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École d'été internationale - Du 19 au 23 juin 2023

From territories to the global village : How to protect people in a globalize environment ?

GRADES
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The EHDS: focus on connected objects and electronic health records

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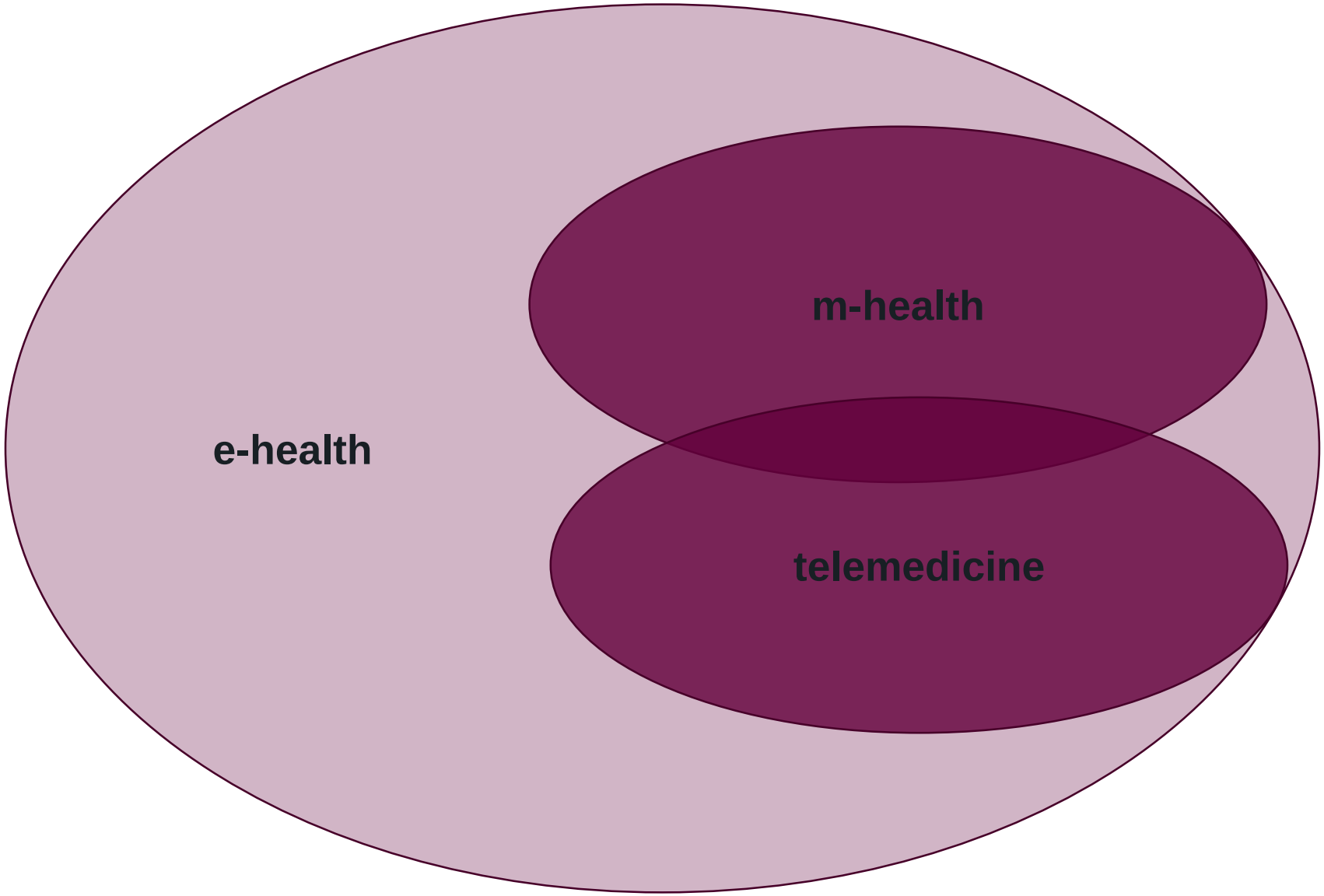
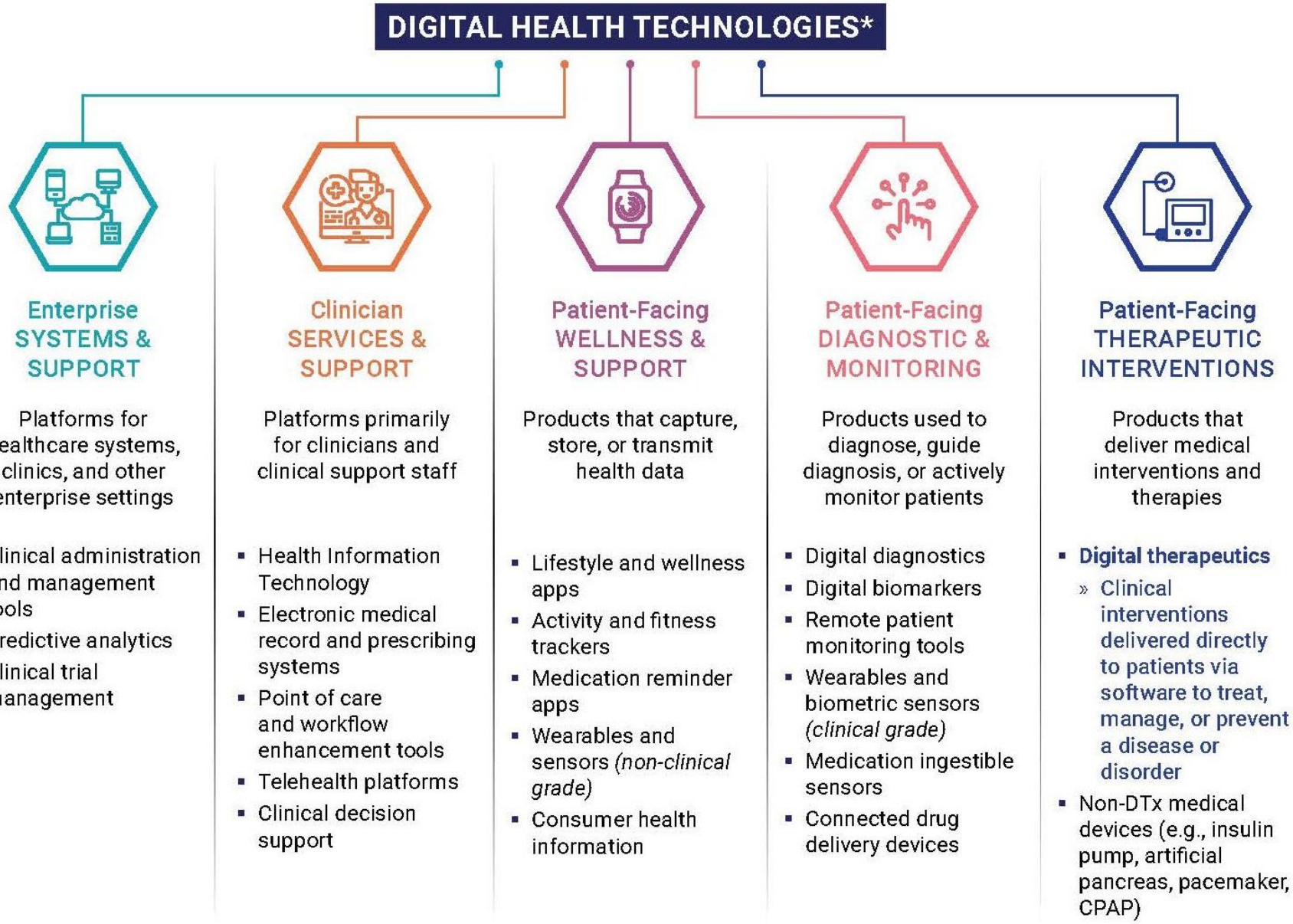
VILLE DE SCEAUX À LA CROISÉE DES TALENTS

université PARIS-SACLAY | FACULTÉ JEAN MONNET DROIT-ÉCONOMIE-MANAGEMENT

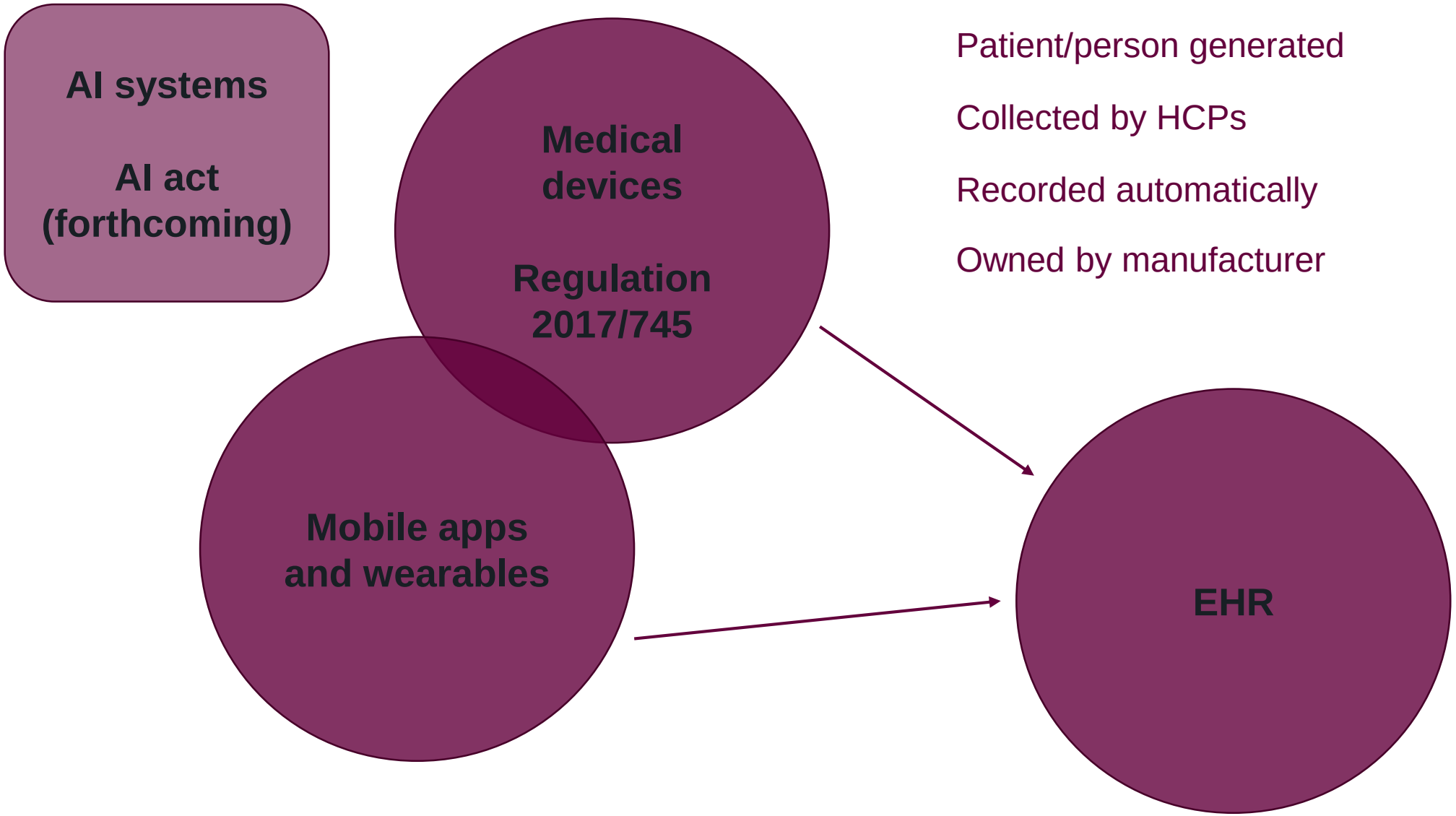
EUGLOH


m-health
e-health
telemedicine



Categorizations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.

Electronic health data



Patient/person generated

Collected by HCPs

Recorded automatically

Owned by manufacturer

Reminder

Medical device

any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used […] for one or more of the following specific medical purposes:
[…]
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

Regulation 2017/745 (MDR), art. 2(1)

Reminder

Medical purposes of a medical device

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

Regulation 2017/745 (MDR), art. 2(1)

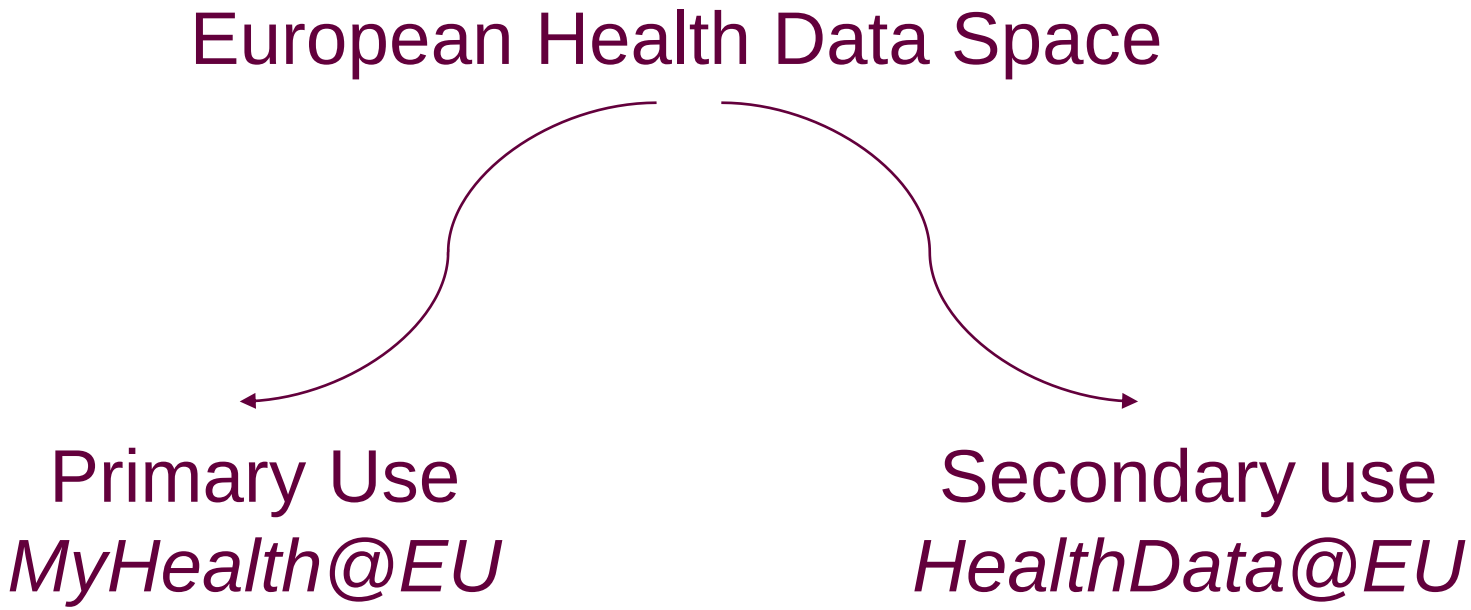
Reminder

It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device

Regulation 2017/745 (MDR), recital 19

‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles

art. 2(1)(o) of the proposal


European Health Data Space
Primary Use
MyHealth@EU
Secondary use
HealthData@EU

Objectives of the regulation:

- natural persons have control over their own electronic health data
- natural persons benefit from a range of health-related products and services
- researchers, innovators, policy-makers and regulators can make the most of available electronic health data

Explanatory memorandum of the proposal (impact assessment)

Three policy options of varying degrees of regulatory intervention and two additional variations of these options were assessed

Option 2+: Intervention with medium intensity:

- mandatory (self-)certification of EHR systems
- voluntary label for wellness applications
- a cascading effect in medical devices that aim to be interoperable with EHR systems

-> best balance between effectiveness and efficiency in reaching the objectives

Explanatory memorandum of the proposal (impact assessment)

Mandatory self-certification for EHR systems processing one or more priority categories (= for primary use) of electronic health data *i.e.*

- patient summaries
- electronic prescriptions
- electronic dispensations
- medical images and image reports
- laboratory results
- discharge reports

art. 5(1) of the proposal

Self-certification = EHR systems should prove compliance with essential requirements on interoperability and security, set at Union level

↓

Also applicable to medical devices and high-risk AI systems (which don’t fall within the definition of medical devices) that claim interoperability with EHR systems

Wellness applications may be connected and supply data to EHR systems and their interoperable format is relevant for data portability purposes
However, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them, a certification scheme for these applications would not be proportionate. A voluntary labelling scheme should therefore be established as an appropriate mechanism for enabling the transparency for the users of wellness applications regarding compliance with the requirements, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security

Recital 35 of the proposal

EU database of interoperable EHR systems and wellness applications

Medical devices and AI systems : registration should be maintained under the existing databases established respectively under Regulation 2017/745 and AI act but the compliance with interoperability requirements should be indicated when claimed by manufacturers

Electronic data which must be made available for secondary use:

- EHRs
- person generated electronic health data, including medical devices, wellness applications or other digital health applications
- electronic health data from medical registries for specific diseases
- electronic health data from clinical trials
- electronic health data from medical devices and from registries for medicinal products and medical devices

Micro-enterprises (*i.e. less than 10 employees and EUR 2 million annual turnover and/or annual balance sheet)* are excluded from the obligation to make their data available for secondary use in the framework of EHDS

Thank you for your attention

Supportive slides

At the same time, data benefiting from specific legal protection such as intellectual property from medical device companies or pharmaceutical companies often enjoy copyright protection or similar types of protection. However, public authorities and regulators should have access to such data, for instance in the event of pandemics, to verify defective devices and protect human health. In times of severe public health concerns (for example, PIP breast implants fraud) it appeared very difficult for public authorities to get access to such data to understand the causes and knowledge of manufacturer concerning the defects of some devices. The COVID-19 pandemic also revealed the difficulty for policy makers to have access to health data and other data related to health. Such data should be made available for public and regulatory activities, supporting public bodies to carry out their legal mandate, while complying with, where relevant and possible, the protection enjoyed by commercial data. Specific rules in relation to the secondary use of health data should be provided.

Reminder

Software that cross-references patient-specific data with the drugs that the doctor is contemplating prescribing, and is thus able to provide the doctor, in an automated manner, with an analysis intended to detect, in particular, possible contraindications, drug interactions and excessive dosages, is used for the purpose of prevention, monitoring, treatment or alleviation of a disease, and therefore pursues a specifically medical objective, making it a medical device

That is not the case, however, for software that, while intended for use in a medical context, has the sole purpose of archiving, collecting and transmitting data, like patient medical data storage software

ECJ, 07/12/2017, C-329/16