ALEXIS ABBOUD, CENTER FOR BIOLOGY AND SOCIETY

FOURTH ANNUAL CONFERENCE ON GOVERNANCE OF EMERGING TECHNOLOGIES: LAW, POLICY, AND ETHICS

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# PRINCIPLE VS. PRACTICE IN OPEN SCIENCE DATA-SHARING CONSORTIA

# RECENT POLICY INITIATIVES

- Improve medical outcomes in the United States
- Encourage data sharing and collaboration for clinical and research purposes
- Accelerate formation of medical information commons



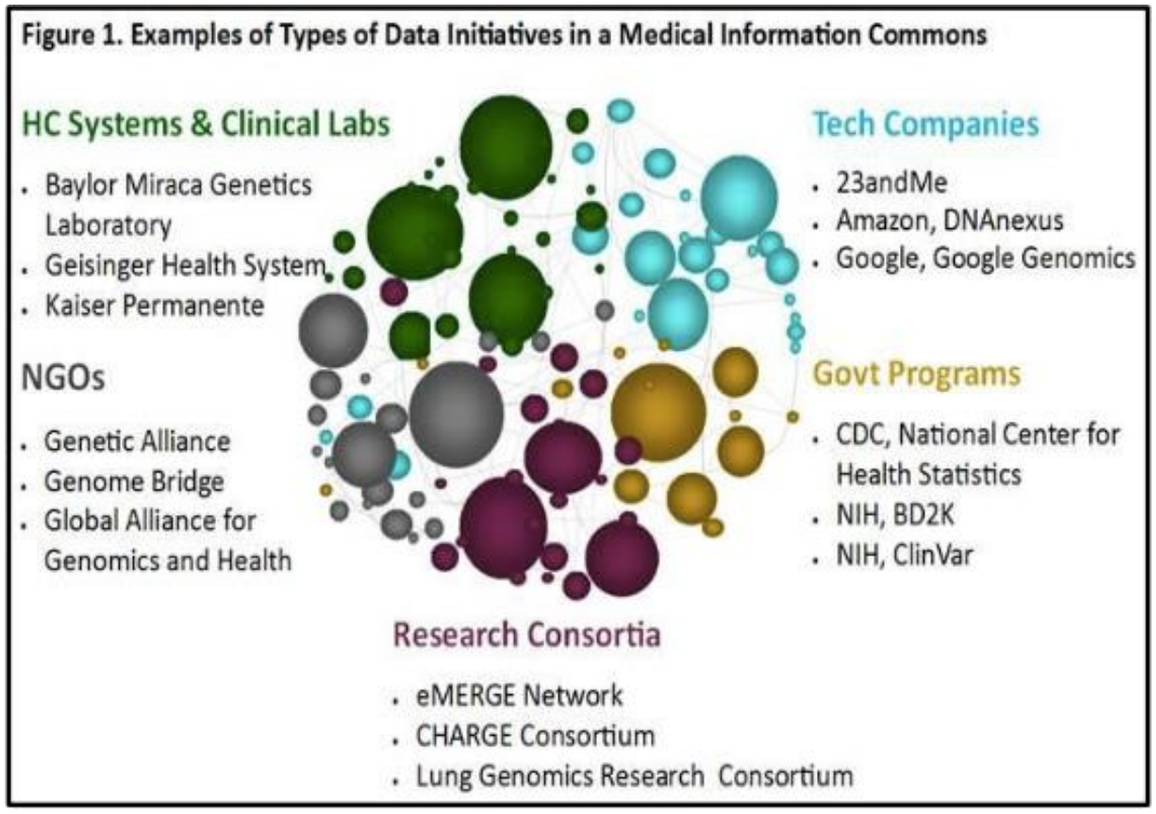
# MEDICAL INFORMATION COMMONS

- A commons: a resource used by all and owned by none
- A medical information commons: a network of diverse health, medical, and genomic data on large populations
  - Central issue: protecting the rights and interests of individuals contributing data to the commons
- Policies established piecemeal
- Lack of infrastructure, policies, and practices for a national or global commons

# LANDSCAPE ANALYSIS OF EXISTING CONSORTIA

- Determine current policies and practices of existing consortia
- Identify problems and successes of established consortia

- Consortia analyzed include:
  - Sage BioNetworks
  - BRCA Share
  - dbGap
  - Protein Data Bank



# OPEN SCIENCE PRINCIPLES

- Commitment to open science
  - Explicit links to Bermuda Principles, Fort Lauderdale Principles
  - Internal, institution specific principles
- Main theme:
  - To encourage data sharing while protecting rights of participants

# MAJOR TAKE AWAY

*open science policies are difficult to put into practice*

# FIVE EMERGING ISSUES

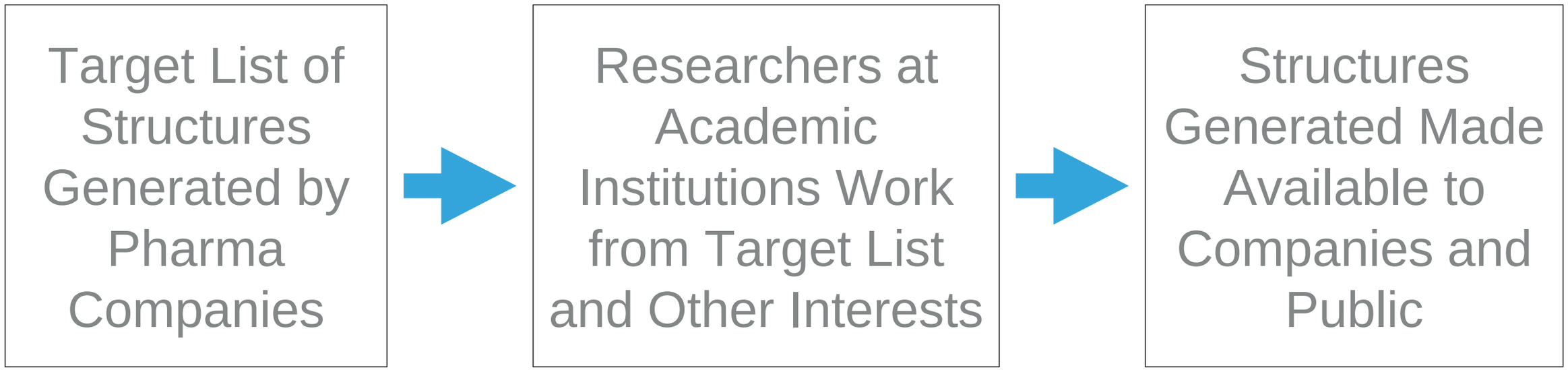
1. Intellectual property rights and incentivizing participation
2. Access to data

SGC

MONTREAL NEUROLOGICAL INSTITUTE AND HOSPITAL
*McGill University*

# STRUCTURAL GENOMICS CONSORTIUM

- A collaborative between pharmaceutical companies and academic researchers interested in drug targets and the relevant biological structures



# STRUCTURAL GENOMICS CONSORTIUM

- Changing IP Policy:
  - 2004: “what if” clause that allowed for assertion of IP rights in circumstances for which it might be necessary to foster subsequent development
    - Not invoked over 5 year period
  - 2009: retrospective implementation of strict IP rule - no “what if”
- Described as socializing process: first see the benefit of the consortium before asking them to give up patent rights[3]

# MONTREAL NEUROLOGICAL INSTITUTE

- An institution-wide open science policy:
  - Data shared freely within the Institute
  - Institute itself would become a “no patent zone”

- Develop an open science framework for an academic institution
  - Richard Gold at the Centre for Intellectual Property Policy (CIPP) at McGill’s Faculty of Law
  - Interviewed Institute researchers about obstacles

# MONTREAL NEUROLOGICAL INSTITUTE

- Obstacle: Need for researchers to benefit from research prior to release
  - Intellectual property rights
  - Loss of competitive advantage
  - Reaction of commercial partners
  - Threat to future funding
- Obstacle: Safeguarding patients' rights

# SECOND EMERGING ISSUE

## 2. Access to data

ONE MIND™

# ONE MIND

- Facilitates the development of diagnostics, treatments, and cures for brain illnesses and injuries while striving to reduce the stigma associated with brain disorders
- Develop an open model for neuroscience research:
  - Creation of high-quality sharable research data
  - Standardization of common data elements and common data entry systems
  - Linking data: molecular, clinical, and demographic

# ONE MIND

- Original Mindset: Contact between data generators and data users would taint analysis
  - Contact constrained
- Recent changes connecting data generators and users
- No contact between patient groups and researchers
- Balance between the value of contact between individuals and risk of contact

# CONCLUSIONS FOR MEDICAL INFORMATION COMMONS

- Widespread commitment to open science principles and data sharing
- Real world application difficult
- Groups evolve and adapt to problem solve
- Future Steps: Continued landscape analysis & stakeholder interviews

# ACKNOWLEDGMENTS


- “Building the Information Commons” (NIH ELSI R01 HG008918), Co-Principal Investigators Robert Cook-Deegan and Amy McGuire




# QUESTIONS?

# PRINCIPLE VS. PRACTICE IN OPEN SCIENCE DATA-SHARING CONSORTIA

- Sources:
  - 1. Amy McGuire and Robert Cook-Deegan, NIH ELSI R01 HG007 grant
  - 2. “Building a Framework for Open Science at the MNI: Report for comments from the MNI Executive Group, October 2015”
  - 3. Interview with Aled Edwards. 16 October 2015
  - 4. Interview with Stephen Johnson. 17 December 2015
  - https://www.nih.gov/precision-medicine-initiative-cohort-program
  - http://energycommerce.house.gov/cures
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  - http://www.thesgc.org
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  - http://apps.mni.mcgill.ca/yourstory/
  - https://cbs.asu.edu/resources

# BUILDING A MEDICAL INFORMATION COMMONS

- NIH ELSI grant to establish best policies for creating such a medical information commons
- PIs: Amy McGuire and Robert Cook-Deegan
- "Develop … a framework for sharing data and building a medical information commons with informed input … from key expert stakeholders [and] from members of the public"[1]



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