

Demystifying Real-World Data – Insights for Patients

Data Privacy, Security and Ethical Considerations

Chloé ANTOINE

Legal Researcher at CRIDS (University of Namur)

chloe.antoine@unamur.be

*Real4Reg Workshop
October 14th, 2024*



The RWD Journey



Data collection

(e.g. electronic health records, patient surveys)



Data deletion

(or data anonymization, where applicable)



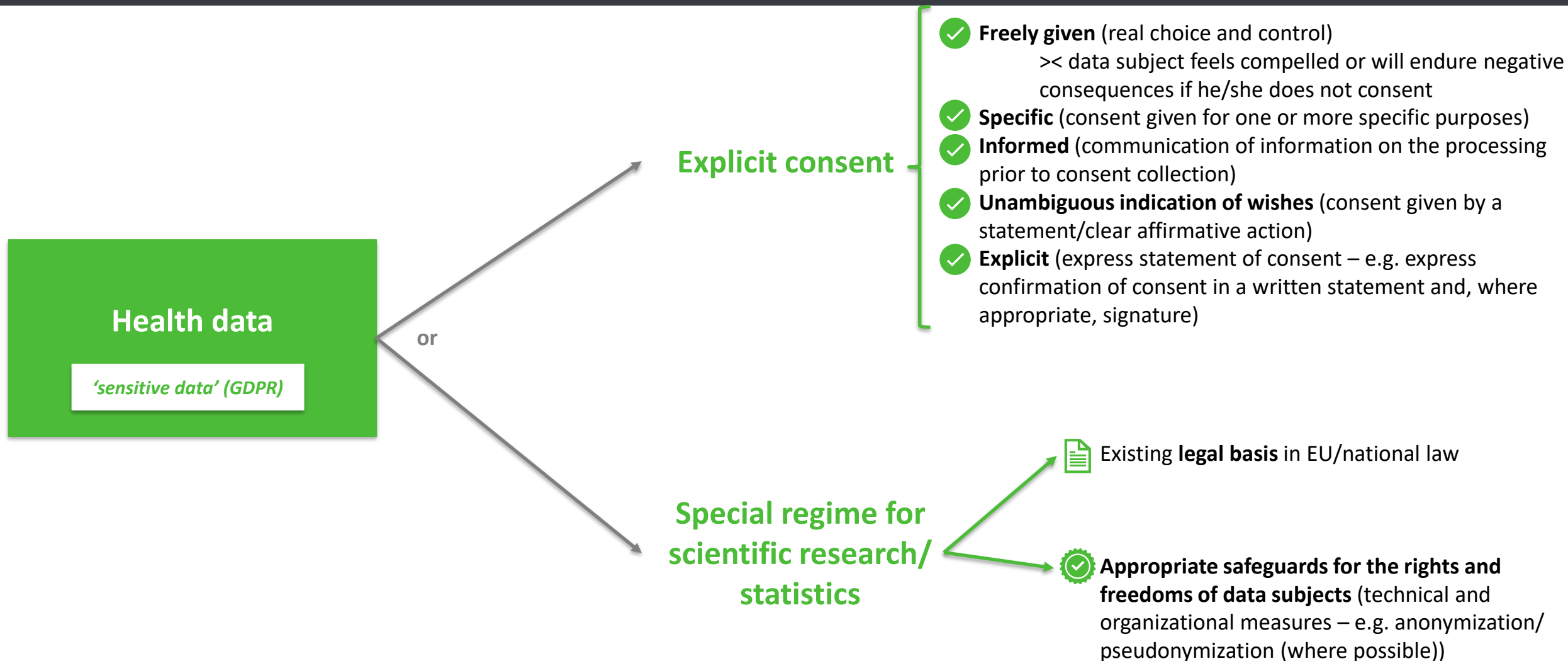
Data processing

(e.g. for improving patient care, for regulatory decision-making, for scientific research, for statistics)

Outline


- ① How may RWD be **collected**?
- ② What '**safeguards**' apply to the use of RWD?
- ③ What are your **rights**?

How may RWD be collected? (1)



How may RWD be collected? (2)

Importance of providing appropriate information



GDPR requirement

Identity and the contact details of the controller
Contact details of the DPO (where applicable)
Purposes of the processing
Legal basis for the processing (if consent: information on the possibility to withdraw consent)
Recipients or categories of recipients of personal data (where applicable)
Information on international data transfers (where applicable)
Data storage period
etc.

Note regarding the special regime for scientific research/statistics

Obligation to inform (subject to appropriate safeguards) if (i) data not directly obtained from the data subject; and (ii) provision of such information would involve a disproportionate effort or proves impossible

Ethics

e.g. application to scientific research: research purpose, methods used, possible outcomes, possible risks, discomforts, or inconveniences that could be faced by participants

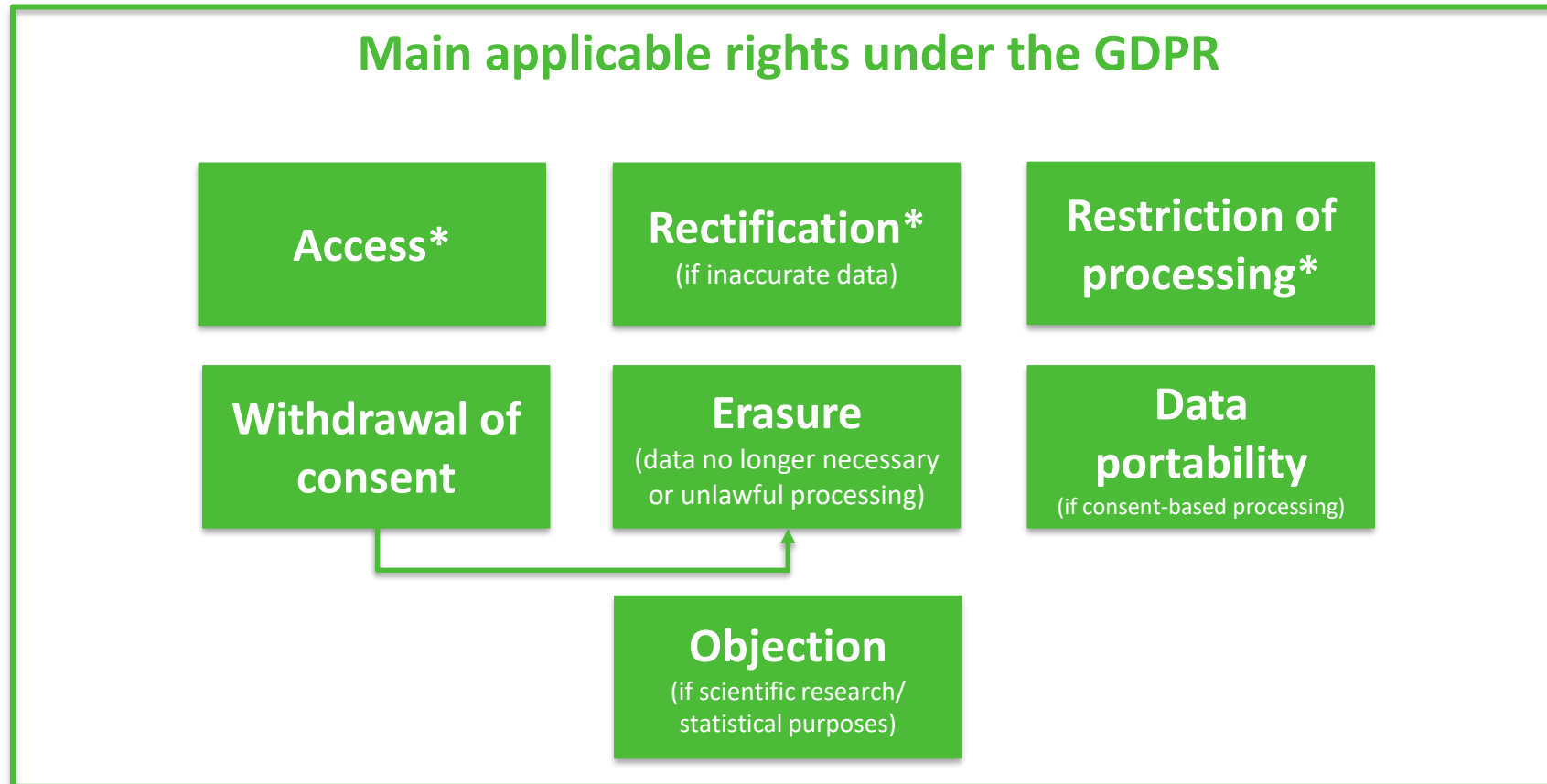
What 'safeguards' apply to the use of RWD?

GDPR principles

Lawfulness, fairness & transparency	Personal data processed in a lawful, fair and transparent manner
Purpose limitation	Personal data collected for explicit, specified and legitimate purposes and not further processed in a way that is incompatible with those purposes (N.B.: further processing for scientific research/statistical purposes not considered incompatible with initial purposes)
Data minimization	Personal data are adequate, relevant and limited to what is necessary in relation to the purposes pursued
Accuracy	Personal data are accurate and kept up to date (where necessary)
Storage limitation	Personal data are kept in a form which permits identification (i.e. non-anonymized form) for no longer than necessary for the purposes pursued <ul style="list-style-type: none">• Longer period allowed if processing for scientific research/statistical purposes (implementation of appropriate technical and organizational measures)
Integrity and confidentiality	Appropriate security of personal data (appropriate technical and organizational measures ensuring protection against unauthorized/unlawful processing and against accidental loss, destruction or damage – e.g. pseudonymization , encryption)
Accountability	Controller responsible for complying with the above principles and able to demonstrate compliance with them.

// ethical considerations

What are your rights?



***If for scientific research/statistical purposes: possible derogations to these rights in EU/national law**

(if likely to render impossible/seriously impair the achievement of the specific purposes and if derogations necessary for their fulfilment)

Thank you!

