting a new horizontal organisation, with important cash disbursement to hire key staff and set up operations, the Commission could involve RIs from the beginning, supporting the involvement of their senior staff members in any new constructions, keeping these as lean and cost-effective as possible. This recommendation seems even more logical following the recent important cuts to the EU4Health and Horizon Europe programmes.