

ACCESS TO PERSONAL DATA FOR SCIENTIFIC RESEARCH IN THE PERSPECTIVE OF DEVELOPING INNOVATIVE MEDICINE

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THE CRIDS

Research Center on Information, Law & Society

- **Since 1979**, Interdisciplinary Research Center on ICT (law, ethics, socio-organizational aspects & communication)
- 60 members (academics & researchers)
- 6 research departments
- **Today** - in addition to numerous previous projects :
 - 4 H2020 projects: TeSLA, INSPEX, PROTECT & SPARTA
 - 4 SMART projects
 - 2 FEDER projects: mHealth & Wal-cities, etc.

CRIDS RESEARCH DEPARTMENTS

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Intellectual
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& Internet

**ROBOTS & AI
ARE THE TOPICS OF THE YEAR !**

THE LIS Department (Liberties & Information Society)

The LIS Department may claim more than 40 years of expertise and experience in studying, teaching and implementing data protection rules and the right to freedom of expression, both in general and in specific areas such as adequacy decisions, transfer of personal data outside Europe, data protection authorities, e-government, smart cities, e-health, e-archiving, CCTV, surveillance, big data, datamining, cloud computing services and machine learning or AI. It has also been studying cybercrime and cybersecurity for many years.

THE LIS Department (Liberties & Information Society)

The LIS Department also analyses the legal qualifications of the relationship between individuals and information, notably at the crossroads between the right to informational self-determination and intellectual property rights.

THE LIS Department (Liberties & Information Society)

The members of the LIS Department have authored hundreds of scientific publications (books, articles and book chapters).

They are often involved in research projects at national, European and international level.

Some are also experts to the Council of Europe, the European Commission, the European Parliament, public or private bodies or authorities, governments and parliaments, in Belgium or abroad.

LAW, NORMS AND FREEDOMS IN CYBERSPACE

DROIT, NORMES ET LIBERTÉS DANS LE CYBERMONDE

Liber Amicorum Yves Poulet

Sous la direction de
Elise Degrave
Cécile de Terwangne
Séverine Dusollier
Robert Queck

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LE RÈGLEMENT GÉNÉRAL SUR LA PROTECTION DES DONNÉES (RGPD/GDPR)

Analyse approfondie

Sous la direction de
Cécile de Terwangne et Karen Rosier

Avant-propos d'Yves Poullet

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VULNÉRABILITÉS ET DROITS DANS L'ENVIRONNEMENT NUMÉRIQUE

Sous la coordination
d'Hervé Jacquemin et de Marc Nihoul

Collection de la Faculté de droit de l'UNamur



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TIMESLOT IS SHORT



How to conceive the access of researchers to personal data for scientific research in the perspective of developing innovative medicine?

Outline of the presentation

- I. Different models of data sharing
- II. The theory of the *essential facilities*
- III. Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the *free flow of non-personal data in the European Union*

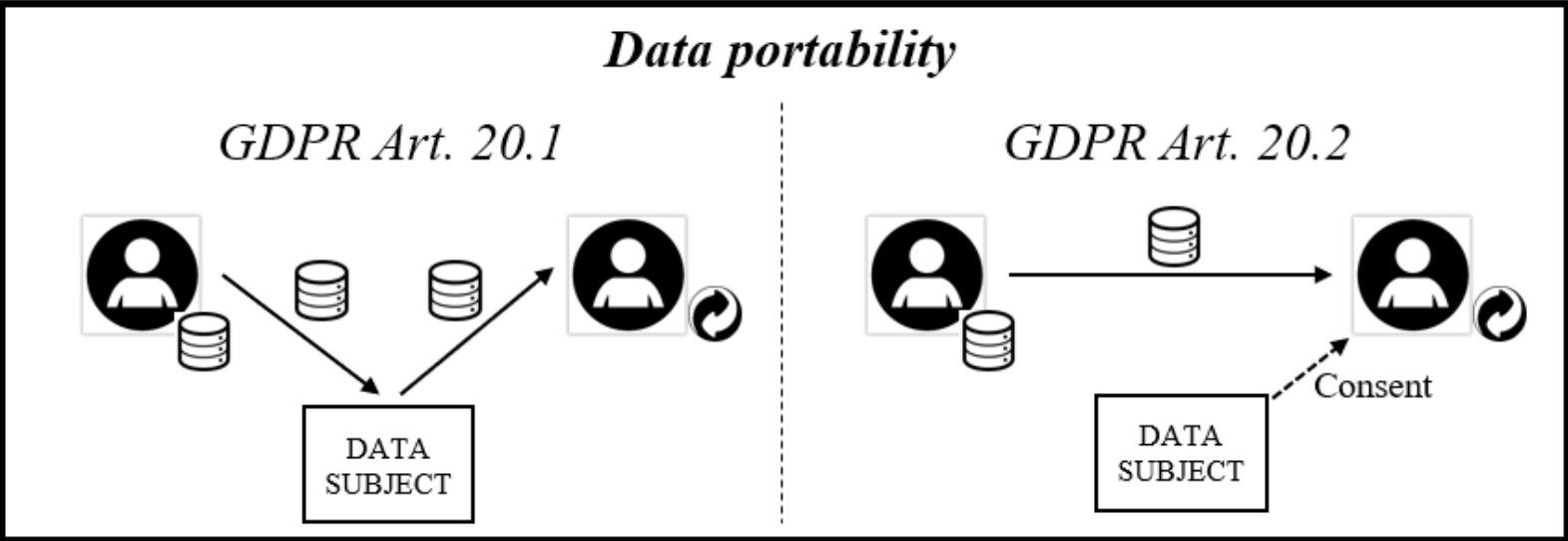
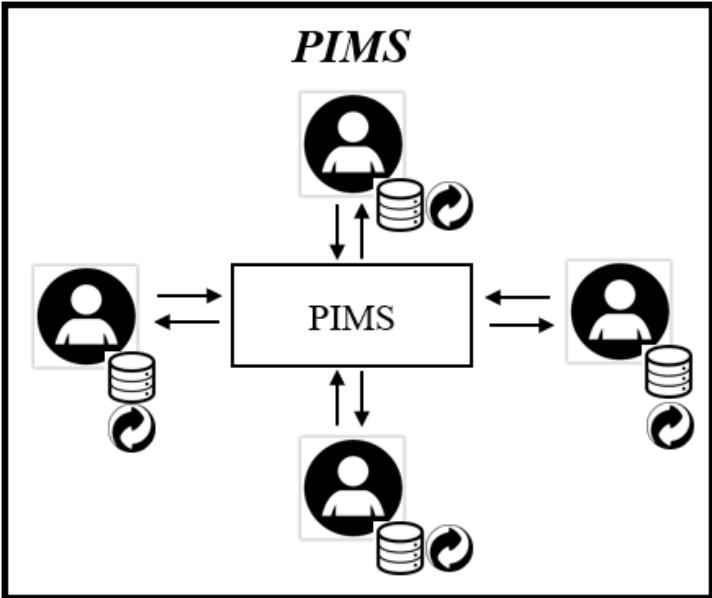
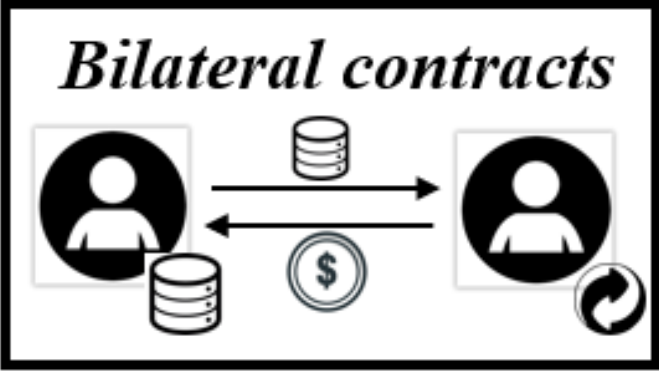
Outline of the presentation

IV. Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information

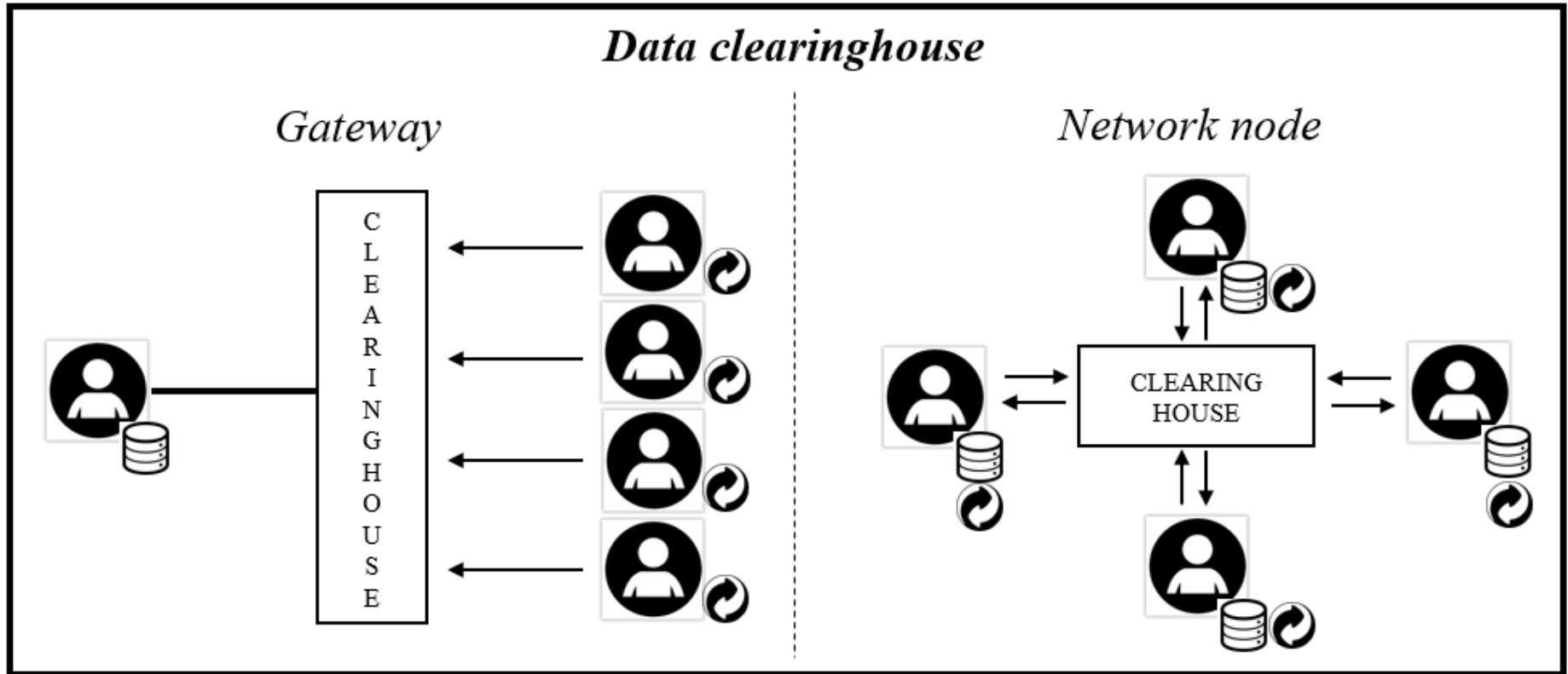
V. GDPR rules for accessing personal data for scientific research

**Conclusions :
The future of accessing data for scientific research?**

I. Different models of data sharing © Thomas TOMBAL - CRIDS



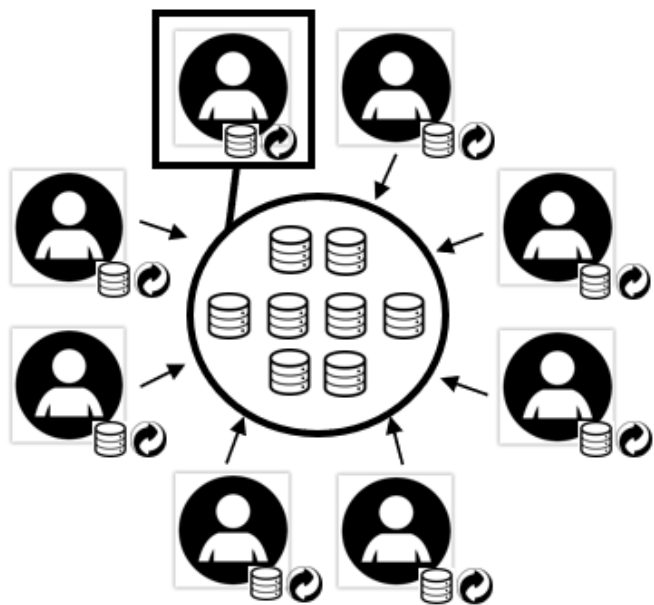
I. Different models of data sharing © Thomas TOMBAL - CRIDS



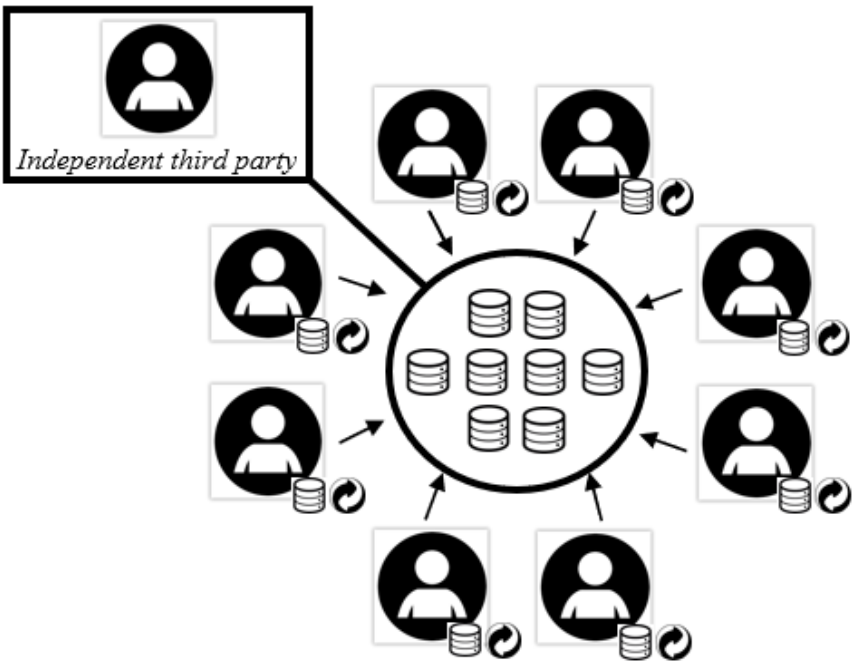
I. Different models of data sharing © Thomas TOMBAL - CRIDS

Data pools

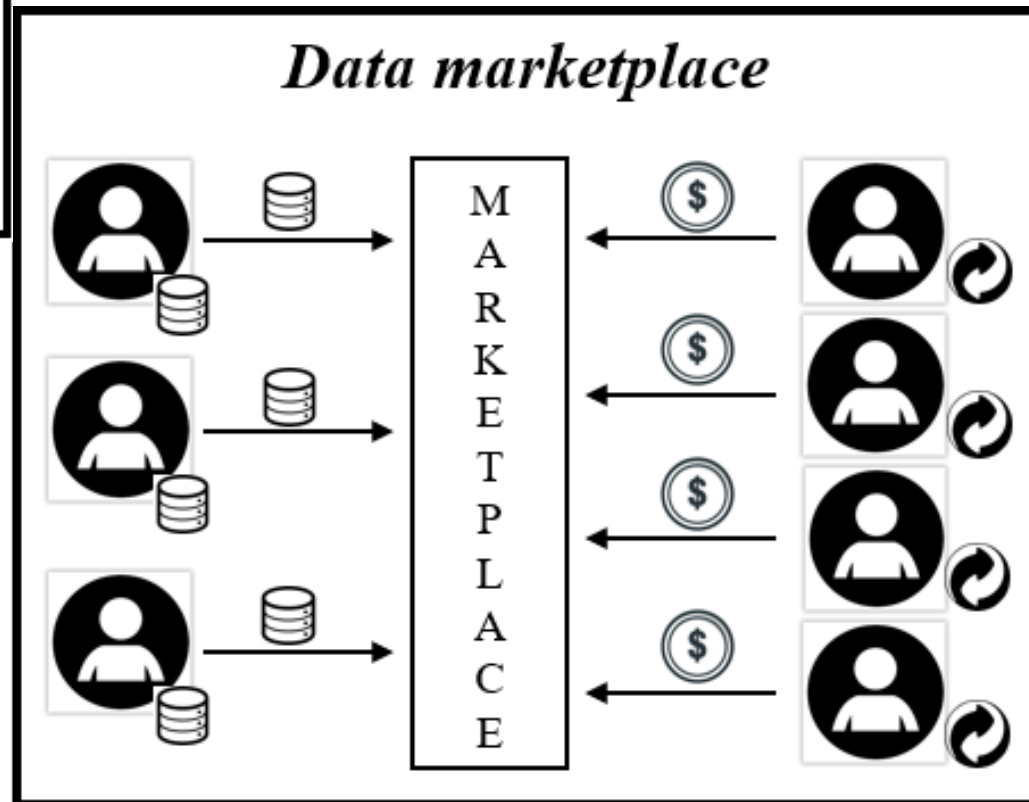
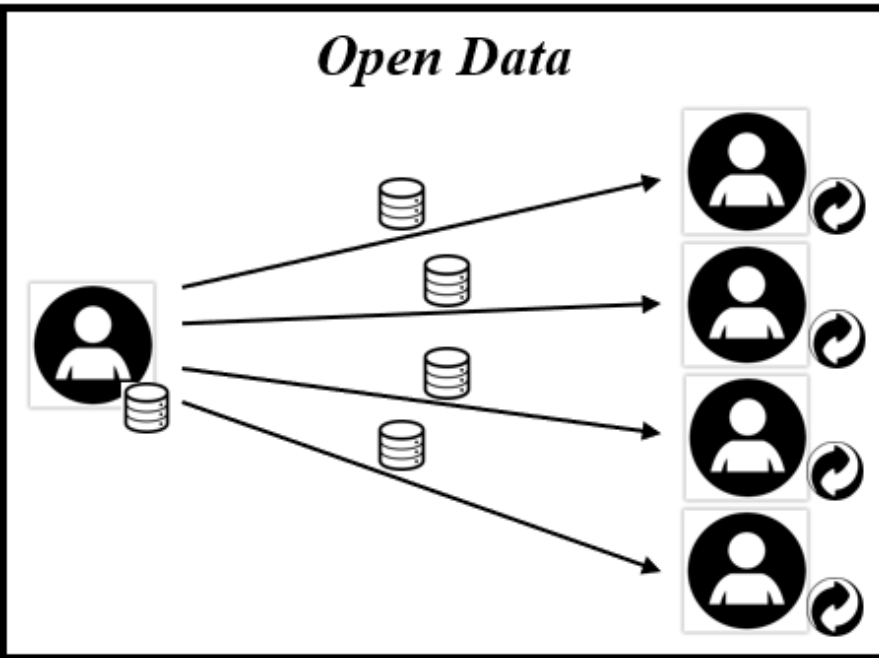
Industrial data platforms



Data trusts



I. Different models of data sharing © Thomas TOMBAL - CRIDS



II. The theory of the *essential facilities* and the Digital Single Market © Michael LOGNOUL - CRIDS

**Objective : enhance competition
(Competition Law, US, 1912)**

How? The dominant actor on the market may be obliged to cooperate with competitors and allow them to access an essential facility in a non-discriminatory way and under fair conditions

Usual conditions for accessing an essential facility :

- 1° No objective reason to deny access to the facility;**
- 2° Access denial excludes de facto all competition on the market related to the use of the essential facility;**
- 3° Access denial prevents the release of a new good/service the owner of the facility doesn't offer and which could potentially attract consumers;**
- 4° there must be an essential facility – it must be truly indispensable to enter the market and for the competition to be effective.**

Application to scientific research?

Could research data qualify as
essential facilities?

III. Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the *free flow of non-personal data in the European Union*

- 1° Forcing geographic localization for data is forbidden except for public security reasons;**
- 2° Public authorities keep the right to access data localized in another Member State;**
- 3° Code of conduct for developing data portability for professionals.**

BUT :

HOW TO MANAGE HETEROGENOUS SETS OF DATA?

IV. Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information

It establishes a set of minimum rules governing the re-use and the practical arrangements for facilitating the re-use of

(...) research data under the conditions of article 10

+ without prejudice of the GDPR

Article 2.9°:

'Research data' means documents in a digital form, other than scientific publications, which are collected or produced in the course of scientific research activities and are used as evidence in the research process, or are commonly accepted in the research community as necessary to validate research findings and results.

Article 10 : “Open access to research data”

1. Member States shall support the availability of research data by adopting national policies and relevant actions aiming at making publicly funded research data openly available (‘open access policies’), following the principle of ‘open by default’ and compatible with the FAIR principles. In that context, concerns relating to intellectual property rights, personal data protection and confidentiality, security and legitimate commercial interests, shall be taken into account in accordance with the principle of ‘as open as possible, as closed as necessary’. Those open access policies shall be addressed to research performing organisations and research funding organisations.

Article 10 : “Re-use of research data”

2. Without prejudice to point (c) of Article 1(2), research data shall be re-usable for commercial or non-commercial purposes in accordance with Chapters III and IV, insofar as they are publicly funded and researchers, research performing organizations or research funding organizations have already made them publicly available through an institutional or subject-based repository. In that context, legitimate commercial interests, knowledge transfer activities and pre-existing intellectual property rights shall be taken into account.

V. GDPR rules for accessing personal data for scientific research



**Data subject
role?**

Data Controller

Compatibility test

Compliance with art. 89?

**Compliance with additional
national legislation for HD?**

**Additional conditions specific to
the data controller?**



Data Processor

```
graph LR; DP[Data Processor] --> B1[On DC's instructions : OK]; DP --> B2[Compliance with art. 89? NO]; DP --> B3[Compliance with additional national legislation?]; DP --> B4[Additional conditions specific to the data controller?];
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On DC's instructions : OK

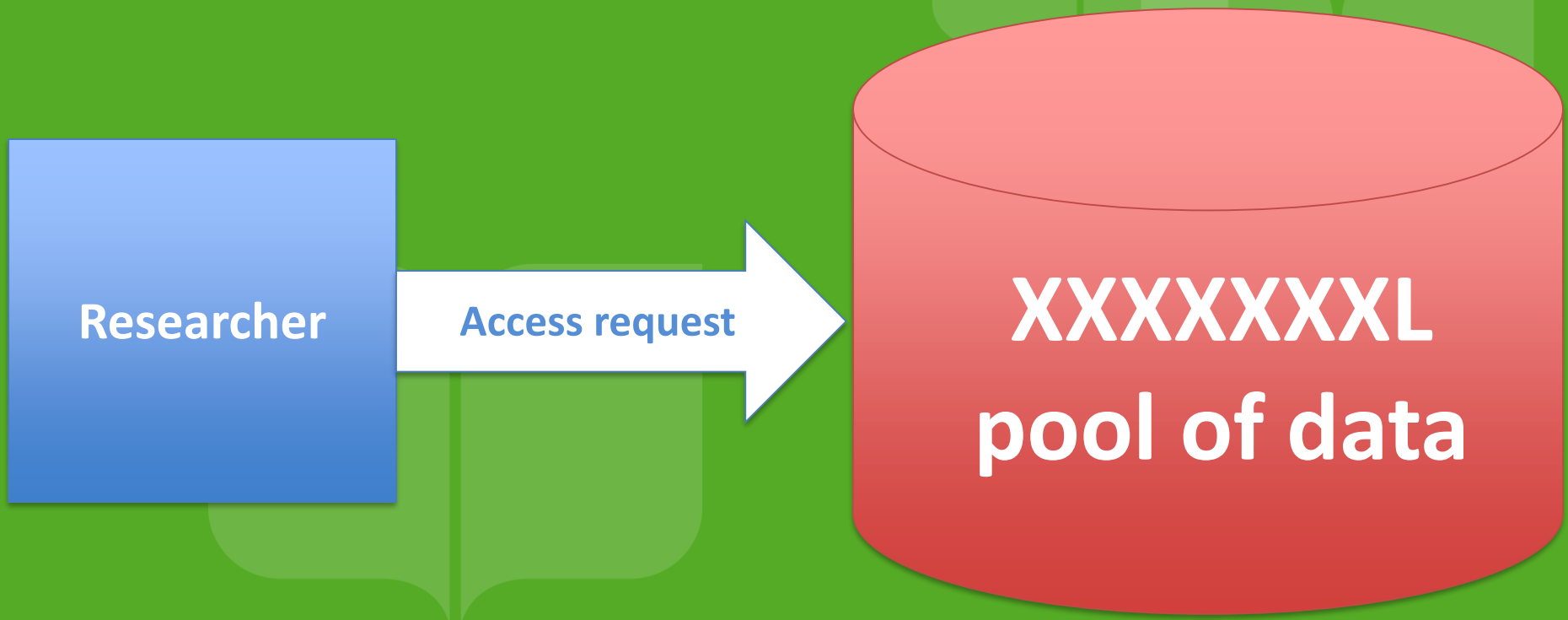
Compliance with art. 89? NO

**Compliance with additional
national legislation?**

**Additional conditions specific to
the data controller?**

CONCLUSIONS

The future of accessing data for scientific research?



CONCLUSIONS

The future of accessing data for scientific research?

Centralization of all raw data ('research data') in one big database ('Big Data') in Europe with non-discriminatory access (via a platform) and under fair conditions for (commercial and non commercial) scientific research (artificial intelligence & machine learning)?

CONCLUSIONS

The future of accessing data for scientific research?

Still to be solved :

- 1° How to manage the localization of heterogeneous datasets (PD (localization possible) & NPD (localization non authorized))?
- 2° Where is the data subject in this scheme? Where are DS's rights? Less control over PD requires collective & individual compensation.

CONCLUSIONS

The future of accessing data for scientific research?

BUT :

1° Is data centralization the only solution?

2° The production of scientific knowledge should be analysed with regard to the functioning of the economic system and, regarding medical research, with regard to the organization of the public health system and citizens' effective access to medicines and medical devices.

THANK YOU FOR YOUR ATTENTION !

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