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IEEE Standards Association and IEEE European Public Policy Committee
Response to the European Commission's Survey:

Digital Health Data and Services – The European health data space

The IEEE Standards Association (IEEE-SA) and IEEE European Public Policy Committee (EPPC) are pleased to provide the supplemental information in response to the European Commission's Digital Health Data Survey.

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Facilitating improved access to and exchange of health data is crucial to ensure increased accessibility, availability and affordability of healthcare, to stimulate innovation in health and care for better treatment and outcomes, and to foster innovative solutions that make use of digital technologies, including Artificial Intelligence (AI). The collection, access, use and re-use of health data in healthcare poses specific challenges, in particular in finding the balance between measures facilitating data sharing while preserving individuals' interests and rights, including with respect to the protection of their personal data.

Advances in computational power paired with massive amounts of data generated in healthcare systems make it ripe for AI applications. Thus far, the use of algorithms in medicine has shown many potential benefits to both doctors and patients as well as significant challenges. However, regulating these algorithms is a challenging task as no universal approval guidelines currently exist. Further, the people creating algorithms often lack health/clinical training to understand how to treat patients. Technologists might need to learn more about medicine while clinicians might need to learn about the tasks of specific algorithms.

Without a clear understanding of how an algorithm works, patients might not be willing to let their data be used to help with their medical needs. This is a difficult question for many to answer but probably boils down to feeling confident in an algorithm's decision making ability. Correct decision making is a function of the structure of the data used as input, which is vitally important for correct functionality. Incorrect data inputs mean the algorithms will give incorrect results. It is quite possible that the people creating an algorithm are unaware that the data input is inaccurate until it is too late, and at that point the algorithm could lead to medical malpractice. These are areas where global technical standards, developed through open consensus processes, can contribute to solutions.

[IEEE P2673 - Standard for Patient Digital Biomedical Data Files with 3D Topological Mapping of Macroanatomy and Microanatomy for Use in Big Data and Augmented Intelligence Systems](#) seeks to develop not only a framework but includes requirements to assure compliance with ethical design and value-based design standards to assure (1) patient data security with full access, sharing, and user control of their personal data; and (2) protection of the professional fiduciary relationships between physicians and patients.

Proper understanding of the limitations of algorithms by clinicians and proper understanding of clinical data by programmers is key to creating algorithms usable in the healthcare setting. Defining the standards necessary for an algorithm to be deemed sufficiently accurate for healthcare applications, while addressing the potential sources of error in the algorithm's decision-making and being transparent about where an algorithm thrives and where it fails, could allow for public acceptance of algorithms.

Many of the concerns regarding trust, ethical considerations and education on the use of autonomous systems are prevalent in many industries beyond just health. The IEEE Standards Association offers many different platforms to educate and drive a level of "confidence" in responsible use of AI systems through development of technical standards and certification programs.

Defining and understanding "ethics" in autonomous systems is equally important. Some resources include the [IEEE SA Ethically Aligned Design Glossary](#), the IEEE [Global Artificial Intelligence Systems \(AIS\) Well-being Initiative Industry Connections Program](#), and the IEEE [Ethics Certification Program for Autonomous and Intelligent Systems \(ECPAIS\)](#) work.

Precision medicine is not exclusively dependent on deep learning tools such as AI or machine learning. The future of precision medicine rests largely on the ability to exchange and access health data via open source. Integrating real world data into research through openly and securely exchanged health data in the form of metadata is critical to success. Metadata is a growing application in the use of blockchain/distributed ledger technologies (DLTs) management of health data transparency and other open portability challenges especially as it relates to data generated from health and medical wearables or in-body devices. Development of global technical standards would be significant in addressing these challenges and it could open doors to innovation in the development of therapeutics. IEEE wishes to offer several pertinent resources:

[IEEE 1752.1\(™\)-2021 - IEEE Approved Draft Standard for Mobile Health Data](#)

Standardizing mHealth data and metadata will improve the ease and alignment accuracy of aggregating data across multiple mobile health sources (semantic interoperability) and will reduce the costs of using this data for biomedical discovery, improving health, and managing disease.

[IEEE P2418.6\(™\) - Standard for the Framework of Distributed Ledger Technology \(DLT\) Use in Healthcare and the Life and Social Sciences.](#) This standard provides a common framework for distributed ledger technology (DLT) usage, implementation, and interaction in healthcare and the life and social sciences, addressing scalability, security and privacy challenges.

[Tech and Data Harmonization Enabling Decentralized Clinical Trials Industry Connections Program.](#) This program seeks to create frameworks for data interoperability, security and validation in the use of digital health tools and real world to enable efficacy in decentralized clinical research.