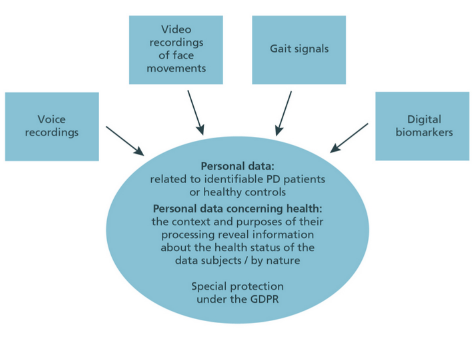
Noémi Bontridder, *FAQ – Data protection*, EraPerMed project DIGIPD, Research Centre Information, Law and Society (CRIDS), University of Namur, April 2024
https://www.digipd.eu/en/FAQ.html

This FAQ complements the WP5 report:
Noémi Bontridder and Cécile de Terwangne, *The use of digital biomarkers and machine learning methods in the healthcare sector: GDPR Compliance*, WP5 Report, EraPerMed project DIGIPD, Research Centre Information, Law and Society (CRIDS), University of Namur, July 2022
https://www.digipd.eu/content/dam/scai/scai-digipd/faq/DIGIPD_WP5_REPORT.pdf

1. Which digital personal data does the consortium process?



pp. 6-9 of the report

2. Who are controller and processors in the project?

Controller

DIGIPD Consortium
Decides the purposes and essential means of the processing operations

Processors

CEO Portabiles Healtcare Technologies
Collects gait signals on behalf of the consortium

Amazon Web Services
Temporarily stores gait signals on behalf of the consortium

pp. 10-11 of the report

3. Can the consortium instruct Amazon Web Services (AWS) to store personal data on its behalf, taking into account Schrems cases?

Amazon Web Services (AWS) is part of a European Code of Conduct (CISPECloud)

→ The consortium can instruct AWS to store personal data on its behalf

p. 33 of the report

4. On which lawful basis are the processing activities carried out in the project? And after the project if digital biomarkers could be used in medical practice?

Research purposes (Art. 6.1.f + 9.2.j GDPR / Art. 5.1.b GDPR)
Consent is not the lawful basis for the processing activities, but it is legally required as an ethical standard / procedural obligation
Appropriate safeguards must be implemented (i.a. pseudonymisation) in accordance with the GDPR.
Some national legislations specify required measures (i.a. the Luxemburg law and Belgian law).

↓

Medical purposes (Art. 6.1.f + 9.2.h GDPR)
The processing must be carried out under de responsibility of a professional subject to the obligation of professional secrecy or by another person subject to an obligation of secrecy

pp. 21-25 of the report

5. What are the obligations of the consortium when the PD patients exercise their rights?

Right of access

- confirm as to whether personal data concerning him or her are being processed;
- provide access to the personal data;
- provide a set of information;
- provide a copy of the personal data undergoing processing.

Unless (cumulative conditions):
- it is likely to render impossible or seriously impair the achievement of the specific purposes;
- derogations are necessary for the fulfilment of those purposes;
- the applicable Member State law provides for such derogation (e.g. the Luxemburg law and Belgian law);
- appropriate safeguards are implemented pursuant to the GDPR and the Member State law.

Right to rectification

- rectify inaccurate personal data;
- complete incomplete personal data;
- communicate the rectification of personal data to each recipient to whom the personal data have been disclosed (unless this proves impossible or involves disproportionate effort).

Unless (cumulative conditions):
- it is likely to render impossible or seriously impair the achievement of the specific purposes;
- derogations are necessary for the fulfilment of those purposes;
- the applicable Member State law provides for such derogation (e.g. the Luxemburg law and Belgian law);
- appropriate safeguards are implemented pursuant to the GDPR and the Member State law.

Right to erasure

- erase personal data concerning him or her without undue delay;
- communicate the erasure of personal data to each recipient to whom the personal data have been disclosed (unless this proves impossible or involves disproportionate effort).

Unless (cumulative conditions):
- it is likely to render impossible or seriously impair the achievement of the specific purposes;
- appropriate safeguards are implemented pursuant to the GDPR.

Right to restriction of processing

- stop processing the personal data concerned during the indicated period;
- communicate the restriction of processing to each recipient to whom the personal data have been disclosed (unless this proves impossible or involves disproportionate effort);
- inform the data subject before the restriction of processing is lifted.

Unless (cumulative conditions):
- it is likely to render impossible or seriously impair the achievement of the specific purposes;
- derogations are necessary for the fulfilment of those purposes;
- the applicable Member State law provides for such derogation (e.g. the Luxemburg law and Belgian law);
- appropriate safeguards are implemented pursuant to the GDPR and the Member State law.

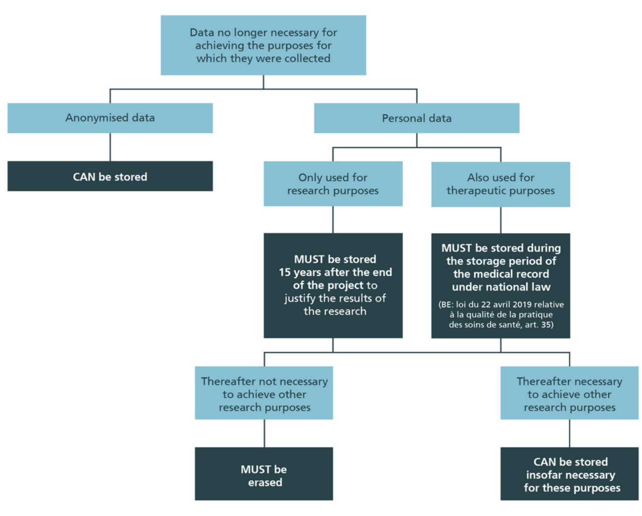
Right to object

- EITHER demonstrate compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject;
- OR no longer process the personal data.

Unless (cumulative conditions):
- it is likely to render impossible or seriously impair the achievement of the specific purposes;
- derogations are necessary for the fulfilment of those purposes;
- the applicable Member State law provides for such derogation (e.g. the Luxemburg law and Belgian law);
- appropriate safeguards are implemented pursuant to the GDPR and the Member State law.

pp. 40-46 of the report

6. Is there a duty to keep the data collected during the project after the end of this project? Which data must be kept?



p. 16 of the report

7. What information must ICM and UL (on behalf of the consortium) provide to the PD patients and healthy controls (the data subjects)?

Modalities:
- concise, transparent, intelligible and easily accessible form, using clear and plain language
- in writing / by other means (e.g. electronic means) / orally when requested by the data subject, provided that the identity of the data subject is proven by other means. Possibly combined with "standardised icons"
- free of charge

Personal data collected from PD patients and healthy controls by ICM / UL at the time the personal data are obtained:	**Personal data indirectly obtained** within one month after obtaining the personal data / earlier:
• the identity and the contact details of ICM / UL	
• the contact details of the data protection officer	
• the purposes of the processing	
• the legal basis for the processing	
• the legitimate interests pursued	
	• the categories of personal data concerned
• the recipients or categories of recipients of the personal data	
• the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period	
• the existence of the right of access, rectification or erasure of personal data or restriction of processing	
• the right to object to processing (explicitly brought to the attention of the data subject and presented clearly and separately from any other information)	
• the right to lodge a complaint with a supervisory authority	
	• from which source the personal data originate
• the existence of automated decision-making, including profiling, and meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject	
	Unless (non-cumulative conditions): • the provision of such information proves impossible / would involve a disproportionate effort / is likely to render impossible or seriously impair the achievement of the objectives of the processing • obtaining or disclosure is expressly laid down by Union or Member State law to which the consortium is subject and which provides appropriate measures to protect the data subject's legitimate interests • the personal data must remain confidential subject to an obligation of professional secrecy regulated by Union or Member State law, including a statutory obligation of secrecy

pp. 34-40 of the report

8. Which information regarding the automated decision-making must be provided to the data subject?

Meaningful information about the logic involved sufficiently comprehensive for the data subject to understand the reasons for the decision → The rationale behind the decision → The criteria relied on in reaching the decision → The model used: a mathematical abstraction used in automatic learning methods, which provides a simplified description of the data to solve the task to be performed

pp. 36-37 of the report

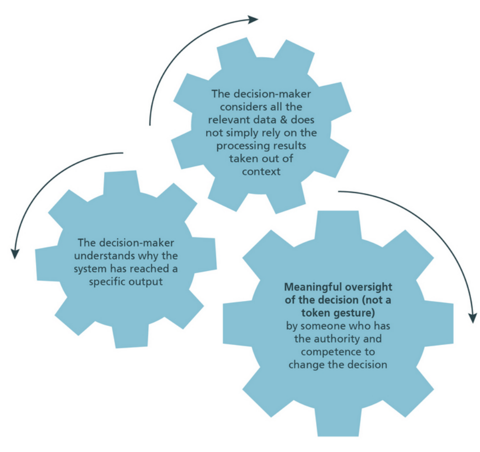
9. Why must meaningful information about the logic involved in automated decision-making be provided where the latter is not based solely on automated processing?

The processing must be fair and transparent

→ Where the physician is making automated decisions, (s)he must:
- inform the data subject therebout
- provide meaningful information about the logic involved
- explain the significance and envisaged consequences of the processing

p. 36 of the report

10. How to ensure human involvement in the decision?



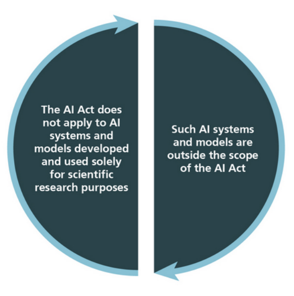
pp. 26-27 of the report

11. Which elements characterize an algorithm as "understandable"?

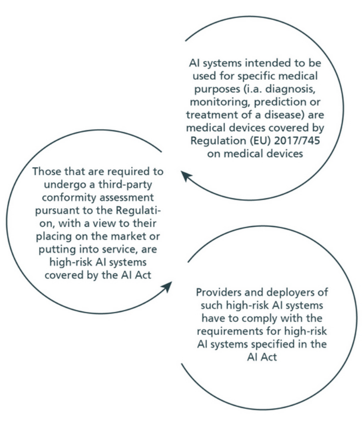
Evidence or reason(s) for all outputs	**Understandable to individual users**	**Correctly reflecting the system's process for generating the output**
The system delivers an explanation (evidence, support or reasoning) for each output →	The explanation is understandable to the recipient →	The explanation is accurate: it correctly reflects the system's process for generating the output

P. J. Phillips et al., Four Principles of Explainable Artificial Intelligence. Draft NISTIR 8312, 2020

12. Will the AI Act apply to AI systems developed and used for medical research?



13. Will the AI Act apply to AI systems developed and used for medical practice?



14. Which AI systems developed and used for medical practice are high-risk AI systems pursuant to the AI Act?

AI-based medical devices required to undergo a third-party conformity assessment pursuant to Regulation (EU) 2017/745 on medical devices, with a view to their placing on the market or putting into service, are high-risk AI systems pursuant to the AI Act

↓

These include:
- active devices intended to allow direct diagnosis or monitoring of vital physiological processes
- software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes

15. To which conformity assessment procedure will be subject the AI systems developed and used for medical practice?

AI-based medical devices shall be subject to the conformity assessment procedure established by Regulation (EU) 2017/745 on medical devices

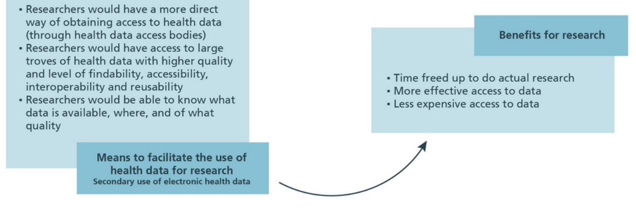
↓

Where the assessment must be made by a third-party (notified body), the requirements for high-risk AI systems established by the AI Act shall be part of that assessment

↓

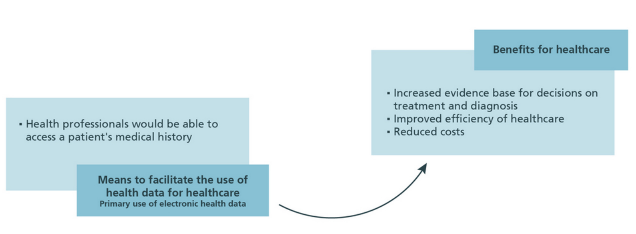
Part of the procedure related to control of technical documentation established by the AI Act also applies

16. How is the EU Commission aiming to facilitate the use of health data for medical research with its proposed Regulation on a European Health Data Space?



COM(2022) 196 final

17. How is the EU Commission aiming to facilitate the use of health data for healthcare with its proposed Regulation on a European Health Data Space?



COM(2022) 196 final