VIEWS AND OPINIONS

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HEALTH DATA ECOSYSTEMS: SHARING HEALTH DATA TO FACILITATE MEDICAL PROGRESS

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Sharing health data in a meaningful way that preserves privacy is the foundation of a well-functioning digital health data ecosystem. A digital ecosystem implies that stakeholders are embedded in the necessary conditions to collect, store, share, and use health data electronically. Health data ecosystems can provide many benefits to society, including effective personalised medicine for patients, greater innovation in research, and improved policymaking. As an integral part of these health data ecosystems, the pharmaceutical industry already contributes substantially to them by investing in and sharing health data in order to facilitate medical progress. While many countries have recognised the value of health data ecosystems, Switzerland lags massively behind when it comes to secondary health data usage. To change this, Switzerland needs to develop a coherent strategy to create a health data ecosystem involving all relevant stakeholders.

SHARING DATA RESPONSIBLY WITHIN HEALTH DATA ECOSYSTEMS FOR GREATER SOCIETAL IMPACT

The pharmaceutical industry is committed to responsibly sharing data in health data ecosystems to foster collaboration and innovation that can have a sustainable impact on society. Aggregated health data from population-level sources – including electronic health records, wearable technologies, health insurance claims, health registries (or burden of disease registries), clinical trials, drug consumption analyses, and other research – can not only significantly boost innovation and medical progress but can also lead to better policymaking and more efficient, sustainable healthcare systems.

Drawing from over 100 years of experience with responsibly handling sensitive data in clinical trials, the pharmaceutical industry upholds robust data protection standards for all stakeholders involved, including patients, academics, and public institutions. The pharmaceutical industry supports both financial and non-financial incentives for structuring and sharing data, such as reciprocity, equal exchange of value, and intellectual property-based mechanisms for a functioning ecosystem. It fosters the principle of providing qualified scientific researchers access to anonymised participant-level data and full clinical study reports (**CSRs**) from clinical trials to conduct legitimate scientific research.

PHARMACEUTICAL INDUSTRY'S COMMITMENT TO DATA SHARING INITIATIVES

One example of the pharmaceutical's commitment to responsible data sharing is its participation in the global effort of the US National Academy of Medicine (**NAM**) (formerly the Institute of Medicine) to develop principles for responsibly sharing clinical trial data. Another initiative is HARMONY, a private-public partnership that receives funding from industry and the EU's Horizon programme. The HARMONY project aims to leverage health data to deliver information that will help to improve patient care, in particular in the field of rare blood cancers, where data is scarce. Specifically, the project gathers, integrates, and analyses anonymous patient data from a number of high-quality sources. This helps specialists in the field to define clinical endpoints and outcomes for these diseases that are recognised by all key stakeholders. Another Innovative Medicines Initiative 2 (**IMI2**) project is Big Data for Better Outcomes (**BD4BO**), which focuses on maximising the potential of big data in order to improve health outcomes and European healthcare systems. A fourth initiative, backed by funds from the public and foundations, is UK Biobank, a large-scale biomedical database and research resource containing in-depth genetic and health information from half a million UK participants. The database is globally accessible to approved researchers, both from academia and private industry, who undertake research into the most common and life-threatening diseases. The platform is based on reciprocity. The UK Biobank encourages researchers to share their findings by publishing in open access scientific journals. Once results are published, researchers are required to return their results to the UK Biobank so they can be shared with other scientists, who can then test the findings or use them to advance their own work.

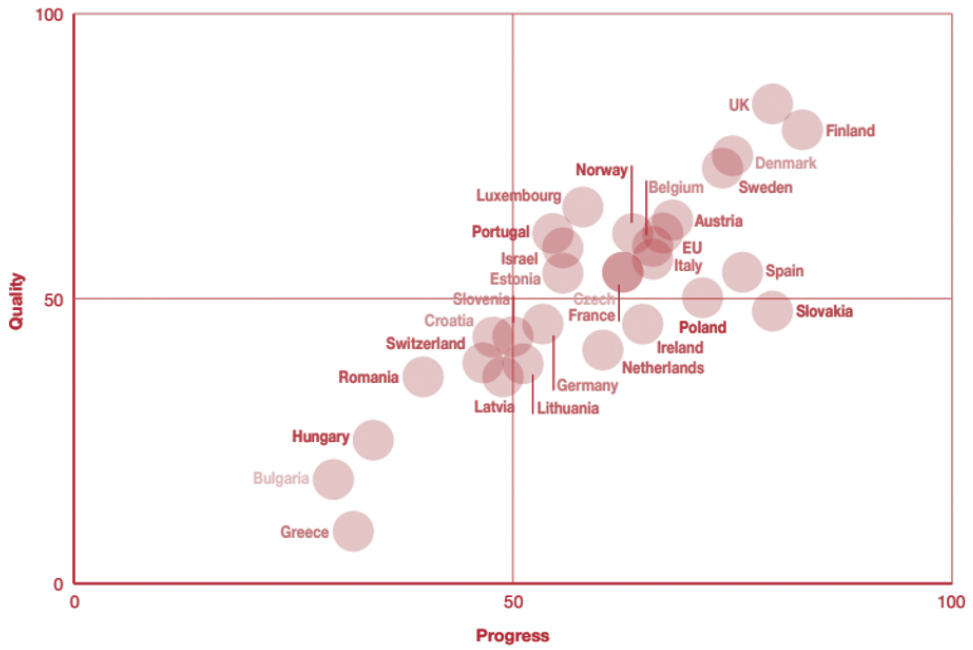
BENEFITS OF HEALTH DATA ECOSYSTEMS

Health data ecosystems hold many benefits, also in regard to clinical trials. Not only do they allow those running clinical trials to better find and match potential candidates who have the appropriate profile, but health data ecosystems can also help simplify many processes used in clinical trials. For example, the emerging concept of decentralised clinical trials, where patients do not have to enter a hospital to participate in a study, depend on patients' ability to collect their health data electronically and safely submit it to the organisation collecting the clinical data. Another example of the use of health data ecosystems is the possibility to build synthetic control arms. With access to longitudinal health data from different sources, researchers can emulate *in silico* eligible populations and randomised trials, including the generation of control groups from real-word evidence and hybrid-design trials.[1] This is particularly important for areas with small samples, for example in rare diseases. Synthetic control arms can also help alleviate the inherent ethical dilemmas of placebo treatments.

SWITZERLAND'S UNTAPPED POTENTIAL

The benefits of a robust, national health data ecosystem, however, currently remain untapped in Switzerland. The country lags massively behind in terms of taking advantage of the potential of digitalisation in its healthcare system. There are no regulatory incentives for structuring and sharing health data, structured health data are scarce, and, if existent, they are often locked up in silos, which is why there is little to no primary and secondary usage. This is reflected in Switzerland's very low ranking in a European index measuring secondary use of health data that was created by the non-profit, multipartner Open Data Institute (**ODI**) based in the UK (see **Figure 1**).[2]

Figure 1: Secondary use of health data in Europe: Country policy rankings



Source: Adapted from ODI report (2021), Figure 1[2]

Switzerland's research-based pharmaceutical industry has been making efforts to unlock the potential of a digital transformation in the Swiss healthcare system. This is shown by a study conducted by the BAK Economics consultancy firm.[3] The analysts found that digital elements are becoming increasingly prevalent in patents in the pharmaceutical sector. However, these patents are being filed in the US and Asia, and Switzerland is losing ground. This comes to the detriment of patients, who will lose their privileged access to innovative medicines and therapies.

But Switzerland is far from being a lost cause. Within Switzerland lies the potential of high-quality health data due to its excellent institutions, well-educated professionals in healthcare, and its competitive and innovative industry. To unleash this potential, Switzerland needs to develop a coherent strategy to create a health data ecosystem while involving all relevant stakeholders in the process. To facilitate this process, Interpharma has published a booklet (available in French and German) in which industry experts outline different factors to be included in a strategy for a successful digital health data ecosystem and provide a roadmap demonstrating what such a strategy could look like.

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