

Protecting Privacy and Security in Machine Medicine

Protéger la vie privée et la sécurité dans la médecine-machine

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#MachineMD #Privacy



Personal Health Information and GDPR

- Subject Matter
 - Protection of natural persons with regard to the processing of personal data
- Territorial scope
 - EU and outside the EU (extraterritorial effect)
- Material Scope
 - **Personal Data:** any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly
 - **Sensitive Data** (list): genetic data, biometric data, data concerning health.
- Jurisdiction EU/MS:
 - The organisation and delivery of health and social care are the responsibility of the MS
 - Art. 168 TFEU: the Commission can promote public health and support cooperation between the MS + the Commission can take action to stimulate innovation and the development of the DSM



Deidentification and Pseudonymisation

- Deidentification (anonymisation)
 - anonymous information does not relate to an identified or identifiable natural person
 - GDPR does not concern the processing of such anonymous information
- ‘Pseudonymisation’ Definition (GDPR, art. 4)
 - Processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information
 - Additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person
- ‘Pseudonymisation’:
 - appropriate technical measure to safeguard the personal data, such as encryption = obligation of security of processing



Big Data, AI and GDPR: Obstacles

- **“Big” Data:** Principles relating to processing of personal data Personal data shall be processed:
 - Lawfulness of processing
 - purpose limitation
 - data minimisation
- **DPIA**
 - in particular using new technologies and where the processing is likely to result in a high risk to the rights and freedoms of natural persons
 - processing on a large scale of special categories of data
 - prior to the processing, the controller shall carry out an assessment of its impact



Public Good and Personal Data Donation

- Lawfulness of processing (GDPR, art. 6) :
 - the data subject has given **consent** to the processing for one or more specific purposes (consent freely given, specific, informed and unambiguous)
 - processing necessary for the **performance of a contract**
 - processing necessary for compliance with a **legal obligation** to which the controller is subject
 - processing necessary to protect the **vital interests** of the data subject or of another natural person
 - processing necessary for the **performance of a task** carried out in the **public interest**
 - processing necessary for the purposes of the **legitimate interests** pursued by the controller or third party



Beyond the GDPR: Health in the DSM and AI Strategy

- EC Communication on Health and Care in the Digital Single Market, 25 April 2018, COM (2018) 233
 - EU support: funding and standardisation.
 - Cooperation between MS. Ex. : 13 European countries have signed a declaration for delivering cross-border access to their genomic information (April 2018)
- EC Communication on Artificial Intelligence for Europe, 25 April 2018, COM(2018) 237
- EC Communication on Building Trust in Human-Centric Artificial Intelligence, 8 April 2019, COM(2019) 168
 - *Ex. : the Commission will support, in coordination with MS, the development of a common database of health images initially dedicated to the most common forms of cancer, so that algorithms can be trained to diagnose symptoms with very high accuracy.*
- HLEG AI Ethics Guidelines for Trustworthy AI, 8 April 2019

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