

# Health Data For Research

## GDPR challenges

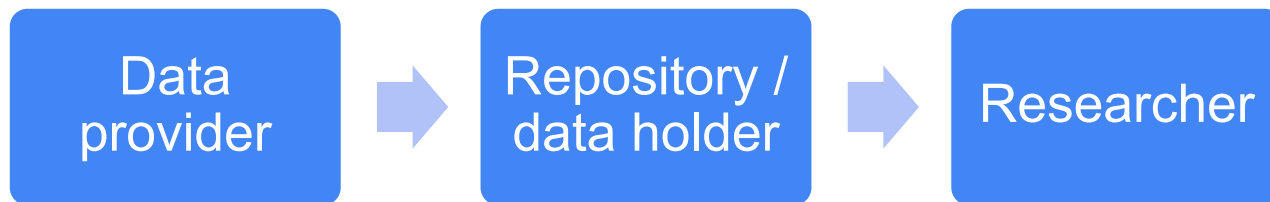
Emilie Kraaikamp, DANS

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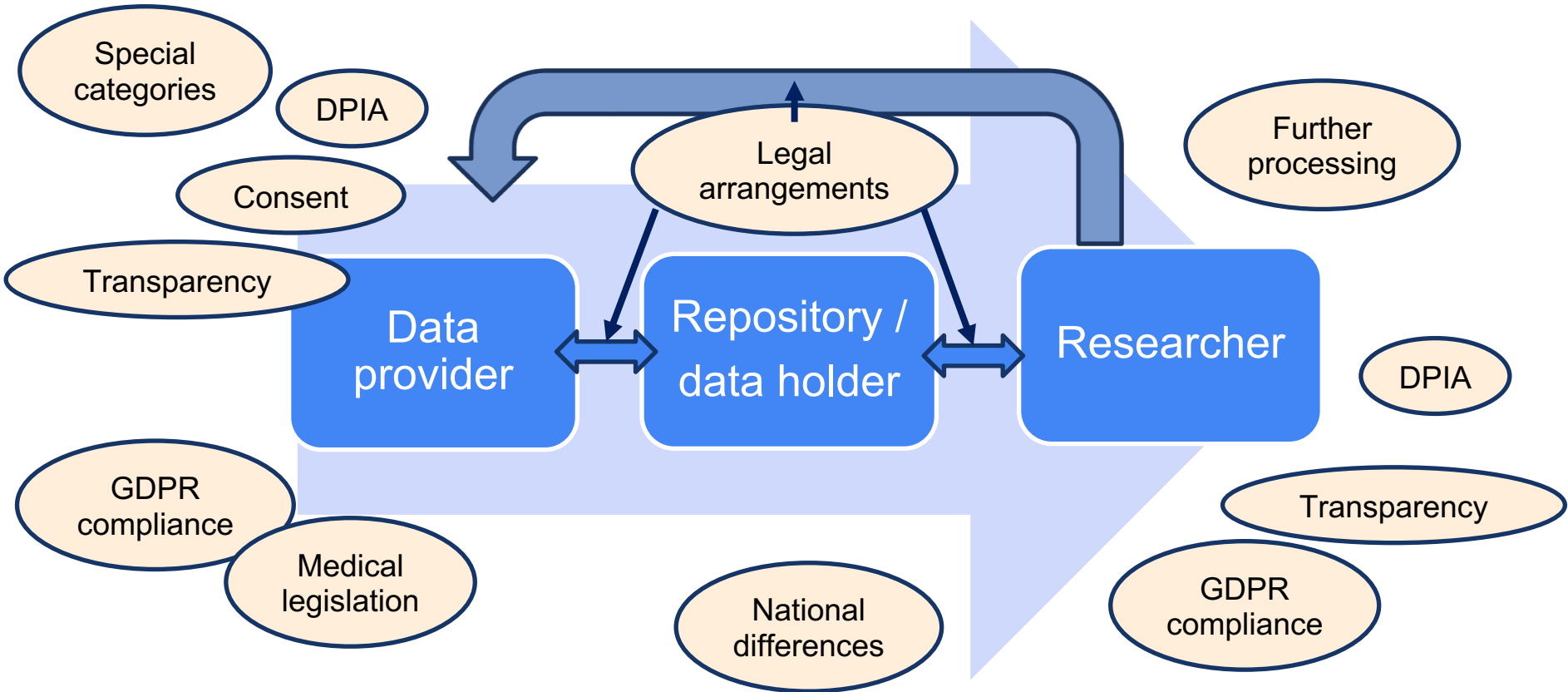


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# A simple data flow



# A more realistic data flow...



# Challenges for secondary data use

- Consent
  - Consent is given for an original purpose – is the new research compatible?
  - GDPR allows further research within the research domain – is the domain defined?
- Transparency
  - Transparency is needed towards the data subjects – requires informing them
- Combining data
  - *The above applies*
  - Risk of generating (more) personal data – requires careful assessment



Researcher depends on data provider

# International collaboration - barriers

“**Contrary** to creating a single method of using data for research in Europe, Article 89 in particular has **compounded the fragmentation** that existed with the previous Directive 95/46/EC. Furthermore, disparate conditions for processing health and genetic data, which are considered special categories, have resulted in **diversity in access and processing of these data for research.**”

*Rita T Lawlor, The impact of GDPR on data sharing for European cancer research, The Lancet Oncology, Volume 24, Issue 1, 2023, Pages 6-8, ISSN 1470-2045, [https://doi.org/10.1016/S1470-2045\(22\)00653-2](https://doi.org/10.1016/S1470-2045(22)00653-2).*

- Differences in national implementation laws, especially on the use of special categories of person data
- Different policies on national level

# The European Health Data Space (EHDS)

European Commission, proposal EHDS: Apart from supporting individuals to take control of their health data and supporting better healthcare delivery, it aims at providing **a consistent, trustworthy and efficient set-up for the use of health data for research** (secondary use)

- [TEHDAS project](#):
  - 25 EU countries developing EU principles on health data

- “The main obstacle is different interpretations of the General Data Protection Regulation (GDPR).”

*TEHDAS Results: EU-wide collaboration needed to optimise health data use for research and innovation 14-09-2023*



Thank you for your attention.

Questions?



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