



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)

Digital Health

Clinical Admin ABILITY, MedIOX, IMPRIVATA, ClearDATA, AuthenticData, next, OSI, koreo, MedIOX, IMPRIVATA, ClearDATA, AuthenticData	Digital Med Devices proteus, Sotera, GenapSys, vitalconnect, integrity, sensible, patientsafe, Rhythm, Sotera, Sense, GenapSys, vitalconnect	EHR/EMR iMGT, patientKeeper, practice fusion, corventis, medivo, CoreCloud, LifeNexus, dr, SunLifeLink, medivo, OSI, AkiliLex	
Population Health Mgmt PRIVIA, R. Ante, MzaKENTIVE, CASTLIGHT, keas, wiscventive, nif, acelle, limeade, ZeOmega, KINSEER, TANGO	Online Health Communities wsr, omada, Glow, @sharecare, patientslikeme, OneOfHealth	Patient Engagement WellDoc, eliza, simple, LINCOR, glooko, Silverlink, AXIAL, simple, LINCOR, glooko	Genomics SVBio, genophen, 10x, teq, genophen, 10x, teq, Counsyl
Medical Big Data STATION, APXIO, ZEPHYR, FLATIRON, bina, AYASDI, STATION, APXIO, ZEPHYR, FLATIRON, bina, AYASDI	Services Search ZocDoc, Brighter, ZocDoc, Brighter	Doctor Networks sermo, DICOM, Grid, QuantasMD, sermo, DICOM, Grid, QuantasMD	teleHealth Vaso, Teladoc, DOCTOR, Care.com, Lively, motherknows, Q-Medic, Core.com, Caring.com, vitalconnect
Mobile Fitness / Health Apps LARK, Netpulse, mindbloom, every move, FITSTAR, Swify, LARK, Netpulse, mindbloom, every move, FITSTAR, Swify	Remote Monitoring Lively, motherknows, Q-Medic, Core.com, Caring.com, vitalconnect	Healthcare Mobile Communications voalte, IQMAX, tigerText, vocera, voalte, IQMAX, tigerText, vocera	Healthcare Marketing evant, appature, evant, appature
IOT Health & Wellness fitbit, BASIS, BODYMEDIA, Willblags, striv, fitbit, BASIS, BODYMEDIA, Willblags, striv	Online Health Destination lumosity, Sites, HealthCentral, Healthguru, HealthNation, hopply, Healthine	Robotics myomo, myomo	Healthcare Marketing evant, appature, evant, appature

<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

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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



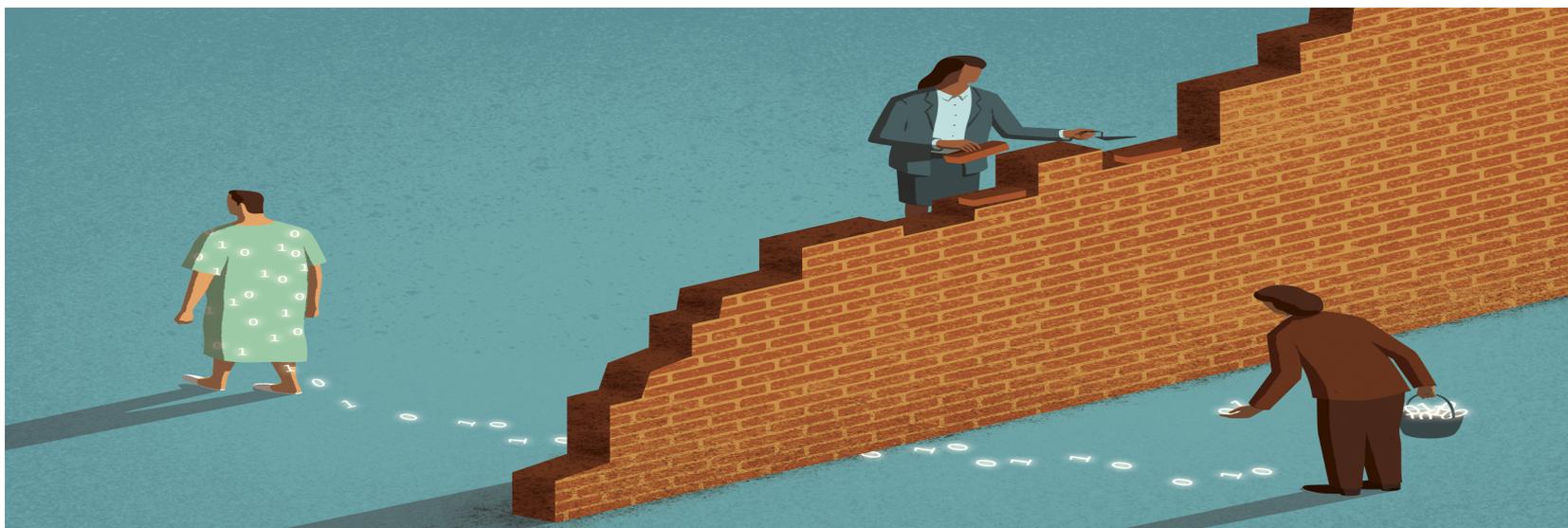


Two forthcoming papers

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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 1st, 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



**To be Findable:**

- F1. (meta)data are assigned a globally unique and eternally persistent identifier.
- F2. data are described with rich metadata.
- F3. (meta)data are registered or indexed in a searchable resource.
- F4. metadata specify the data identifier.

To be Accessible:

- A1 (meta)data are retrievable by their identifier using a standardized communications protocol.
- A1.1 the protocol is open, free, and universally implementable.
- A1.2 the protocol allows for an authentication and authorization procedure, where necessary.
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To be Interoperable:

- I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
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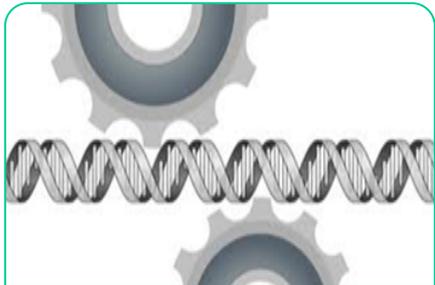


Governance of IPR, data sharing and competition law





The IP & Trade Secrets issue in AI & Big Data



PATENTS 



Copyright 



TRADEMARK 



Data Base Protection 



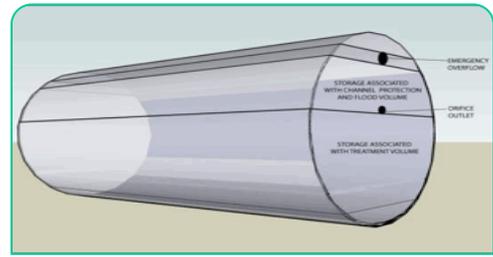
Trade Secrets 



Regul. Excl. 



Domain name 



Design 

Faculty of Law **Example: Recent complications in the 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. Franer, 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.

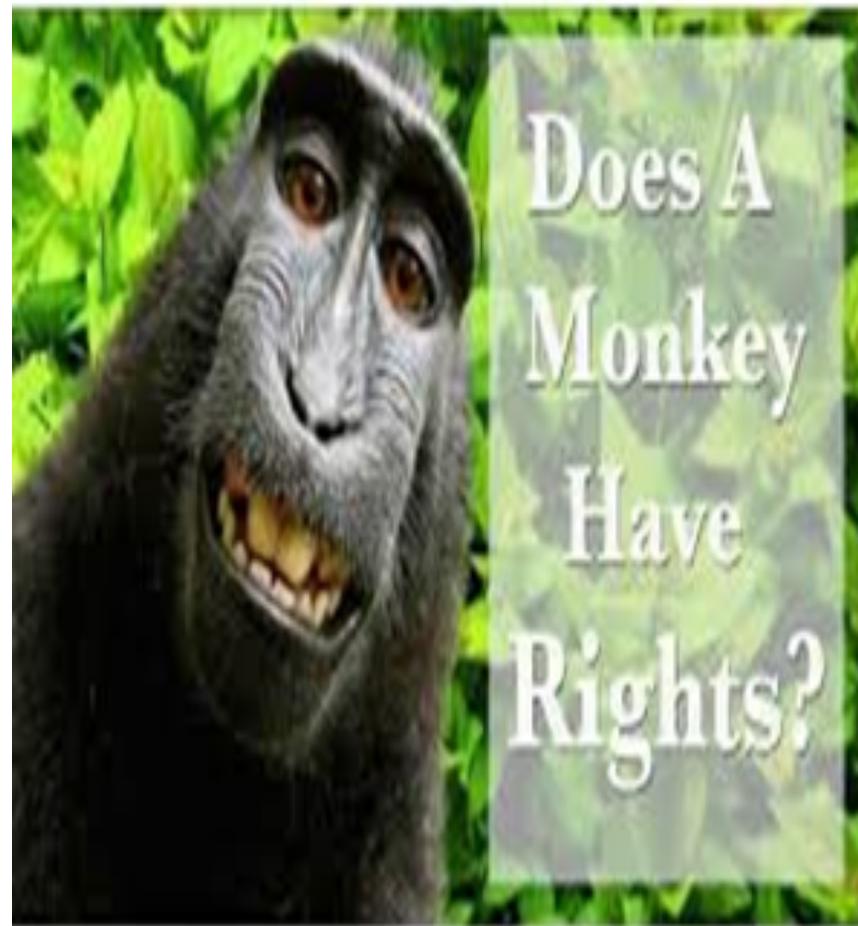
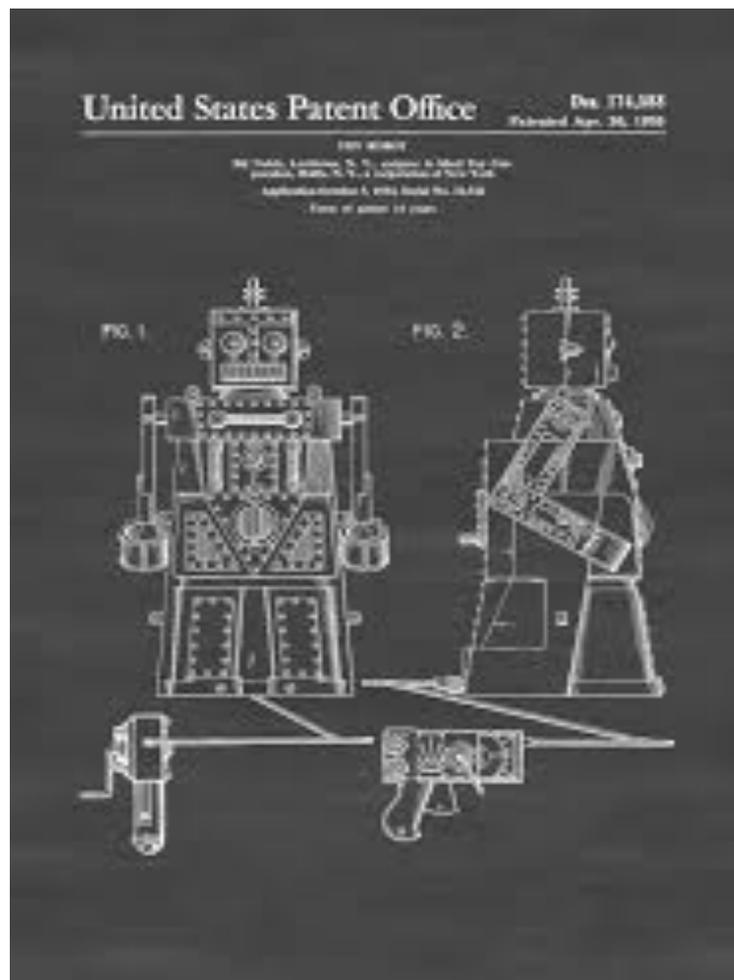
Data from clinical trials, including participant-level data, are being shared by sponsors and investigators more widely than ever before. Some sponsors have voluntarily offered data to researchers,^{1,2} some journals now require authors to agree to share the data underlying the studies they publish,³ the Office of Science and Technology Policy has directed federal agencies to expand public access to data from federally funded projects,⁴ 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.^{7,8} In 2005, the International Committee of Medical Journal Editors

08:42
12/4/2017





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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Controlled access & personal data protection

Income to sustain

Income to curate quality data

Competition & Access & Fairness

IPR policies

Innovation audits and valuation

The GDPR
General Data Protection Regulation
MANAGE AND GOVERN YOUR COMPANY DATA

Competition

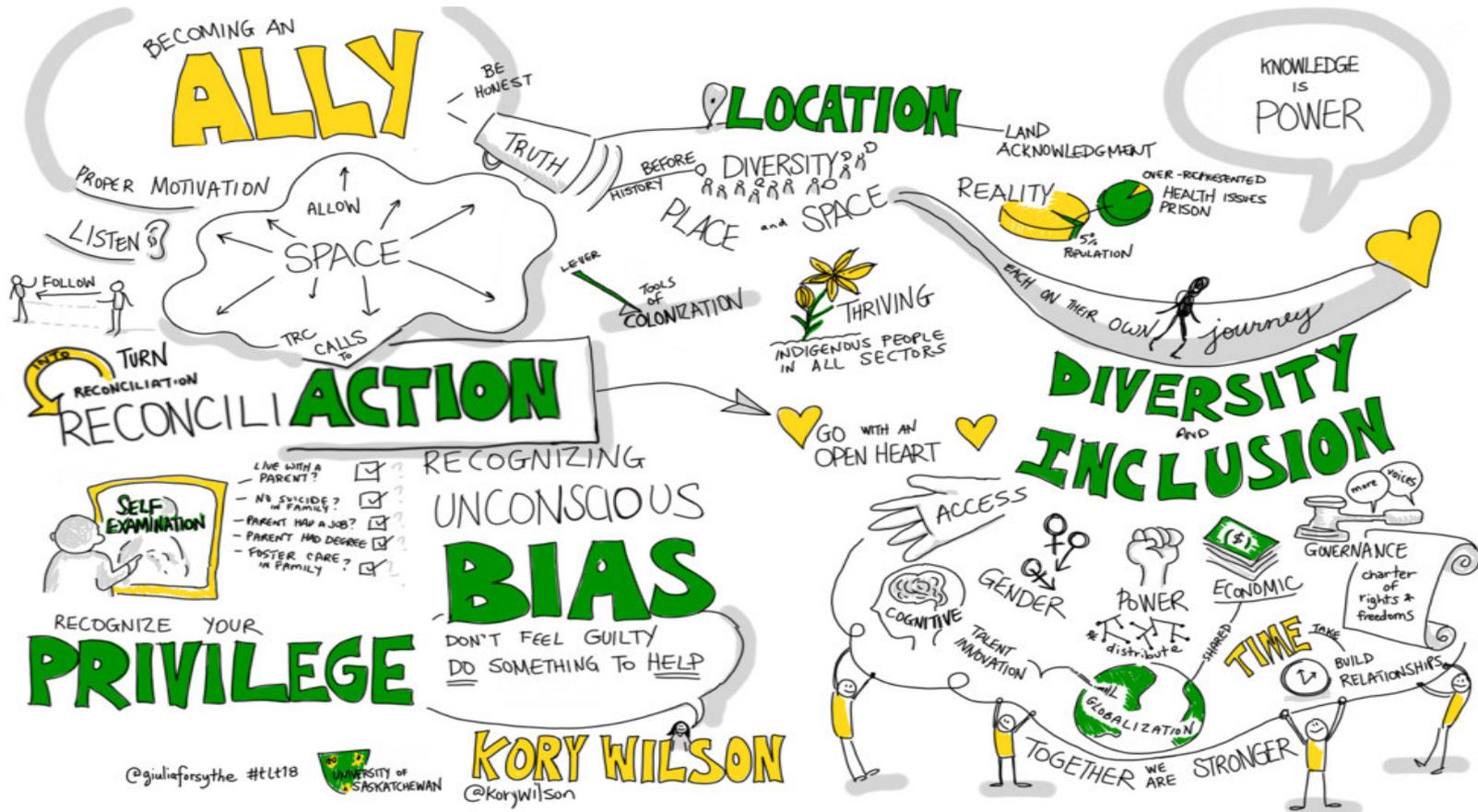


Safe Harbor & Privacy Shield
(what's going on?)





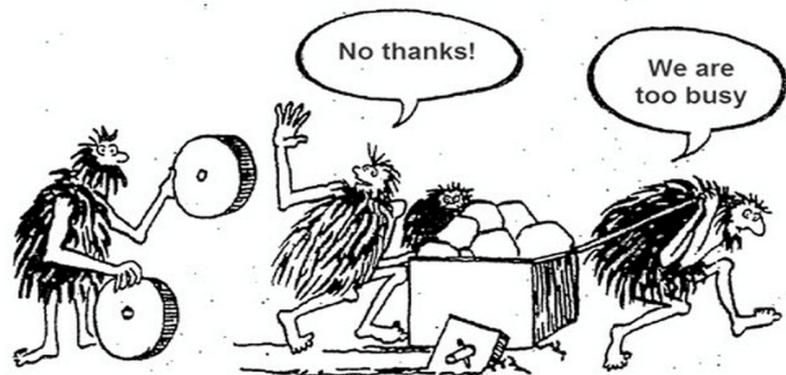
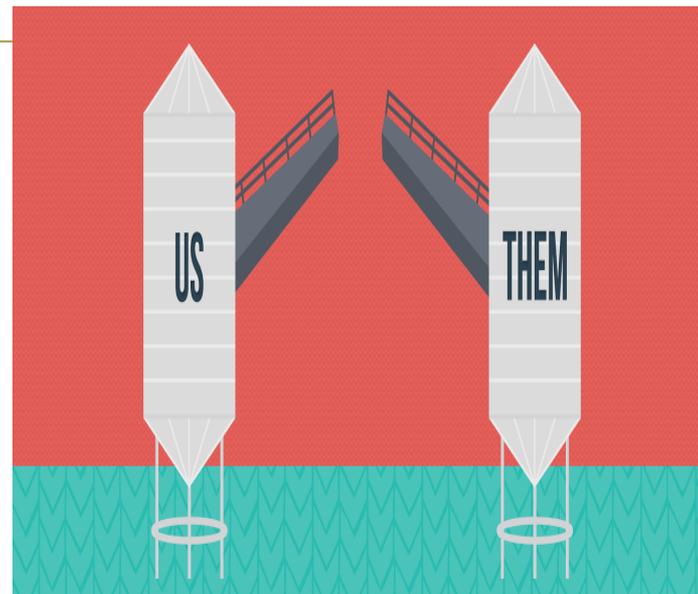
6. BIAS, Fairness and socio-economic justice







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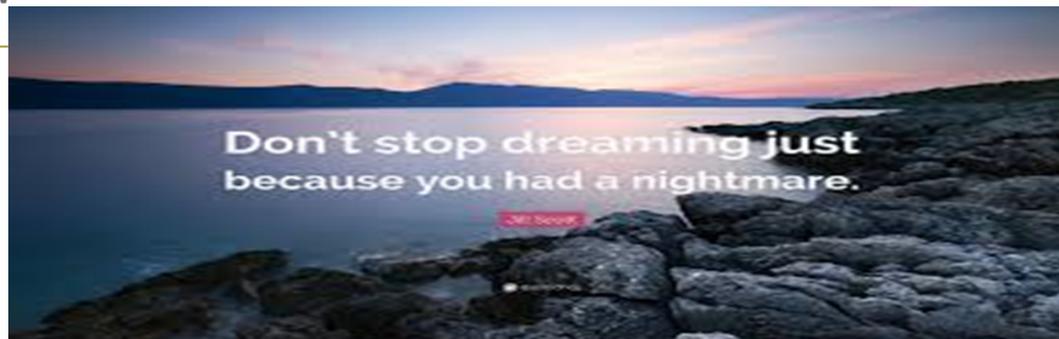




Alexa,
negotiate
Brexit



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?

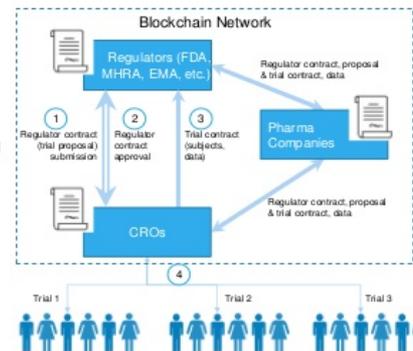
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Use Case: Clinical Trials - Smart Contracts

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

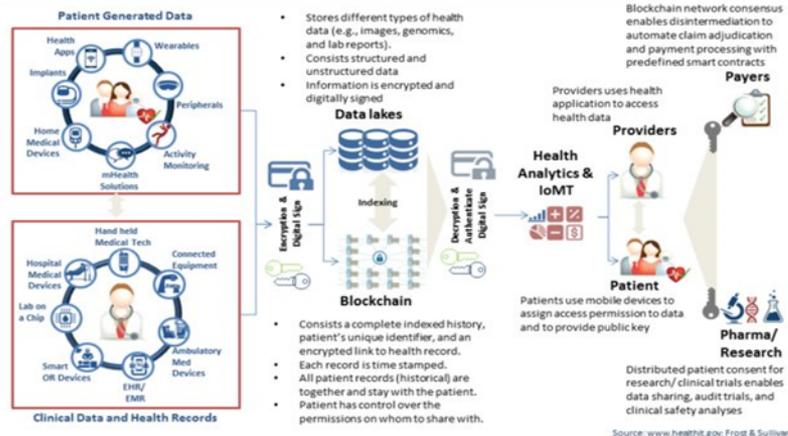
- Timothy Nugent et. al. demonstrated the usage of smart contracts on a private Ethereum blockchain network for Tamiflu drug clinical trials management.
- The private network consisted of regulators, pharma, and contract research organizations (CROs).
- Smart contracts have two layers – regulatory and trail.
 - The regulatory contract consists of trial protocol, end point, time lines, and methods.
 - Trial subjects and data are appended to trail 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://1100one.research.com/articles/3-25-17/v1>

7

Blockchain Technology – Promising Use Cases for Healthcare Industry





The current CeBIL projects

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1) ICE AGE



2) JURFAST



3) Reconceptualising Reproductive Rights



4) POLICYAID



5) Collaborative Research Programme in Biomedical Innovation Law (the "CeBIL" programme)

ново nordisk fonden

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



UNIVERSITY OF
COPENHAGEN



INNOVATION

MIND THE GAP

HARVARD
LAW SCHOOL



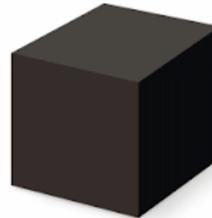
HARVARD
MEDICAL SCHOOL



UNIVERSITY OF
CAMBRIDGE



Michigan Law
UNIVERSITY OF MICHIGAN LAW SCHOOL



Antibioti

Orphan
drugs

Precision
& Black
box

New

Manufacturi
ng Biologics



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

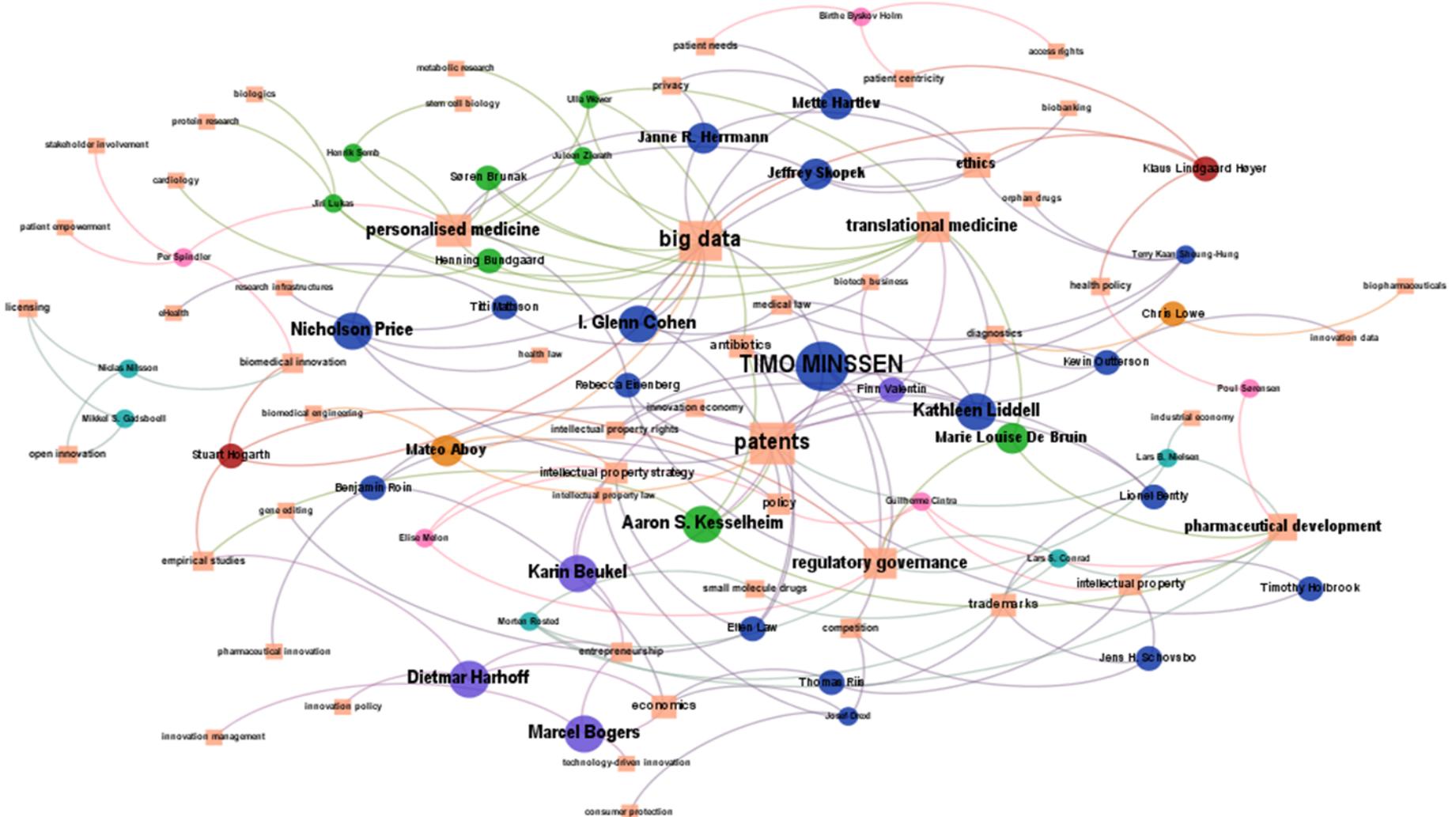


Figure 3: Mapping of Expertises in CeBIL's expert and support network



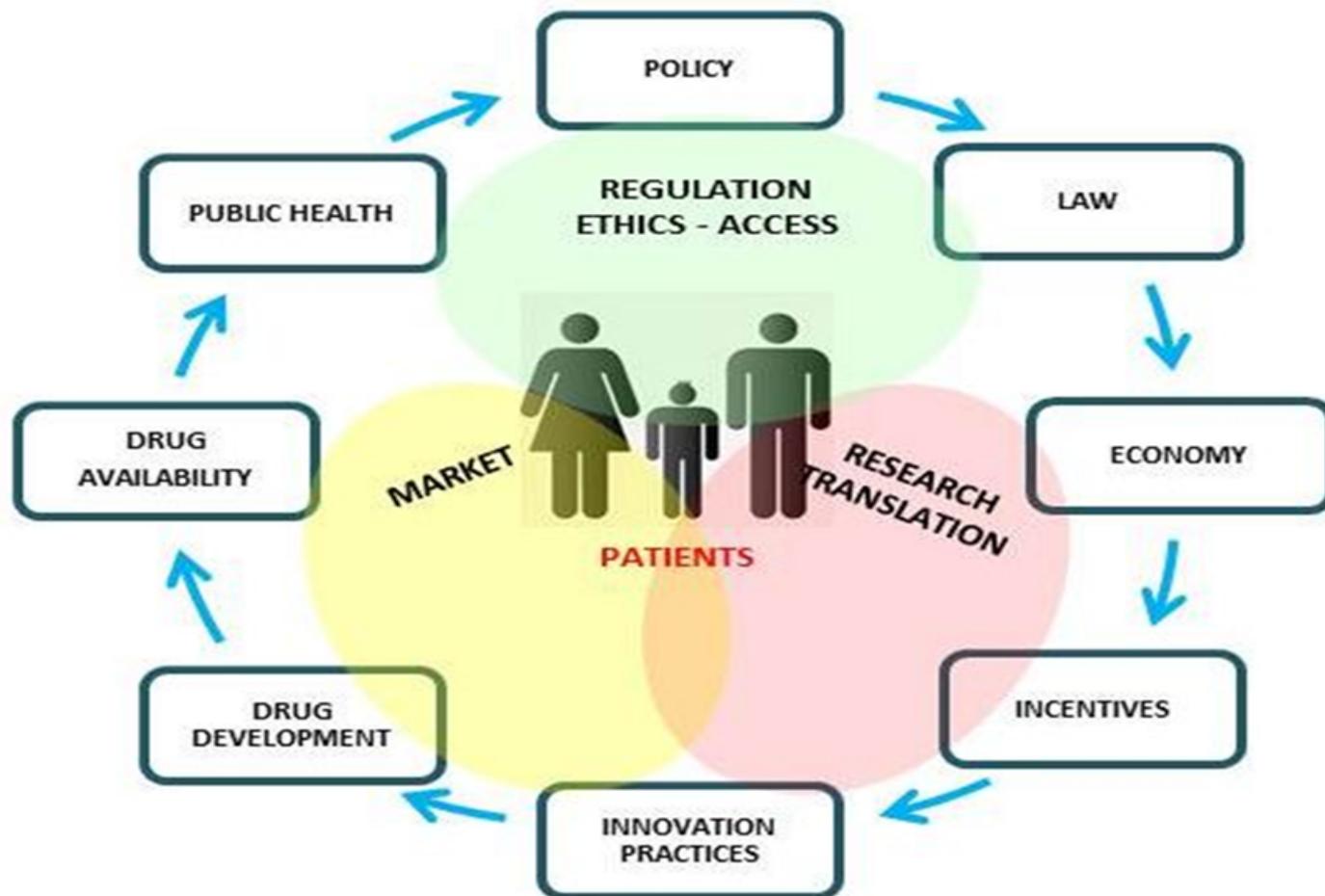
Why CeBIL?

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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





E-mail: Timo.Minssen@jur.ku.dk

Facebook: [CeBIL.Center](https://www.facebook.com/CeBIL.Center)

Twitter: [@CeBIL_Center](https://twitter.com/CeBIL_Center)

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

Web: www.cebil.dk

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



novonordiskfonden





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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



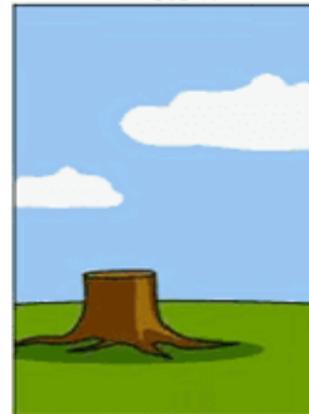
How the project was documented



What operations installed



How the customer was billed



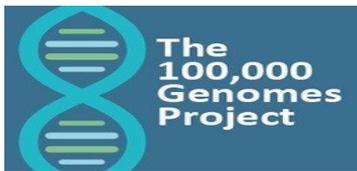
How the helpdesk supported it



What the customer really needed



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



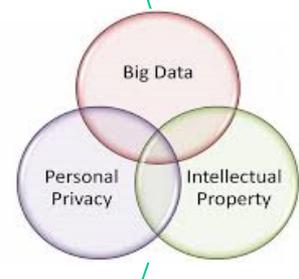
1. Regulation of digital health products & services



5. R&D incentives & regulation in precision medicine



2. Data transparency & clashes with Personal Data protection



4. Data accumulation, standards & competition law



3. Data transparency & Clashes with IPRs and CCI





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



eHealth



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