GDPR – LARGER RESEARCH COLLABORATIONS

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OUR BUSINESS

We are a global pharmaceutical company specialized in discovering and developing innovative treatments for brain diseases

BELIEFS

We are

Patient-Driven
Courageous
Ambitious
Passionate
Responsible

STRATEGIC GOAL

We will

Grow Lundbeck to create value for all our stakeholders

OUR PURPOSE

More than **700 million** people are affected by brain diseases worldwide, which equals to 13% of the global disease burden*

At Lundbeck, we are tirelessly dedicated to restoring brain health, so every person can be their best

*https://www.ifpma.org/wp-content/uploads/2016/01/2012_IFPMA_Position_Paper_on_MNDs.pdf

OUR KEY FIGURES

Revenue

Our 2018 revenue reached DKK 18,117 million.

Employees

We are approximately 5,000 employees across four divisions.

History

Lundbeck was founded by Hans Lundbeck in Copenhagen more than 100 years ago, in 1915.

Global presence

We are headquartered in Denmark and located in more than 50 countries.

Ownership

Our largest shareholder is the Lundbeck Foundation, which holds approximately 70% of the shares.

Treatments

Our products are registered globally in more than 100 countries, and our legacy portfolio of invented products reach more than 50 million patients worldwide yearly.

AGENDA

1. Lundbeck

2. GDPR in brief

3. Data Controller vs. Data Processor

4. Centralised set-up vs. Decentralised set-up
   - Examples

5. Lessons learned

GDPR IN BRIEF

- **Scope of GDPR:**
  - Territorial
  - Material

- **Definition of data:**
  - Personal data includes online identifiers and location data
  - Pseudonymous data – personal data subject to technological measures so it no longer directly identifies an individual without the use of additional information.

- **Challenges in regards to research agreements with multiple parties**
  - Data Controller, Joint Data Controllers and Data Processors?

DATA CONTROLLER VS DATA PROCESSOR

- **Data Controller**
  - Determines the purpose and means of processing personal data
  - Obligation to ensure contracts with processors comply with the GDPR
  - Controllers will have to establish or amend technical or organisational measures to ensure and prove that the processing of personal data fully complies with the GDPR requirements

- **Data Processor**
  - Responsible for processing personal data on behalf of a controller
  - Obligation require processors to maintain records of personal data and processing activities
  - Processing on behalf of a controller must be set out in a contract or other ”legal act”, according to criteria articulated under the GDPR

JOINT DATA CONTROLLERS

- **Definition – art. 26**
  - two or more controllers jointly determine the purposes **and** means of processing, they shall be joint controllers.
  - Broad interpretation of the definition
    - C-25/17 (Jehovah Witnesses in Finland) – no written instruction is required and access to data in question is not determining. Exerts influence is sufficient.
  - An arrangement shall be made duly reflecting the respective roles and relationships of the joint controllers

CENTRALISED SET-UP

- The collaborators decide on a direction together
- An external agent (CRO) is chosen to manage the contract, it does not deliver any service.
- It is the collaborators as a whole who get involved in a study and who approve the study design
  - →This is often done through a steering committee or similar
- CRO does not have any deciding vote in regards to which studies the collaboration should undertake

- **Consequences:** All European collaborators are viewed as Data Controllers, despite they never receive any data which constitute personal data as defined by GDPR

EXAMPLE 1: Centralised set-up

- **Set-up:**
  - Pharma companies constitute the Consortium – HLU only European entity who is obligated to comply with GDPR
  - Consortium contracts with a legal entity (CRO) for this project which main role is to organise the studies that shall be run by the Consortium.
  - Data only from patients in US
  - All members of the Consortium are part of a steering committee
  - The steering committee decides which studies to perform, the study design and thereby the means and purpose of processing of personal data

- **Consequences:**
  - HLU imposed the GDPR regulation on all Consortium members
  - Obligations and rights pursuant to the GDPR had to be reflected in the Consortium agreement
  - A joint controller agreement had to be signed by all Consortium members
  - HLU has to enter into a separate data processing agreement with CRO for each study, as CRO will act as Data Processor.

DECENTRALISED SET-UP

- A collaboration is established to create a ”one-stop” point for new studies to obtain funding.
  - E.g.
    - A collaboration/partnership can invite third parties to apply for funds
    - Studies are selected prior to setting up the collaboration

- An external agent (CRO) is contracted to manage administrative tasks and to contract with third parties who wish to obtain funding
- A collaborator will not have a deciding vote on the study design
- Each collaborator decides independently if they wish to fund a specific study
- Once a study is selected by a collaborator/collaborators, the collaborator/collaborators become an ”advisor” in relation to the study

EXAMPLE 2: Decentralised set-up

- **Set-up:**
  - Pharma companies constitute the consortium – several European entities
  - Studies are selected prior to setting up the consortium
  - All participants in the consortium are part of a committee
  - Committee does not have deciding rights in relation to the studies
  - Separate entity will contract directly with sponsor of the study

- **Consequences:**
  - No GDPR issue as the Pharma companies will not be determining the purpose and means of the processing of personal data
  - One consortium agreement

LESSONED LEARNED

- Picking the right contractual set-up for the collaboration
- Re-evaluation on commitments
- Written evaluation – justification of contractual set-up
- Consistence in interpretation of the GDPR
- Unknown challenges