Value from health data: European opportunity to catalyse progress in digital health

Innovations in digital health are expected to transform health care, health research, and public health in the years ahead. WHO’s digital health strategy emphasises the potential for digital health to transform global health and improve the health of all people.¹ During the COVID-19 pandemic expectations for data and artificial intelligence (AI) have been high, with applications in epidemic modelling, diagnostics, triage and patient outcomes, vaccine and drug development, detection of misinformation, and identification of regions of greatest need.² In the laboratory, open sharing of viral genomes has led to rapid development of diagnostics; in the community, countries have introduced digital contact tracing systems and QR code scanning of travel histories, helping to facilitate effective public health surveillance.³ Yet there are still challenges to overcome before the widespread benefits from data, AI, and digital health can be realised.⁴,⁵ Three of these challenges are crucially important.

First, technical and governance standards must be harmonised. Despite increased use of electronic health records (EHRs), gaps remain in the ability of computer systems and software to exchange and use information, defined as interoperability. Data are collected in ways not harmonised. Despite increased use of electronic health records (EHRs), gaps remain in the ability of computer systems and software to exchange and use information, defined as interoperability. Data are collected in ways not universally recognised, with conceptually different values recorded under the same term. Although there has been steady progress towards the development of universal standards, adoption of these standards by health-care systems lags behind.⁶ Similarly, inconsistent regulatory and governance approaches hinder progress, because legal requirements differ across data types, purpose of use, and jurisdictions. In 2018, the EU introduced the General Data Protection Regulation (GDPR), but the regulatory landscape for health data processing is not cohesive. Health data governance should ensure the ethical use of data and development of trustworthy digital health-care sector.

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health applications, yet it has received comparably little
attention.
Second, there is insufficient clarity over what constitutes
evidence of impact and demonstrable benefit for the many
digital tools with a patient interface and which entities
have authority to assess the evidence.7 Experimental AI
studies provide inadequate insight into the challenges and
impact of heterogeneous real-world care settings. There
is, therefore, a need for innovative health technology
assessment methods to be adopted in a systematic way.
Third, in the complex ecosystem of digital health,
stakeholders are driven by diverging incentives.8
Patients, regulators, pharmaceutical and other commercial
companies, health-care providers, researchers, policy
makers, and investors have different targets, while often using the same health datasets—eg, EHR
or research data. Commercial goals, competition, and
attribution all contribute to a splintered digital health
landscape, slowing progress in data use.
Political will and decisive action are needed to increase
health data access and usability.9 In November, 2020, at
the virtual High-Level Conference Digital Health 2020—
EU on the Move, organised by the German Government,
the European Commission declared its commitment to
the establishment of the European Health Data Space
(EHDS), with the aim of facilitating access and use of
European health data—eg, EHR, genomic, public health,
registry data.9 This initiative’s overall goal is to generate
value for European health-care systems, policy, health
research, and innovation.
A decisive factor for moving digital health forward is
governance. Along with a strong legal foundation in the
GDPR, the EHDS will require effective governance and
ethical oversight.10 With this initiative, Europe has the
opportunity to recall its fundamental values11 and set
upstream and downstream conditions must be guided
by the demands of health equity. Accountability should
not be mechanical checks in an opaque digital ecosystem,
rather an opportunity for all stakeholders to embrace
responsibility and exercise good judgment. The legal
protections afforded to privacy are not intended to be
antithetical to the common good of public health, despite
how it is often portrayed. The legal basis of public interest
for secondary uses of data is an ethically defensible option
when robust oversight of data initiatives is in place and
transparency is guaranteed. Good governance can strike
the right balance between individual protections and
promotion of the common good of health.12
For international data initiatives such as the EHDS to be
trustworthy, they must be infused with our shared values.
Failure to achieve this will perpetuate underuse and misuse
of health data, and poor-performing digital health tools,
ultimately depriving us of much needed health benefits
and causing harms. The COVID-19 pandemic has seen
some actors present binary conceptions of our challenges:
privacy versus health, health versus the economy, or we
versus they. These binaries lock societies into narrow
options. The same binaries could propel our choices in
digital health down a similarly narrow path. The EHDS
should avoid this path by clearly defining the best practices
for fair benefit sharing, transparent and accountable
governance of public and private sector data, true
commitment to public dialogue, and global cooperation.
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1 Executive Board 146/26. Data and innovation: draft global strategy on
digital health. Report by the Director-General, 23 December 2019. Geneva:
3 Wang C, Ng E, Brook R. Response to COVID-19 in Taiwan: big data analytics,
new technology, and proactive testing. JAMA 2020; 323: 1341–42.
5 Gardner L, Ratcliffe J, Dong E, Katz A. A need for open public data standards
and sharing in light of COVID-19. Lancet Infect Dis 2020; published online
7 Ferretti A, Ronchi E, Vayena E. From principles to practice: benchmarking
8 Blasimme A, Fadda M, Schneider M, Vayena E. Data sharing for precision
9 European Commission. Press release. Commission and Germany’s Presidency
of the Council of the EU underline importance of the European Health Data
10 European Data Protection Supervisor. Preliminary Opinion Preliminary
12 Blasimme A, Vayena E. What’s next for COVID-19 apps? Governance and