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# Differences Between Europe and the United States on AI/Digital Policy: Comment Response to Roundtable Discussion on AI

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**Abstract**

For AI policy, there are significant differences between Europe and the United States. The General Data Protection Regulation, which applies not only to European Union companies but also to all American companies with European customers, is more protective than health insurance portability and accountability act for individual health data. Its Article 22 stipulates that citizens cannot be submitted to medical decisions generated by an automated source.

**Keywords**

gender, female, AI, artificial intelligence, AI policy

For AI policy, there are significant differences between Europe and the United States. The General Data Protection Regulation, which applies not only to EU companies but also to all American companies with European customers, is more protective than health insurance portability and accountability act for individual health data. Its Article 22 stipulates that citizens cannot be submitted to medical decisions generated by an automated source.

For the creation and implementation of national health databases, European companies have an advantage over the United States because of their small sizes, single-payer systems, and existing national cohorts.

For instance, France is in the process of developing a national health data platform (Health Data Hub [HDH]), as part of the Healthcare Law of July 14, 2019.[1] It has its origins in the report presented by Cedric Villani to the French government in March 2018.[2] The HDH aims to combine anonymized data from the national insurance system (Assurance Maladie), hospital electronic health records (EHRs), pharmacy claims, and physician data.

Questions remain on the needed infrastructure and the protection of personal data, and these were referred to the National Commission on Informatics and Freedom (CNIL). It expressed concerns about data sharing between public and private players, including startups, and on the planned storage of data on Microsoft's Azure Cloud. Other concerns relate to the risk of reidentification of data, which may be technically possible, despite the fact that French law prohibits it. The HDH leadership answers that the key to data encryption will not be accessible to Microsoft.[1]

Other objections come from hospitals such as the AP-HP health system in Paris, which already have their own EHRs and do not see the need for a burdensome and costly transition to a new structure.

Consumers themselves show reluctance. As of November 2018, they are allowed to create a Shared Medical Dossier (Dossier Medical Partage) where they and their providers can enter all personal health data, from laboratory tests to physician notes and hospital records.

Beyond a few pilot projects, this has largely not been adopted, due to a lack of consumer information, physician reluctance, and technical difficulties such as PDF documents that cannot be modified.

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While this Dossier is under the patient's control, there are also concerns about potential consumer requests to delete all or part of it, which would require a long and burdensome bureaucratic process.[3]

Another difference between France and the United States relates to informed consent. For access to genetic data, US direct-to-consumer platforms such as 23andMe and DNA ancestry are considered 2-sided markets because they have 2 kinds of consumers: individuals seeking information about their own DNA, with or without a doctor prescription, and academic or industry researchers.

In France, individual genetic data cannot be accessed without healthcare professionals' mediation. After medical prescription, tests are performed by an accredited laboratory.

The virtual or presumed consent used in two-sided platforms is not used in academic research and care centers in France.[4]

For the use of AI in clinical practice in Europe and France, in areas such as radiology, pathology and neurology, EU-based companies have to obtain regulatory approval both in Europe and the United States: For example, Cardiologs, a firm that provides assistance to physicians in screening for atrial fibrillation and other arrhythmias, using electrocardiogram records and AI (https://cardiologs.com/), received regulatory clearance in Europe (CE Mark) and Food and Drug Administration (FDA) clearance within 10 months. Similarly, Therapixel offers MammoScreen, a deep learning software that reads digital mammograms to detect and qualify abnormal tissue, and it is simultaneously undergoing FDA and CE clearance. With its many exemptions, multiple tracks, and updates, the FDA's approval process may appear more complex than the CE marking process. The demonstration of robust validation and the monitoring of the diagnostic predictive value of AI software remain a central issue in their wide adoption by the medical community.

## Authors' Note

Our institution does not require ethical approval for reporting individual cases or case series. Informed consent for patient information to be published in this article was not obtained because this commentary does not contain any patient information.

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