
BigData@Heart

WEBINAR - Data Privacy: New Regulation and Implications for Big Data Approaches
29 Nov, 12h CET

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Research Exemptions in the GDPR

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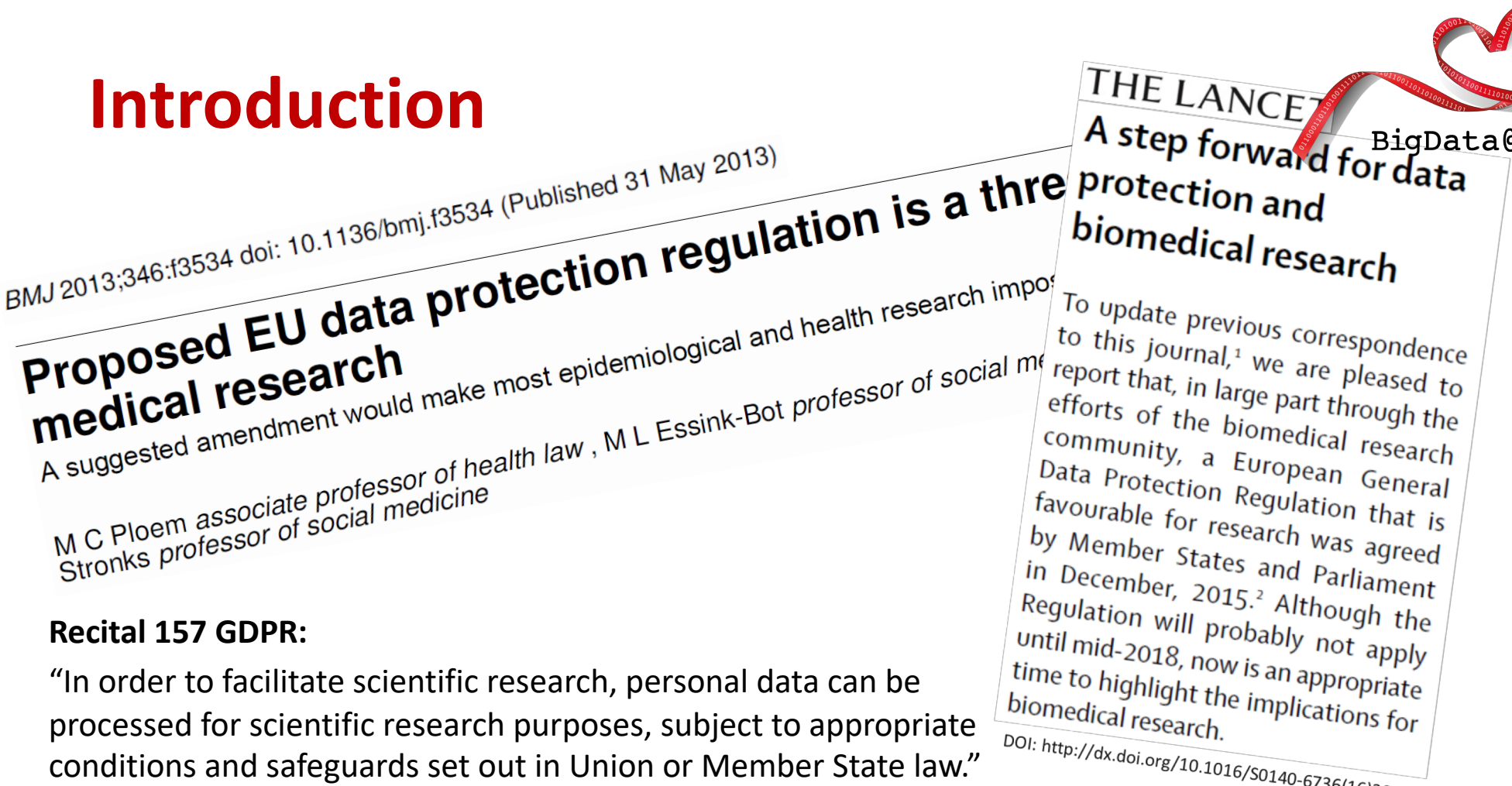
Introduction



BMJ 2013;346:f3534 doi: 10.1136/bmj.f3534 (Published 31 May 2013)

Proposed EU data protection regulation is a thre
medical research

A suggested amendment would make most epidemiological and health research impos

M C Ploem associate professor of health law , M L Essink-Bot professor of social me
Stronks professor of social medicine

THE LANCE

A step forward for data protection and biomedical research

To update previous correspondence to this journal,[1] we are pleased to report that, in large part through the efforts of the biomedical research community, a European General Data Protection Regulation that is favourable for research was agreed by Member States and Parliament in December, 2015.[2] Although the Regulation will probably not apply until mid-2018, now is an appropriate time to highlight the implications for biomedical research.

DOI: http://dx.doi.org/10.1016/S0140-6736(16)30078-2

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Recital 157 GDPR:

"In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law."

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Research Exemptions
General

Research Exemptions from

- Consent Requirements
- General Principles
- Individual rights

Invoking Research Exemptions in the GDPR

- Requires robust data protection and governance (art. 89(1) GDPR)
- Additional guidance on governance needed
  - *For instance in an approved code of conduct (see for example: http://code-of-conduct-for-health-research.eu/)*


Research Exemptions
Consent

Exemption from Consent (Art. 9 GDPR(2)(j) GDPR)

- Needs to be implemented in national law
- Limited/vague points of departure in the GDPR

Broad consent allowed?

- " (..) data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research." (Recital 33 GDPR)


Research Exemptions
Individual Rights

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Rights of data subjects	Research exemptions
Transparency/information	14(5b) GDPR*
Access	89(2) GDPR, needs implementation
Rectification	89(2) GDPR, needs implementation
To be forgotten	17(3d) GDPR
Restrict processing	89(2) GDPR, needs implementation
Object	89(2) GDPR, needs implementation

No Research Exemptions

- Right to lodge a complaint; right to erasure; right to data portability, e.g.

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**only applicable when the data are not obtained from the data subject*

Research Exemptions
General Principles

Storage limitation

- "personal data may be stored for longer periods insofar as the personal data will be processed (..) for (..) scientific (..) research purposes or statistical purposes (..)"

Purpose limitation

- "further processing for (..) scientific (..) research purposes (..) shall, (..) , not be considered to be incompatible with the initial purposes"

Principles in Art. 5 GDPR:

Lawfulness
Fairness
Transparency
Accountability
Purpose limitation
Data minimisation
Data accuracy
Storage limitation
Data security

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New regulation and implications for Big Data Approaches - pharmaceutical industry perspectives

Natacha UDO-BEAUVISAGE

Global data Protection Officer, Laboratoires Servier

Introduction

BIG DATA - Actual opportunities and expectations from all stakeholders from Big Data for the benefit of the patients and healthcare systems

Various sources - clinical trials data (high quality standards)
& real word data (patients real life – medical devices)
Various uses – internal use (inside the pharmaceutical company)
& external use (sharing with academics, hospitals, partners)
Various context - requested by Health authorities (PASS-DUS…)
& IMI consortia

GDPR – Harmonisation & accountability expectations


Primary use

what is stated in the ICF from data protection perspective?*

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	Before GDPR	After GDPR
Legal basis	consent	General trend to move forward from consent • Clear position from some national public authorities (NHS – French and Czech DPA): **legimate interests** • Practices: **still consent**
Scope of ICF	narrow and specific to the study ("exclusively", "restricted to" "limited to"….)	Secondary use provided for
Applicable law	location of sponsor a single legislation	Location of patients ? Location of sponsor ? Patchwork of legislations (article 9.4)

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** Informed Consent Form mandatory for participating to a clinical trial*

Secondary use

secondary use compliant with data protection legislation in force?

COMPLEXITY	
Impact of local legislation	• Autorisation from local DPA? • Mandatory submission to local EC? • Information (individual, prior, general…) to be provided to patients?
Impact of initial scope of ICF	• what about ethics when narrow consent? • Need to analyse each ICF (amended according to local requirements) to exclude patients who refused secondary use or accepted certain areas of research (recital 33)
Scientific research	• No definition – narrow or broad concept? • Possible derogations/exemption require national implementation

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CONCLUSION

Need to enhance european research

- Raise awareness of DPA, Ethics Committees and Member States
  Harmonisation of local DPA position/guidance
- IMI specificity (public interest, fundings, PPP, scientific community)

Need for building guidance for secondary use of data

- From scientific, data protection and ethics perspectives
- With risk-based approach inspired by DPIA methodology
- With appropriate Safeguards and
- With involvement of patients associations

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A basic model for datasharing in BigData@Heart

Evert-Ben Van Veen

Partner, Senior Consultant, Medlaw

Basic model datasharing

- Datasharing is at the heart of BD@H
- BD@H is not one study, but many studies
- Each study can use various data sources
- Data can be shared in various ways
- *Hence model must accommodate a very varied practice*
- <u>common principles</u>
  - Building blocks

Building blocks

- balance methodological requirements with privacy by design and data minimisation in the data chain
- embed that in a research protocol
  - Is the ‘defence’ for why data of a certain kind are needed for the research
  - Also why the research may contribute to better health
- perform a Data Protection Impact Assessment (DPIA) when necessary
  - Might already have been the case
- Adjust when that follows from the DPIA

Building blocks 2

- whether personal data may be released for research, will be decided by the data source
  - There is no central BD@H committee
- Data source should be compliant
- Whether data may be released for ‘further use’ …
  - Original consent (if any)
  - New consent (if possible and necessary)
  - National legislation following 9.2.i and j GDPR
  - Own governance system of data source
  - Type of data

Only anonymous ?

- We did not choose for only anonymous or consent
- fully anonymous data without residual chance of re-identification, are seldom useful for research
- If there is a specific informed consent cap on the data, one cannot circumvent that by making those data anonymous
  - Going back is often not possible
  - Creates bias
  - sometimes a waiver of consent might be feasible
- GDPR and national legislation have more nuanced options

Building blocks 3

- Assure approval for the project
  - Ethics committee
  - Sometimes DPA
- data are transferred under a Data Transfer Agreement (DTA)
- have a data management plan (DMP)at the research database
- be transparent both at the data source as at the requesting researcher about the project

Final remarks

- And if a sound and responsible protocol cannot be executed ..
- WP 7 would like to know
- We are there to support
- And bring the discussion forward
- Also by combining anecdotal rumours on what is not possible under the GDPR into pubs which can bring change when necessary

- Next steps: basic model will be more ‘dynamic’
- Work on ways for citizens and patients participation

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