Scaling up cross border reuse of health data

Version 6, 11 October 2021

Improve the availability of robust health data and facilitate accessibility

Assess and incentivise good data quality

1. Specify EU-wide harmonised data quality assessment methods and metrics, building on existing international data quality initiatives and the growing availability of assessment tools.
2. Health authorities should co-ordinate regular audits of the quality of data collected within their health care organisations and public health agencies.
3. Data sets provided for real world evidence generation should be labelled with fitness for purpose data quality metrics.
4. Incentivise investments in data quality improvement, especially by health and care organisations regarding the systems, culture and training in data collection and curation.

Specify global standards, profiles and mappings for high utility data-sets supporting care, public health and research uses

5. Strengthen the support for Standards Development Organisations (SDOs), including the members of the Joint Initiative Council.
6. Develop high value (core) health data set specifications for which stakeholders should prioritise efforts to adopt interoperability standards, high data quality and enable wide data access.
7. Develop and publish extract, transform and load (ETL) patterns from the most used RWD formats to common data models used for research.

Incentivise mainstream health systems adoption of Europe-wide interoperability standards

8. Conduct a study to assess enablers and hindering factors that affected the use and share of health data during the COVID-19 pandemic.
9. Incentivise all data holders to make their data interoperable and work towards compliance with interoperability standards, including compensation for system upgrade costs.
10. Explore ethically-acceptable incentive, recognition and governance models that will encourage all categories of data holder to share their data more widely for research and public health.
11. Establish multi-country collaborations to extract, share and securely store quality-assured data sets for agreed research questions, using a standard format, for onward data sharing or federated data access.

Promote adherence to interoperability and quality standards within personal health devices and apps

12. Encourage the collection and sharing of structured, interoperable data and high quality within mHealth apps.
13. Establish data quality and data provenance standards for citizen-generated mHealth data, drawing on the ISO technical specification on a quality label for health and wellness apps.
14. Encourage companies and platforms which provide and offer digital health products and services to meet EU-endorsed global standards of data quality and interoperability, with appropriate lead time and incentives to ensure compliance.
15. The flow of mHealth data into the EHDS should be made contingent on adherence to agreed interoperability and quality standards.
16. Make EC financial support contingent on adherence to the specifications outlined in the Electronic Health Record (EHR) Exchange Format, and on collaboration with standards organisations.

Scale up the routine inclusion at source of FAIR metadata

17. Encourage the development of user-friendly design of EHR systems and health data repositories for health and care professionals to capture easily and communicate relevant FAIR metadata.

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Improve data re-use conditions
Promote mutually respectful data use terms
18. Co-develop fair model options for a quid pro quo for data use that are ethically acceptable for all stakeholders. 19. Undertake multi-stakeholder consultation on fair and practical models to identify what kinds of return should be provided, and to whom, for access to health data through the EHDS that is used for the development of innovations. 20. Harmonise at EU level data sharing principles and minimum safeguards. 21. Ensure that results of publicly funded research using health data are published and/or made available to other (public and private) organisations on a pre-competitive basis, to avoid creating data monopolies. 22. Clarify any precautions about the data reliability for reuse and foster transparency about data that is made available through the EHDS.
Health data to be recognised and curated as a societal good by, and for, all stakeholders
23. Facilitate multi-stakeholder fora to discuss which health data need to be prioritised for reuse, why and how this is best achieved. 24. Promote agreement among stakeholders on criteria that define research for the benefit of citizens and patients, and advance research towards areas of unmet medical/societal need. 25. Educate stakeholders (e.g. through webinars and public events) on the benefits of health data use, examining the value of different categories of health data. 26. Establish pilot projects where the benefits of data use are demonstrated for specific use cases.
Develop European harmonised approaches to applying the GDPR
27. Clarify the distinction between the different purposes of data use (e.g. recital 159 of the GDPR). 28. Establish EU-wide principles and minimum safeguards regarding the reuse of health data for research. 29. Establish, monitor, and assess EU harmonised standards for anonymisation for different health data sets. 30. Promote EU consensus and consistency on the appropriate uses of pseudonymised data and appropriate safeguards on the data and the pseudo-identifiers. 31. Develop an EU Code of Conduct under article 40 to promote common understanding of data protection/uniform interpretation of the GDPR in regard to health data. 32. Accelerate research into risk-based data protection and information security, suitable for cross-border big health data reuse. 33. Promote EU consensus, with the support of European policymakers (e.g., Members of the European Parliament) on risk-based principles and safeguards that allow for further use of health data for purposes of development, testing & training and use of AI while avoiding algorithm injustice, ethnic profiling and pervasive data tracking.

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Scale up the capability and capacity to leverage health data

Promote the pan-European implementation of secure data reuse architectures and infrastructures

34. The EC and national eHealth agencies should co-develop harmonised interoperability, quality and minimum information security standards for the EHDS, the systems that feed into it and use data from it.

Co-develop and promote consistent governance rules and operations across the regional and national health data infrastructures in the EU

35. The EC and national eHealth agencies should co-develop harmonised data access rules, terms and governance measures to apply to the EHDS, the systems that feed into it and use data from it.
36. The ethical principles and the governance provisions in the World Medical Association Declaration of Taipei (2016) should be taken into account for the use of personal health data and when drafting consent forms and transparency notices for collecting and reusing personal health data for research.
37. Propose, through multi-stakeholder consultation, the future scope for independent ethics committees as envisaged in the Declaration of Taipei, to assess and approve the establishment of different kinds of personal health data repository and the purposes for which personal health data are used.
38. Ensure adequate compliance frameworks, such as auditability of health data re-uses granted via the EHDS.
39. Develop ways in which all professionals with digital health and health data specialist roles can demonstrate having up-to-date competence relevant to the appropriate uses and protection of health data within their profession.

Agree streamlined pathways for data access and use across borders and data networks

40. Promote and incentivise the use of standards, tools and platforms to accelerate (appropriate, secure) health data sharing across all stakeholders.
41. Standardise access protocols to the EHDS infrastructure, supporting compliance with agreed upon data access terms and conditions.

Promote wider use of real world data and evidence, with transparency about the populations and data sources used

42. Encourage appropriate use of RWD for more evidence-based decision making (i.e. to monitor clinical and cost effectiveness of new and established treatment options), while maintaining RCT as the gold standard for granting market authorisation whenever possible.
43. Health authorities, public health authorities and health insurers should consider themselves, and be regarded by others, as health data sources as well as data users.
44. Promote the transparent declaration of the processes by which health data have been created and any limitations in the data reliability for reuse.
45. Promote transparency about the populations and data sources used for digital innovation development and validation, while ensuring alignment with these principles from the MDR and draft AI Regulation.

Invest in data science and analysis skills to enable reliable data analyses and trustworthy evidence generation and for HCPs to drive better healthcare

46. Evaluate methods of reliably aggregating clinical data from real world sources including registries.
47. Provide training on good data management, data protection and data security to all actors who process health data including healthcare professionals, other healthcare organisation staff, patients and citizens, data managers and data custodians, within professional training, CPD and accreditation schemes.
48. Invest in digital and AI literacy skills for the creators, adopters, purchasers and users of AI solutions.

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Grow public trust

Maintain public transparency on data access conditions and rules

49. Raise awareness on data access conditions and rules, share examples (best practices) of the benefits from using health data via an EU platform/forum managed and supervised by relevant European authorities including the EC, EMA, HMA and others.
50. Publish inventories of the approved uses of data, the agreed returns and the outcomes of data use (respecting R&D confidentiality).
51. Undertake public communication campaigns (at national and EU levels) about examples of secondary use of health data, to increase public trust in digital health, involving policymakers as much as possible
52. Collaborate across stakeholders on a regulatory framework on transparency and traceability for data access criteria and conditions, rules, purposes and uses, aligning with the European Commission's Open Science policy where applicable.

Invest in data literacy, across all stakeholders especially among patients and citizens

53. Establish a multi-stakeholder expert panel on data literacy, at EU and national level.
54. Include a focus on data literacy and digital health in the Digital Education Action Plan.
55. Explore the addition of new, neutral, data literate advocacy professionals acting on behalf of patients and citizens, and on behalf of health professionals.
56. Ensure expectations of digital and data literacy cater for different levels of interest and concern amongst the public to engage in data access and use decision making.
57. Raise awareness among the targeted audience (especially patients, marginalised populations, healthcare professionals, researchers, policymakers) on the importance of health devices and apps, trustworthiness criteria and safeguards.
58. Ethics committees should receive adequate training and expertise resources to assess research protocols for reusing personal data.
59. Raise awareness about research ethic committees/ethical review board activities and decisions, ensuring their greater involvement in data sharing decisions and rules.

Co-develop European data access rules with citizen, data source and data user stakeholders

60. Develop or support the creation of an EU 'fair data label' informing when the re-use of health data is legally and ethically compliant.
61. Develop guidance on decision making rules, including illustrations of example data reuse purposes, example trusted organisations, safeguards that would be normally expected.
62. Involve all stakeholders in development of data access rules and conditions, including transparency rules
63. Involve public representatives on data access decision making bodies.
64. Establish EU-wide criteria and a conformance checklist that data requestors need to fulfil when asking for new personal health data to be collected or to reuse existing personal health data.
65. Facilitate multistakeholder agreement on a categorisation of health data reuses to facilitate more consistent data access decision making.