Analysis of Legal and Regulatory Frameworks in Digital Health: A Comparison of Guidelines and Approaches in the European Union and United States

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Abstract:
The advent of digital technology in healthcare presents many opportunities for the improvement of healthcare systems around the world. It is a significant tool that will enhance the move towards value-based treatment. However, this move needs to be accompanied by strong legal and regulatory frameworks that will not only facilitate but encourage the good use of digital technology. The goal of the study was to assess the amenability and furtherance of regulatory frameworks in digital health by evaluating and comparing legal requirements that are currently in use in the European Union and United States, with respect to the processes, effectiveness and outcomes of the adoption of the current regulatory guidelines. This study was a combination of two research methodologies. The first was a research of current legal and regulatory frameworks in digital health in the European Union and United States with a comprehensive online search for laws, regulations, position statements, policies, green papers, white papers, guidelines and recommendations. This research was complemented with a qualitative research consisting of interviews of key informants in the legal and regulatory landscape by way of purposeful sampling. The questionnaire for the interview consisted of twelve questions relevant to the landscape of digital health. Interpretation of the interviews was carried out by constructing mind maps and using the thematic analysis of Braun and Clarke. The mind maps revealed key features and challenges of the digital health field. The deficiencies of the legal frameworks provided opportunities and recommendations to further develop and strengthen the regulatory landscape.