

# Pharma view on ARO contracting and GDPR

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# Agenda

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- Who am I
- Introduction
- Internal Alignment and LoB buy in
- Price and Overhead
- Co-financed vs. Commissioned Research
- IP Ownership
- IP-transfers and Grant Backs
- Publications
- Risk and Liability
- GDPR
- Thank you!



# Who am I

- Christian de Hemmer Widding  
Senior Corporate Counsel  
R&D Legal at LEO Pharma
- Part of the LEO Pharma Global Legal Team, consisting of 30 people.
- Provide support to our R&D Division
- Mainly involved in Service and Consultancy Agreements, Clinical Trial Agreements and Research Agreement.
- Have previously headed a team of contract lawyers at the Technical University of Denmark and have worked as an attorney-at-Law at LOGOS Legal Services and at Brix Jensen Havemann Law Firm.



# Introduction

- Presentation based on our negotiations with academic institutions, both related to clinical trials and research collaborations.
- Legal department tend to be involved in the difficult cases.
- Attempt to highlight some typical issues when dealing with academic institutions – however we see great variation in how institutions collaborate with industry partners.
- May not be the “Pharma view” but rather the “LEO Pharma view”. We have made a strategic decision to actively seek strong collaboration with academia. To support this, the legal department have also chosen a pragmatic approach when negotiating deals with academic institutions.



# Internal alignment and LoB buy in

- Tendency to leave contract negotiations to legal team.
- Contract/Legal departments in some institutions are covering very diverse areas
  - Lack of understanding of the risks and values in specific project
  - Time spend on negotiating very theoretic risks
  - Lack of tools to mitigate risks
  - Risk of non-compliance to terms of the contract by LoB

Always ensure involvement from institution LoB (and your own)

# Price and overhead

- Fair Market Value (maximum value)
- State aid (minimum value)
- Typically two forms of research collaborations
  - Co-financed research (OH 15-100%)
  - Commissioned research (OH 150-200%)
- The type of collaboration impacts a number of terms in the contract
  - Right to results
  - publications

# Co-financed vs. Commissioned Research

- Co-financed Research
  - Option to acquire IP at market price
  - Institution must publish results
- Commissioned Research
  - IP is typically transferred without additional cost
  - Institutions can sometimes accept not to publish results
- Co-financed Research has many benefits, but:
  - Research on own compounds
  - publications

# IP Ownership

- Institutions right to employees IP
  - In some countries institutions do not have the right to all types of IP of their employees.
  - Copyrights and know-how on exclusive basis
  - Professors privilege (employee to sign off on any transfer)
- Students
  - Unless employed by institution, they are not covered by institutions grant of right.
  - Also not covered by any CDA's
  - Software!



# IP transfers and grant backs

- Field
  - Some institutions will only grant rights within a defined field, rather than to all results of the project.
  - Can be quite cumbersome to negotiate field definition and will always require assistance from LoB.
- Grant back of license to institution
  - Institutions will often ask for a royalty free license to use result for non-commercial internal research, education and health care purposes
  - We will normally accept to grant such license

# Publication

- Publish or perish
  - Often in our interest to see publications
- Publication terms:
  - Review period and removal of confidential information
  - Postponement to ensure patent filing
- Often negotiations on time to review and period of postponement
- Most institutions have policies on this and will not deviate from these
- Discuss with own stakeholders how to handle, especially if patents are likely

# Risk and Liability

- Most Academic institutions seems to be very risk averse
  - Reluctant to give warranties
  - often policies against providing indemnities
  - Will not accept agreements to be governed by laws other than home state
  - Will not accept legal venue other than home state
  - May not be allowed to insure against risk
- Liability negotiations are often long and complicated
  - Consider likelihood of filing law suit against an academic institution

# GDPR

- Institutions outside the EU
  - Geographical scope of GDPR
  - Contractual obligation rather than compliance with GDPR
- Medical records and source documents
  - Make sure to carve out
  - Alternative could be a joint controller set up
- Personal data of institution staff
  - Always ensure right to process personal data for transparency purposes – HCP Privacy Notice
  - Sometimes Privacy Notice if we receive other personal data from employees

# Thank You

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