DATASPACE 4HEALTH
LUXEMBOURG

Legal Framework applicable to the Dataspace4Health project

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This document is intended to be published on the Dataspace4Health website.

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1. CONTEXT

DataSpace4Health (DS4H) project is an open healthcare data exchange ecosystem, focusing on secure data sharing and innovation in medical treatments and research for diabetes and oncology cases, using artificial intelligence (AI). The project, combining health, data sharing and AI, is at the crossroad of several regulations. Here is a quick review of the main regulations under the scope of the project:

2. APPLICABLE REGULATIONS

- General Data Protection Regulation (GDPR)
- Artificial Intelligence Act (AI Act)
- Medical Device Regulation (MDR)
- European Health Data Space (EHDS)
- Data Governance Act (DGA)

3. APPLICATION OF GDPR TO THE PROJECT

Regulation:	Qualifications:	Main requirements:	Main art.:
GDPR	Health data: any data related to physical or mental health of a pers. Sensitive data: require more care. Health data enter this category. Profiling: AI to predict aspects of patients' health Data controllers: Hospitals, University (2dary use), Agence e-Santé, NTT (as dataspace facilitator) Data processors: LNDS, NTT (as IT service provider, PS integrator) AI provider (1mary use), LIH (AI advisory) Research-Specific Exemptions: • GDPR acknowledges the importance of research and provides exemptions from certain rights of data subjects, such as the right to erasure.	• Obligation of transparency towards patients • Consent of patients • Obligation of documentation (drafting of policies, processing registers…) • Adoption of appropriate technical and organizational measures • Privacy by design and by default • Notification of data violation • Cooperation with authorities (CNPD) • These exemptions are subject to conditions, such as not hindering the achievement of research objectives.	Art 5, 6, 9, 12 et s., 25, 28, 32, 33, 35,…

AI Act	AI System High Risk AI system: product covered by EU harmonization legislation (MDR) Providers: potentially NTT, LIH? Deployers: Hospitals Distributor: potentially NTT?	• Roles mapping and attribution • EU Declaration of conformity and CE marking • Obligation of technical documentation • Risk management system • Quality management system • Human oversight • Corrective measures • Cooperation with authorities (CNPD)	Art 6, 9 et s. (sect 2 et 3 chap III) 57 et s. 72, 73,
MDR	AI as a medical device (SAMD): when use for diagnosis, prediction, prognostic, treatment of a disease purposes. Active device intended for diagnosis and monitoring: when used for detecting, diagnosing, monitoring or treating physiologic conditions, states of health, illnesses. Device allowing direct diagnosis: provides diagnosis of the disease by itself or provides decisive information for the diagnosis Manufacturer: potentially LIH, NTT? Distributor: potentially Hospitals, Université, NTT?	• Registration on EUDAMED • EU Declaration of conformity and CE marking • Obligation of technical documentation (UDI system, device description, benefit-risk analysis, PMCF plan and evaluation report, PSUR…) • Risk management system • Quality management system (QMS) • Clinical evaluation and post market clinical follow-up • Post market surveillance system • Clinical investigations and report • General safety and performance requirements • Notification of incidents • Corrective measures	Art 5, 10, 14, 19, 20, 27, 52, 54, 61 et s. 83 et s. 87, 89, 92

		• Cooperation with authorities (Ministry of Health)	
EHDS	Primary use: processing of electronic health data for the provision of healthcare in order to assess, maintain or restore the state of health of the natural person to whom the data relate, including the prescription, dispensation and provision of medical products and devices. Secondary use: processing of electronic health data for purposes other than the purposes for which the data were primarily collected and processed Health data holder: Hospitals and other relevant holders. Health data user: Potentially University, LIH, LNDS, agence e-santé.	• Grant free access to electronic health data to natural person and health professional • Update of data by health professionals • Easy complaints mechanisms • Identification of health professional • Adaptation of rights from GDPR (e.g. opt out) • Integration on the myhealth@eu platform • Implementation of mandatory interoperability components • Technical documentation • CE marking and EU declaration	Art 14 and following. Art 30, 33, 37 and f. 45, 50 to 54,
DGA	Data sharing: provision of data by data subject or data holder to a data user for the purpose of the joint or individual use of such data based on voluntary agreement, directly or through an intermediary Access: data use in accordance with specific technical, legal or organizational requirements without necessarily implying transmission or downloading of data Data Holder: Hospitals and other relevant holders.	**Reuse**: Public sector bodies obligations: • Provides fair, transparent, objective and proportionate conditions and legal basis of reuse, and procedures of reuse • Ensure data preservation and confidentiality • Sets conditions to preserve integrity of the technical systems of environment, check processes and results of processing by re-user.	Art 5, 11, 12, 31

	Data user: Health professionals (e.g. doctors) Data subjects: patients Re-users: scientists Intermediation service provider: potentially NTT	• Ensure contractualization before confidential data transmission • Give information on unique information point • Decide on whether or not to accept reuse of data **Re-user obligations**: • Take technical and organizational measures to prevent re-identification • Inform of an unauthorized reuse • Inform of intent to transfer data in third party countries Data intermediation service: • Notify intentions to provide intermediary services and any modification of info communicated on the unique point • Respect conditions of art 12 DGA **All :** • Take measures to prevent international transfers in contradiction with EU or national laws • Provides minimum volume of admissible data in response to a request • Informs data holder of the existence of a request for access to data concerning them, originating from an administrative authority of a third country, before responding to it	