



# Legal and Ethical Issues in Medical AI:



**AI Beyond-the Hype: Benefits, Challenges and Liabilities**  
**Mackenzie Building, Old Assembly Close,**  
**Edinburgh, 31 May 2019**

**Prof. Jur. Dr. Timo Minssen**  
**Founding Director, Centre for Advanced Studies in Biomedical Innovation Law**  
**University of Copenhagen (DK)**



<http://insights.venturescanner.com/2014/05/06/a-snapshot-of-the-digital-health-landscape/>







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# Aspirations and opportunities in the Health and Life Science sectors



**NORDIC**  
AI

## AI & HEALTH SUMMIT

13. SEPTEMBER 2018  
IN COPENHAGEN





# In comes the lawyer and the current legal and economic realities







# AI & LIABILITY





# Regulatory challenges



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



- Is app or software a “medical device” and hence subject to sector-specific strict obligations?
- Is it a lifestyle & wellness or purely a health product or service?
- What about medical- and cybersecurity?
- Liability across complex value chain for damages resulting from (software, connectivity, machine) faults connecting device?
- How to enhance access, interoperability and standards?





## Regulatory Issues & the Black Box



**Bakul Patel, Associate Center Director for Digital Health of the FDA,  
May 2017:**

*"We're trying to get people who have hands-on development experience with a product's full life cycle. We already have some scientists who know artificial intelligence and machine learning, but we want complementary people who can look forward and see how this technology will evolve."*

# PRIVACY







## Two forthcoming papers

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1. *Science (AAAS): Price, Kaminski, Minssen, Spector-Bagdady: Shadow health records meet new data privacy laws How will research respond to a changing regulatory space?, forthcoming in February 1<sup>st</sup>, 2019*
2. *"Science & Public Policy" (Oxford University Press): Minssen, Rajam & Bogers, Clinical trials data transparency & GDPR compliance: What are the effects on data sharing and open innovation?, forthcoming in April.*





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# The fuel that drives AI: Big Data in the Health & Life Sciences







# The FAIR standard



## To be Findable:

- F1. (meta)data are assigned a globally unique and eternally persistent identifier.
- F2. data are described with rich metadata.
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## To be Accessible:

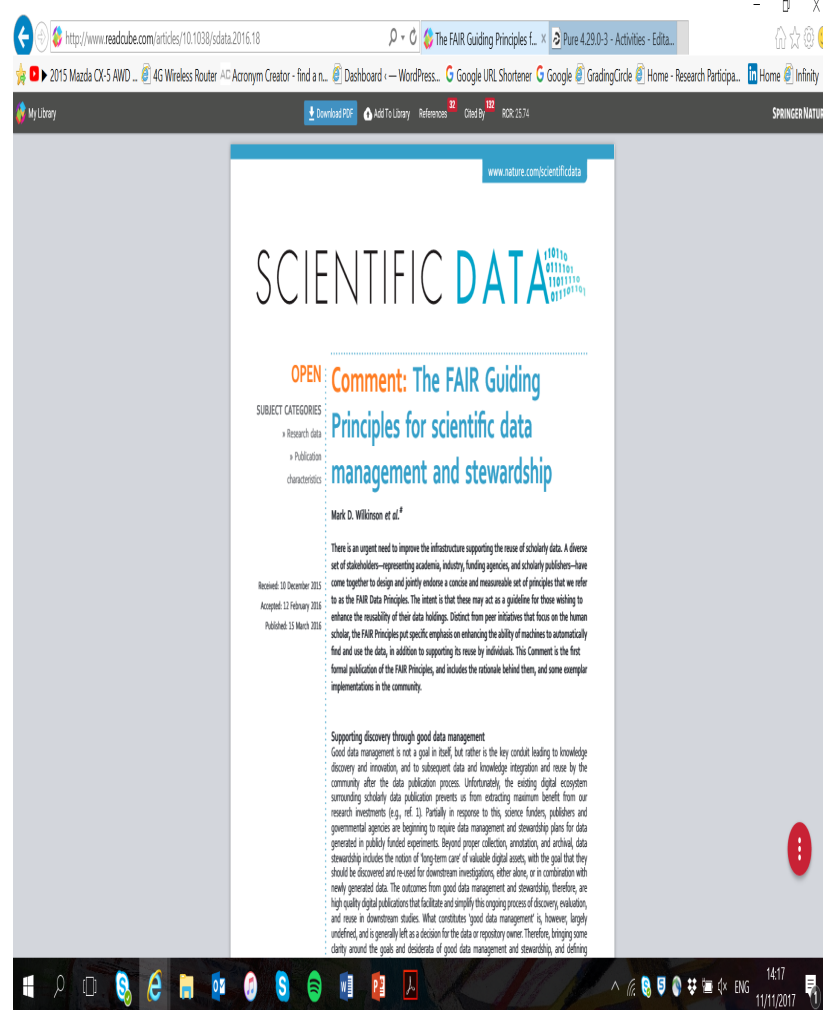
- A1 (meta)data are retrievable by their identifier using a standardized communications protocol.
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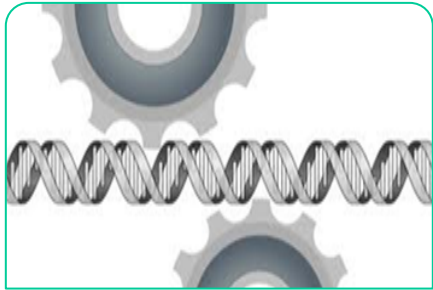


# Governance of IPR, data sharing and competition law





# The IP & Trade Secrets issue in AI & Big Data



**PATENTS**



**Copyright**



**TRADEMARK**



**Data Base Protection**



**Trade Secrets**

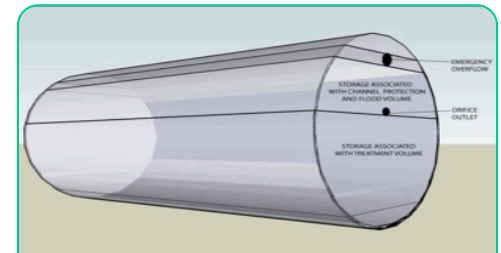


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SCIENCE MEDICINES HEALTH

**Regul. Excl.**



**Domain name**



**Design**





# Example: Recent complications in the Faculty of Law Clinical Trials Transparency context

Preparing\_responsible\_clinical\_trials\_sharing.pdf - Adobe Acrobat Reader DC

File Edit View Window Help

Home Tools NatureBio\_Price&... NEJMe1515172.pdf NEJMp1314691.pdf NEJMe1515172.pdf Comment\_respon... Preparing\_respon... x ? Sign In

The NEW ENGLAND JOURNAL of MEDICINE

## HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Mary Beth Hamel, M.D., M.P.H., *Editor*

### Preparing for Responsible Sharing of Clinical Trial Data

Michelle M. Mello, J.D., Ph.D., Jeffrey K. Francer, J.D., M.P.P., Marc Wilenzick, J.D., Patricia Teden, M.B.A., Barbara E. Bierer, M.D., and Mark Barnes, J.D., LL.M.

Data from clinical trials, including participant-level data, are being shared by sponsors and investigators more widely than ever before. Some sponsors have voluntarily offered data to researchers,<sup>1,2</sup> some journals now require authors to agree to share the data underlying the studies they publish,<sup>3</sup> the Office of Science and Technology Policy has directed federal agencies to expand public access to data from federally funded projects,<sup>4</sup> and the European Medicines Agency and life-threatening conditions in an online database, called ClinicalTrials.gov. The registry included studies that were privately and federally funded and was expanded in 2002 to include most controlled clinical trials after phase 2 for drugs in the FDA approval process. Pharmaceutical companies and their trade associations also made voluntary commitments beginning in 2002 to share clinical trial results.<sup>7,8</sup> In 2005, the International Committee of Medical Journal Editors

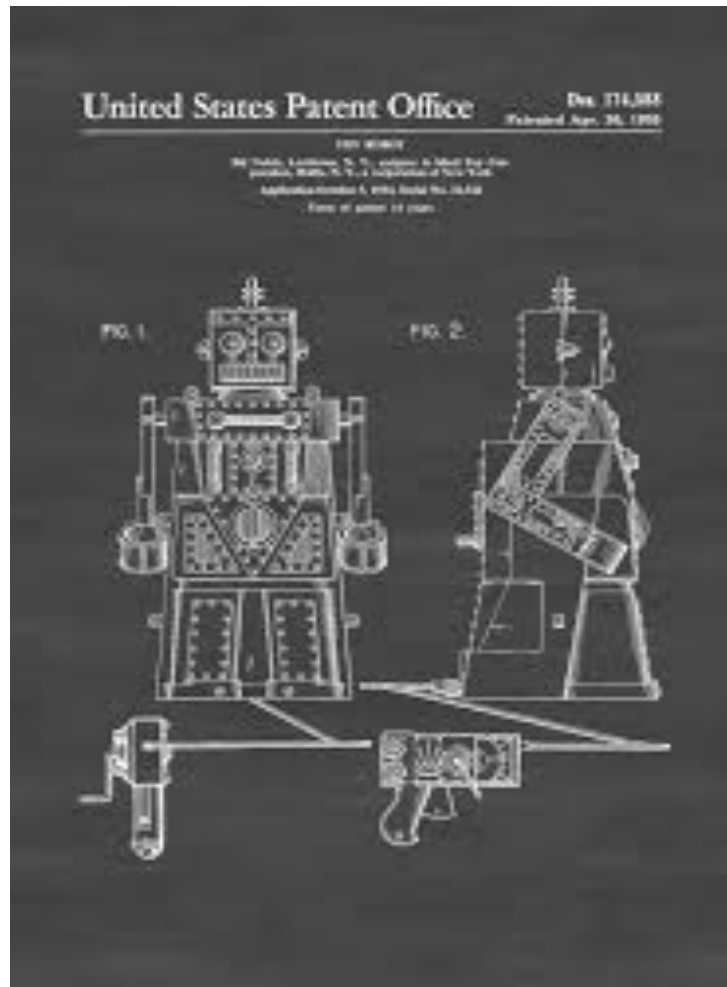
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# IP procedure, legal standing & IP governance



# Governance of high quality data, sharing, competition & new value chains



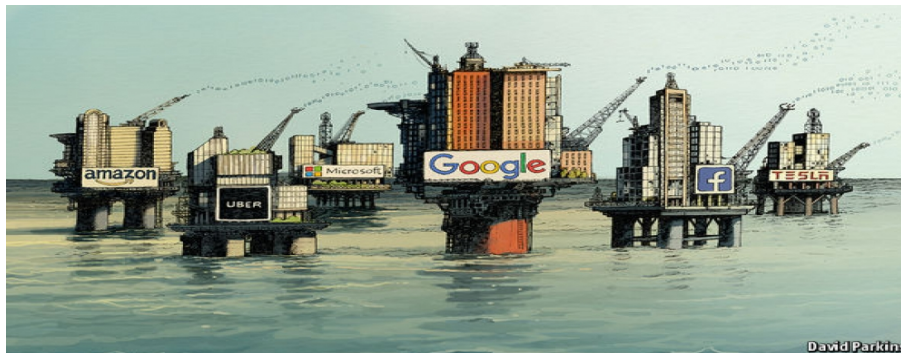
## – Carlos Moedas, EU Commissioner for Research, Science & Innovation

“Our goal is to create a European Open Science Cloud to make science more efficient and productive and let millions of researchers share & analyze research data in a trusted environment across technologies, disciplines and borders”.

## - The Economist on Regulating the internet giants:



“ The world’s most valuable resource is no longer oil, but data: The data economy demands a new approach to antitrust rule”



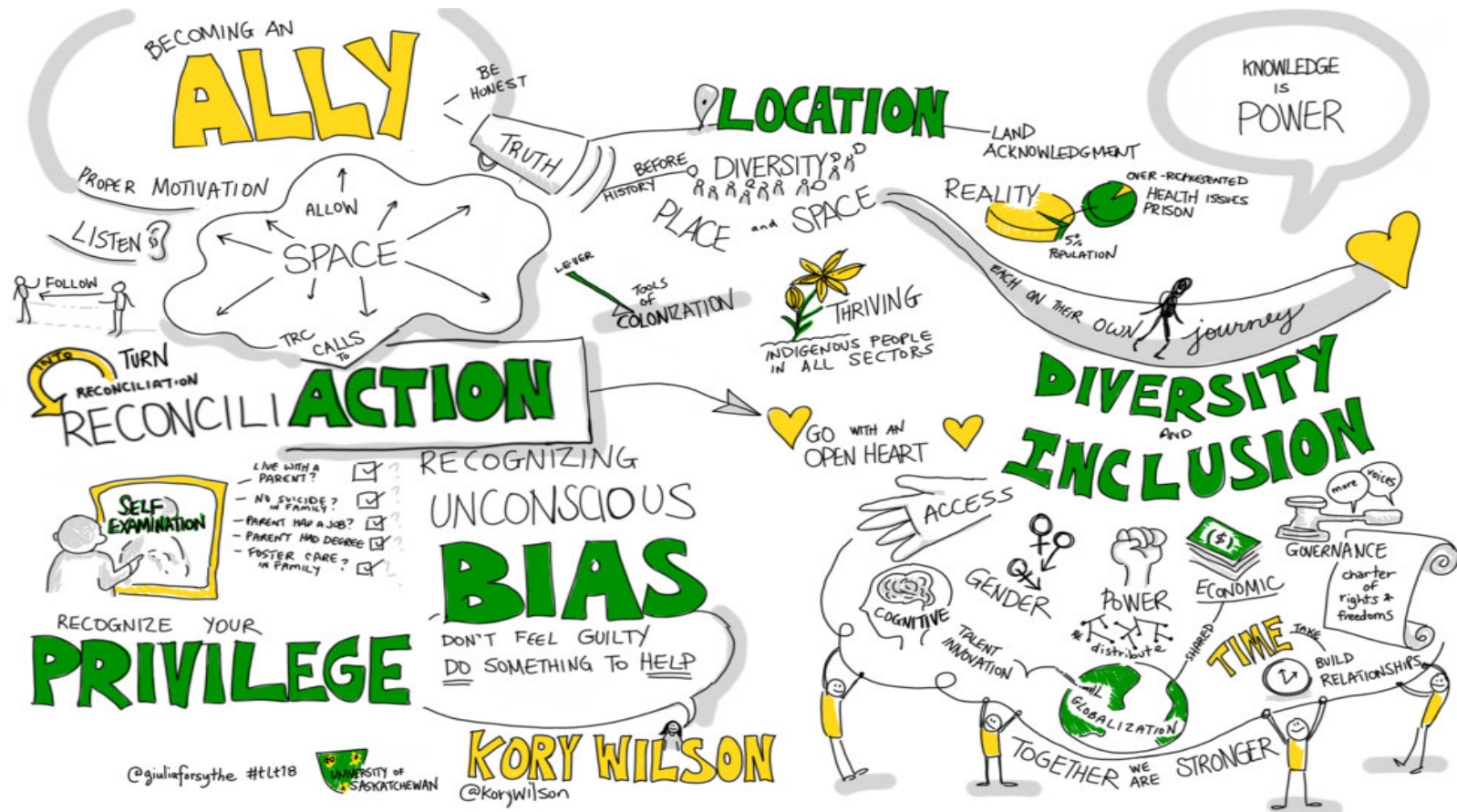


# Beneath the shadows of AI, Big data & openness hyperbole

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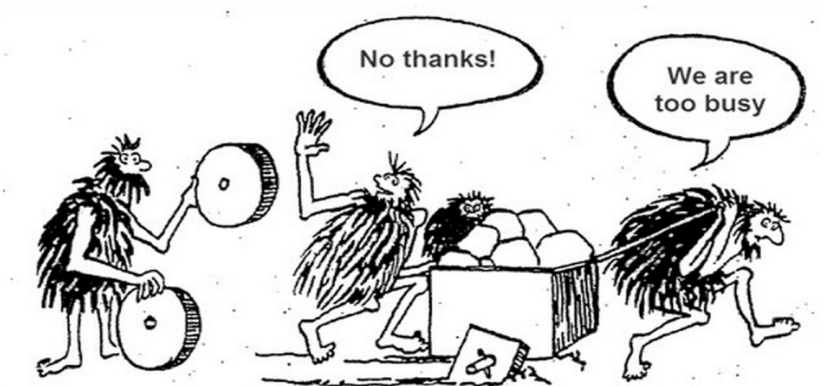
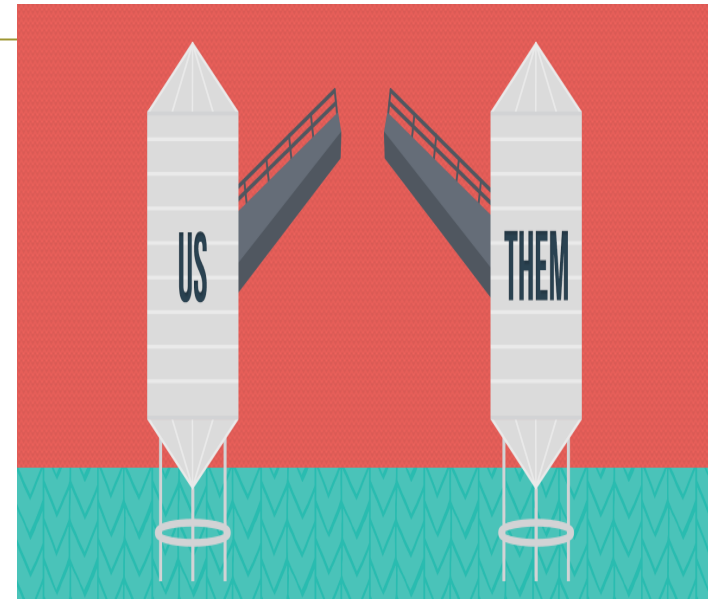
## 6. BIAS, Fairness and socio-economic justice







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## Conclusions



- **AI & Big Data = Paradigm shift that result in overlapping challenges**
- **Complex interplay of regulation & IPRs with new policies & business strategies**
- **Clashes and tensions at the interface of BIG Data/AI, IPRs, privacy & competition.**
- **Recalibration of substantial & procedural laws + governance necessary**
- **SMART & FAIR DATA please!!!! : Need for international studies & strategies**
- **Public involvement crucial to address ethical issues, bias and social welfare**
- **Please invite lawyers to AI parties: they are often quite alright and reasonable !**





# The Blockchain Future?

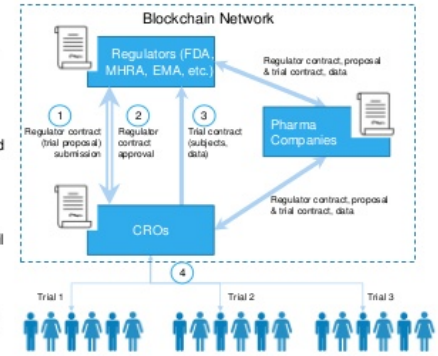
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## Use Case: Clinical Trials - Smart Contracts

Smart contracts could be a solution to clinical trials issues such as end point switching, data dredging, etc.

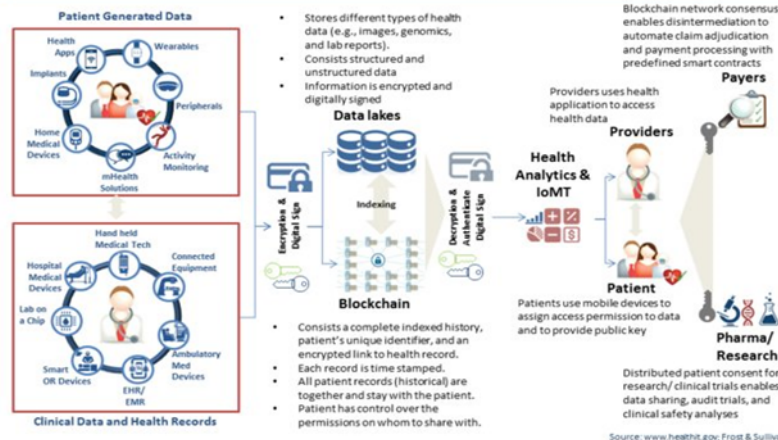
- Timothy Nugent et. al. demonstrated the usage of smart contracts on a private Ethereum blockchain network for Tamiflu drug clinical trials management.
- The private network consisted of regulators, pharma, and contract research organizations (CROs).
- Smart contracts have two layers – regulatory and trial.
  - The regulatory contract consists of trial protocol, end point, time lines, and methods.
  - Trial subjects and data are appended to trial contract, which is owned and managed by CRO.
- Trial protocol on the network ensures protocol adherence and timelines. Each trial data entry is verified, accepted, and stored in all of the nodes the network.



Source: <https://t100research.com/articles/3-2541/v1>

7

## Blockchain Technology – Promising Use Cases for Healthcare Industry



Source: www.healthit.gov; Frost & Sullivan





# The current CeBIL projects



## 1) ICE AGE



## 2) JURFAST



## 3) Reconceptualising Reproductive Rights



## 4) POLICYAID



## 5) Collaborative Research Programme in Biomedical Innovation Law (the “CeBIL” programme)

novonordiskfonden



# CeBIL - Novo Nordisk Research Program Faculty of Law 2018 - 2023

UNIVERSITY OF  
COPENHAGEN



UNIVERSITY OF  
CAMBRIDGE

INNOVATION

MIND THE GAP

HARVARD  
LAW SCHOOL



HARVARD  
MEDICAL SCHOOL



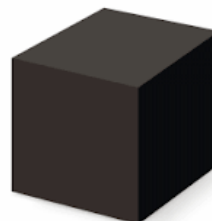
Michigan Law  
UNIVERSITY OF MICHIGAN LAW SCHOOL



Antibioti



Orphan  
drugs



Precision  
& Black  
box



New



Manufacteri  
ng Biologics



# A new Research Program & Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at UCPH, Denmark

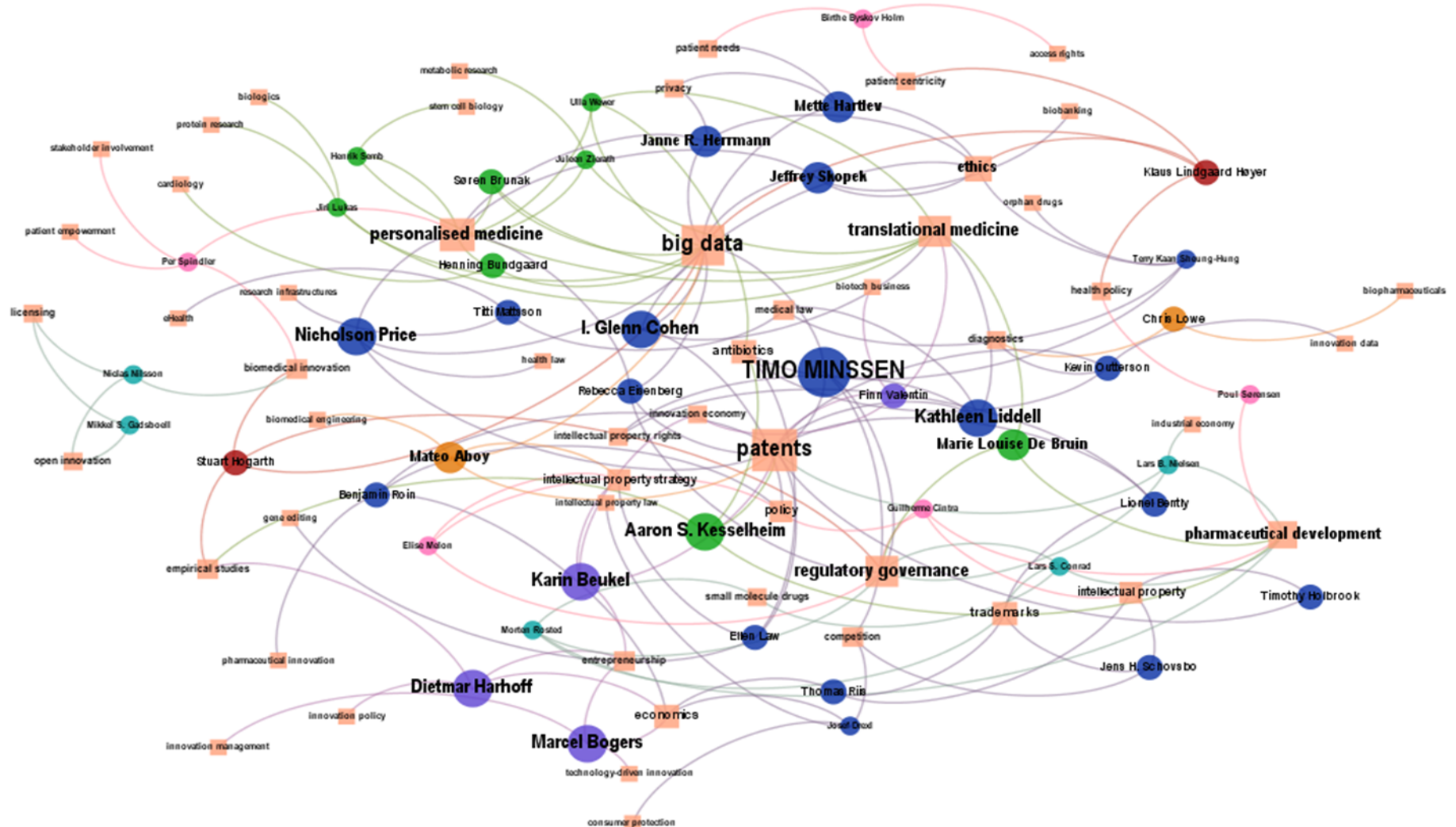


Figure 3: Mapping of Expertises in CeBIL's expert and support network





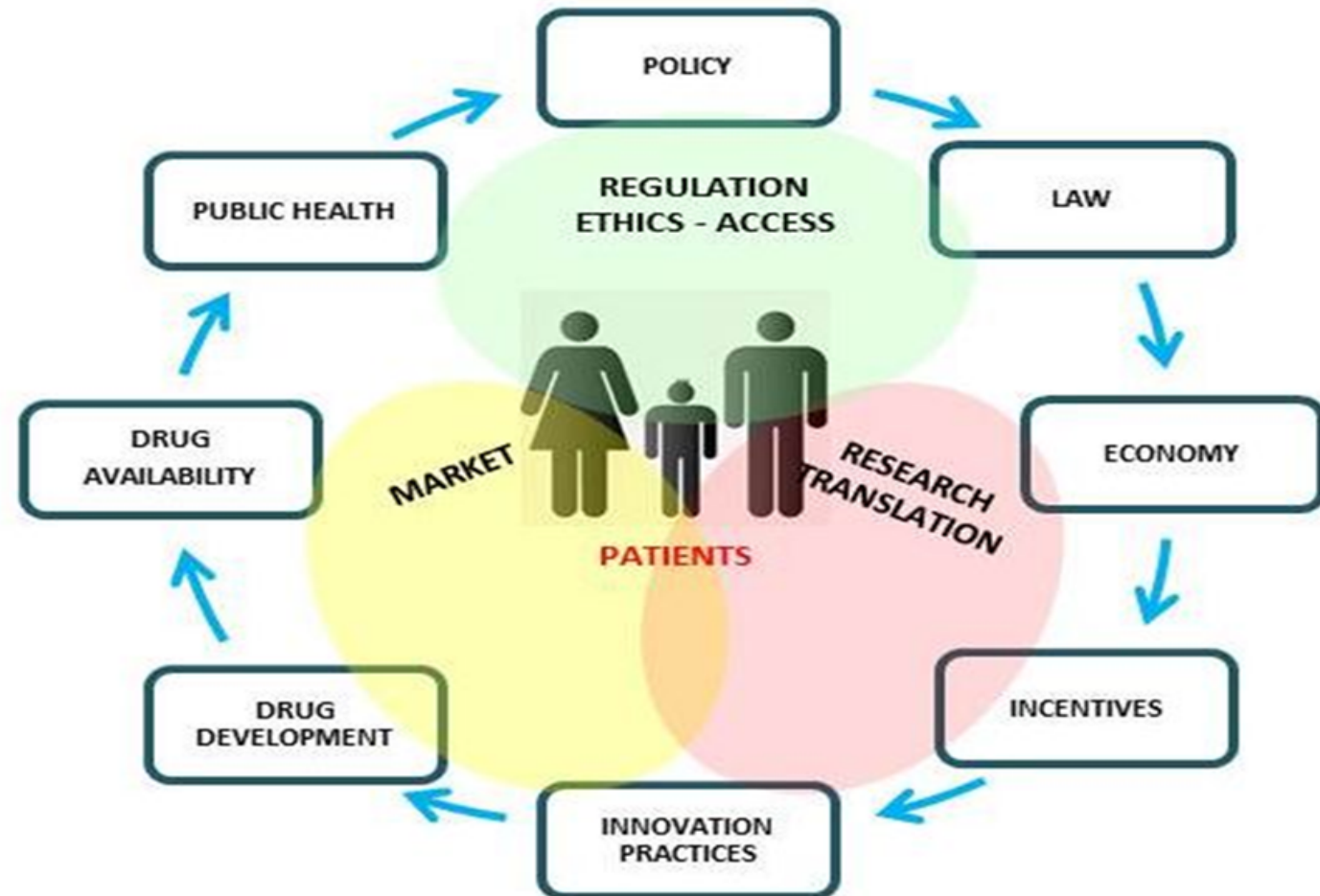
# Why CeBIL?

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- **Informed interdisciplinary analysis**
- **Cataloging & Empirical High Quality Data based studies**
- **Unbiased, well- informed analysis of pressing issues**
- **Linking leading international research on life science frontiers**
- **Informing and educating students and the public**
- **Reaching out for stakeholder input!**
- **Synthesis**
- **Call for action**
- **Ultimate goal: Contribute to socio-economic impact (DK, EU, Global)**

# Multifaceted Legal, Social & Scientific Challenges



## Thanks! Questions or Suggestions?



novo nordisk fonden



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**Twitter:** [@CeBIL\\_Center](https://twitter.com/CeBIL_Center)

**LinkedIn:** <https://www.linkedin.com/in/cebil-copenhagen-3a0756157/>

**Web:** [www.cebil.dk](http://www.cebil.dk)

**News:** <http://jura.ku.dk/cebil/subscribe-to-news-from-cebil/>





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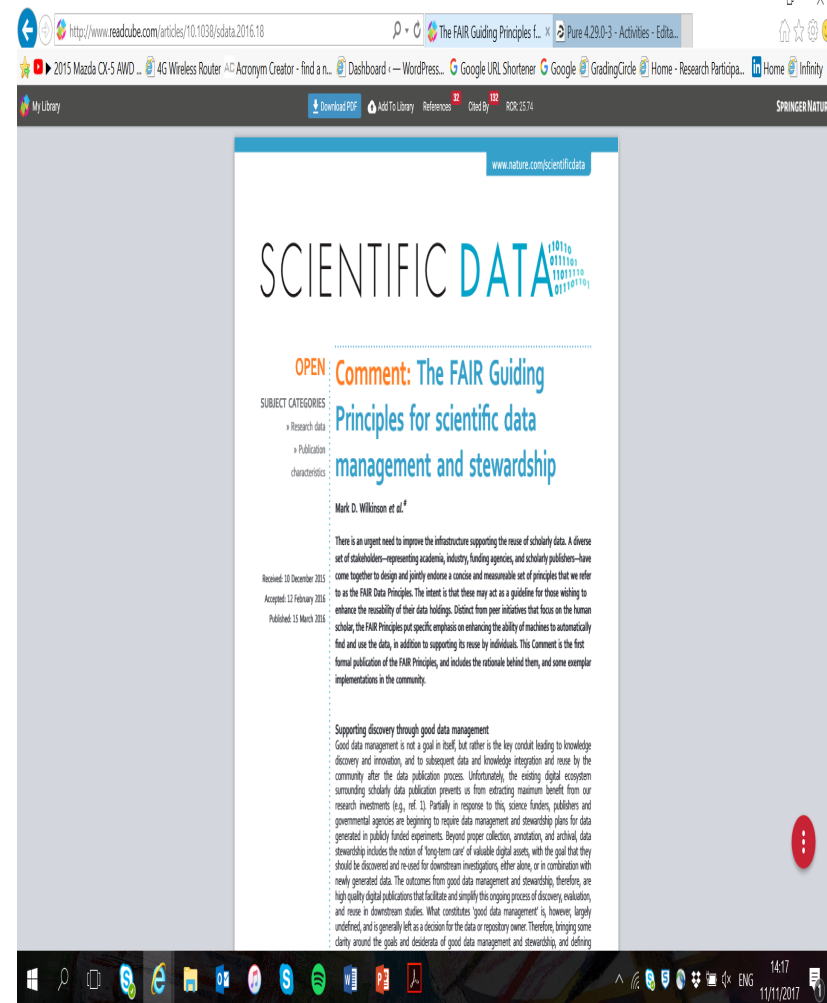
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How the customer  
explained it



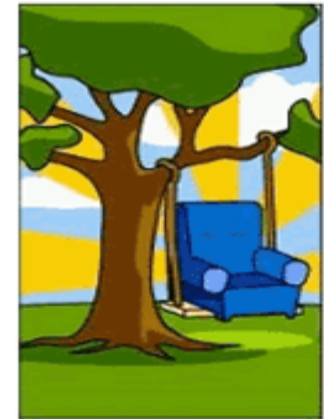
How the project leader  
understood it



How the engineer  
designed it



How the programmer  
wrote it



How the sales  
executive described it



How the project was  
documented



What operations  
installed



How the customer  
was billed



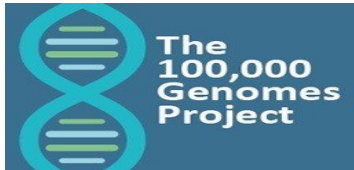
How the helpdesk  
supported it



What the customer  
really needed



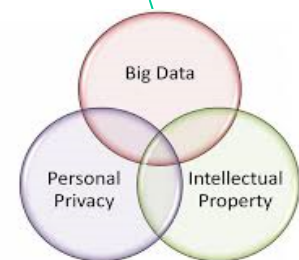
# Selected legal key-challenges to the digitalization of the health & life sciences



## 1. Regulation of digital health products & services



## 2. Data transparency & clashes with Personal Data protection



## 3. Data transparency & Clashes with IPRs and CCI



## 5. R&D incentives & regulation in precision medicine



## 4. Data accumulation, standards & competition law



## What does the EU Commission do and say? 2017 Communication: "BUILDING A EUROPEAN DATA ECONOMY"



### – Carlos Moedas, EU Commissioner for Research, Science & Innovation

"Our goal is to create a European Open Science Cloud to make science more efficient and productive and let millions of researchers share & analyze research data in a trusted environment across technologies, disciplines and borders".

