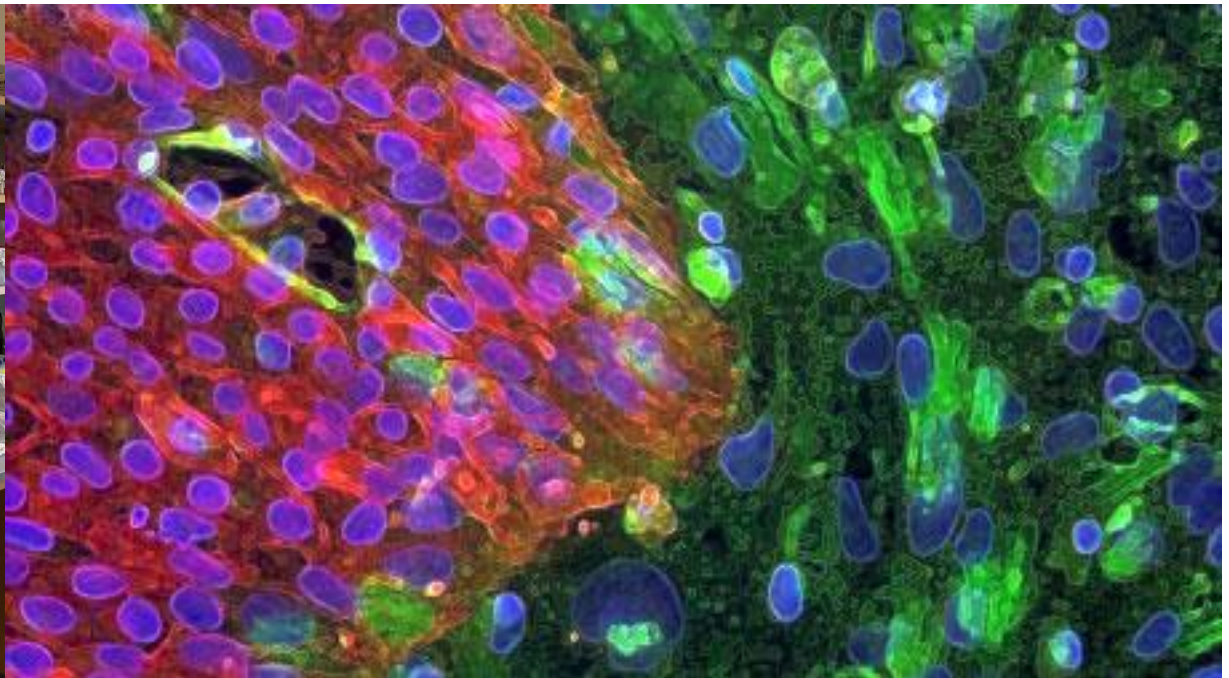


# INTELLECTUAL PROPERTY AND THE MOUSE COMMONS

Tania Bubela



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**SCHOOL OF PUBLIC HEALTH**



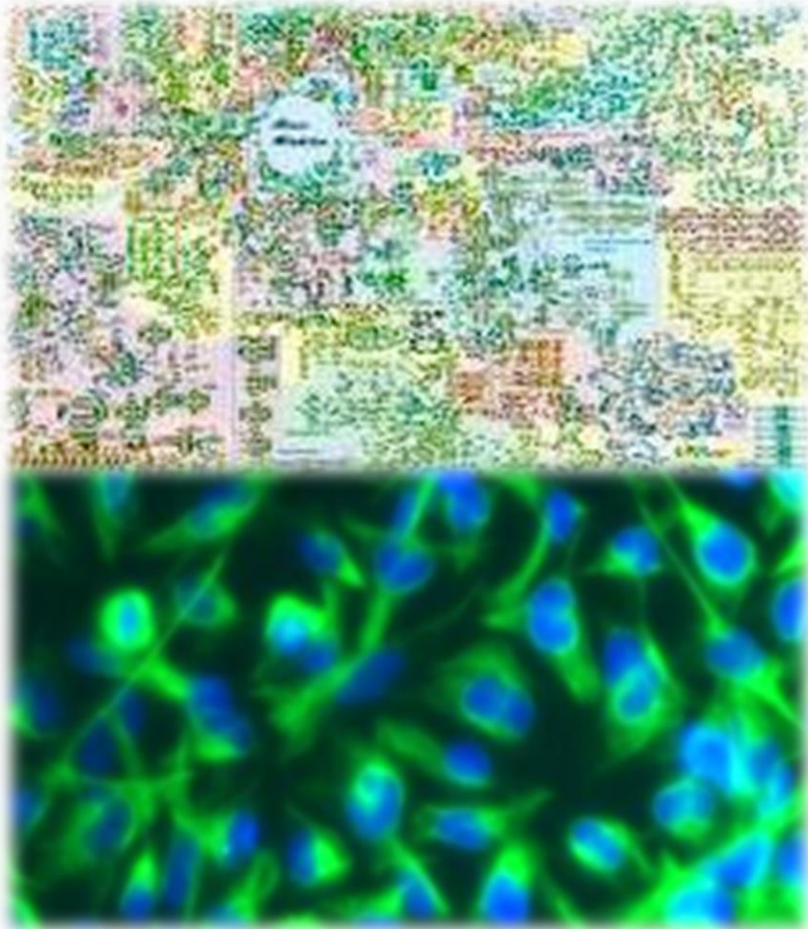
# KEY POINTS



- MTAs mediate exchanges of data and materials.
- MTAs should embody data and materials sharing policies and guidelines for incentivizing the creation of research commons.
- Use simple conditions of use or avoid altogether.
- MTAs should enable knowledge flows, reduce transaction costs for data and materials, and support the pre-competitive research environment.
- Need for more creative and simplified MTAs.



# TRANSLATIONAL FIELDS



- Highly Collaborative
- Multi-national
- Multi-disciplinary
- Multi-sectorial

# PRE-COMPETITIVE RESEARCH



- Raises the level of knowledge for all R&D actors.
- Does not limit appropriation of innovation that is closer to practical application.
- Avoids duplicative research.
- Reduces negotiating costs associated with an abundance of intellectual property rights.

# INFRASTRUCTURE



- Improve the tools and techniques for successful clinical translation.
  - DATABASES
  - BIOREPOSITORIES
  - BIOBANKS
  - GMP
- Promote use of standard research tools and methods.

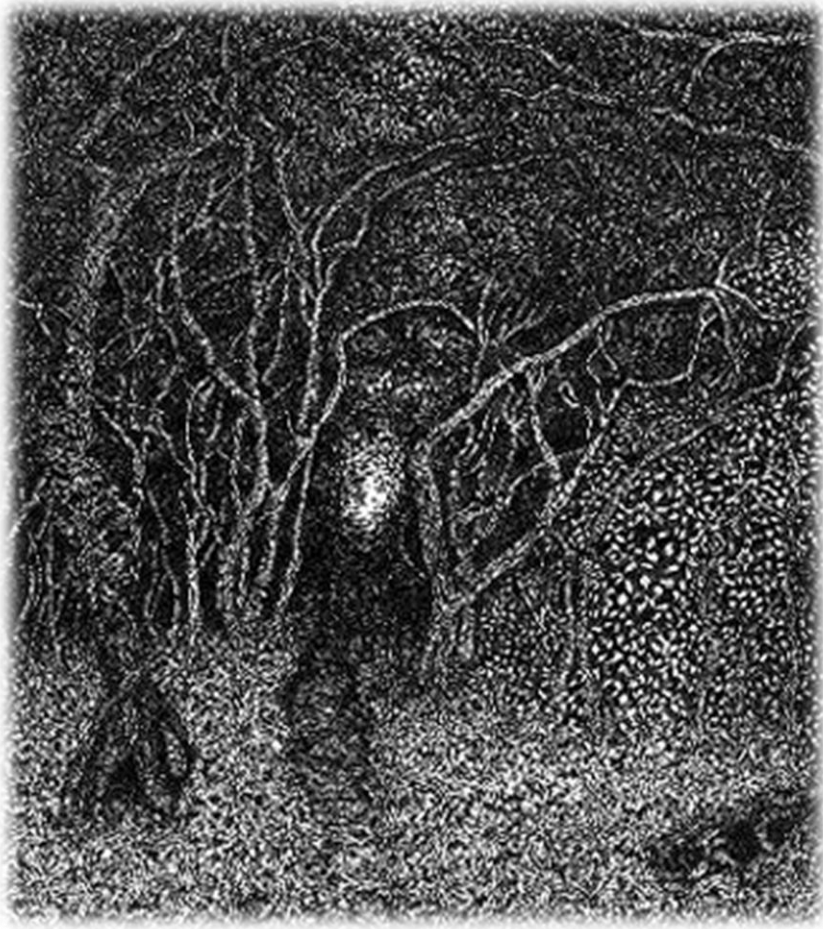
# Value of Infrastructure



- Value enhanced as *more* people use the resource - “network effect”.
- Must be managed to facilitate: use, but also *re-contribution* from the user community, creating a *feedback loop* between withdrawal, value-added research, and deposit.  
(Schofield, et al., *Nature*, 2009)



# INTELLECTUAL PROPERTY RIGHTS



- Issues of IP acquisition
- Issues of IP management
  - Within
  - Output

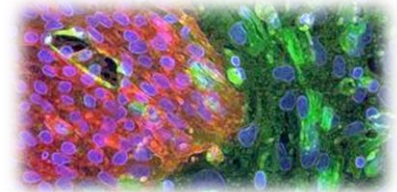
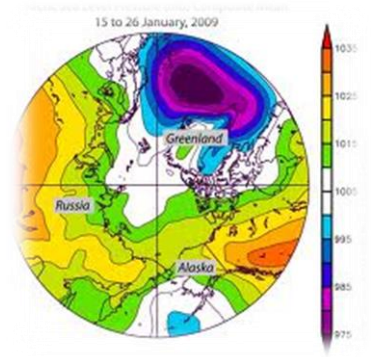
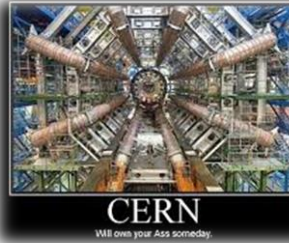


# CONTRACTUAL AGREEMENTS



- Collaborative Research/Consortium Agreements
- Material Transfer Agreements
  - Multi-sectorial
  - International
  - Outcomes Oriented
  - Contracting Cultures

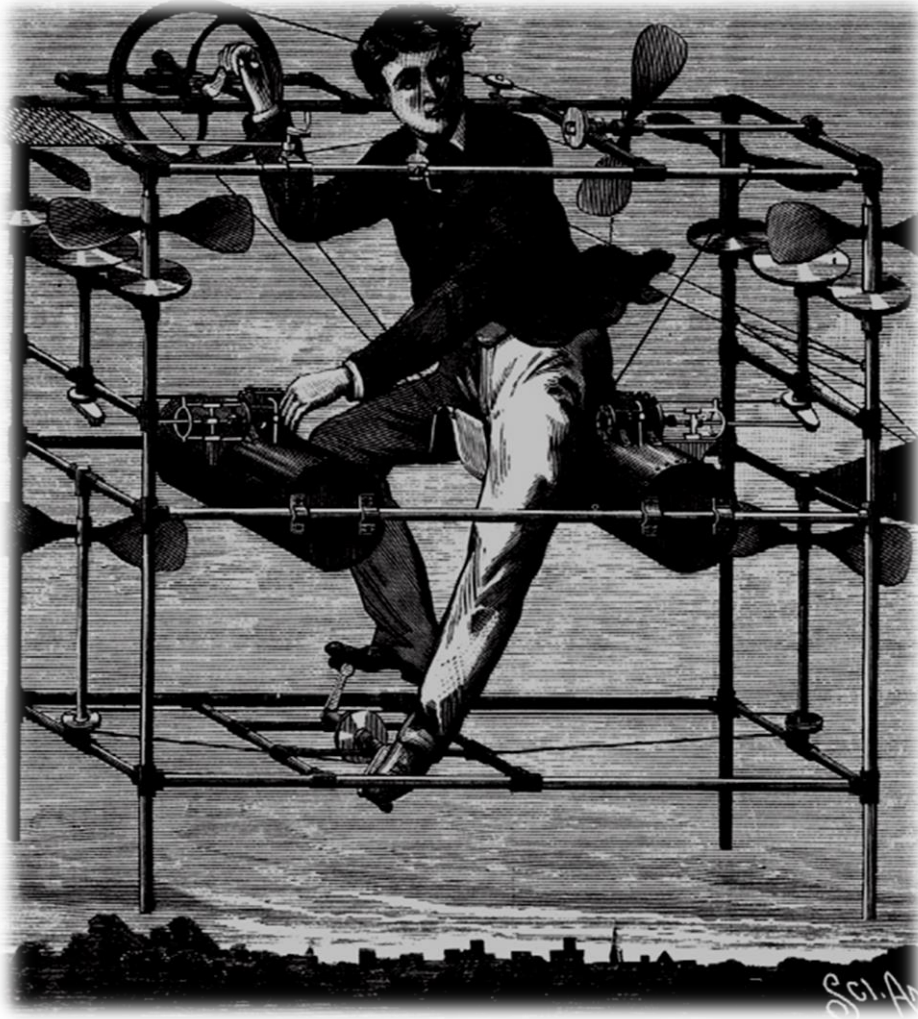
# CHALLENGES NOT UNIQUE





# LESSONS FROM THE MOUSE COMMUNITY ON GOVERNANCE OF RESEARCH COMMONS

# METHODS



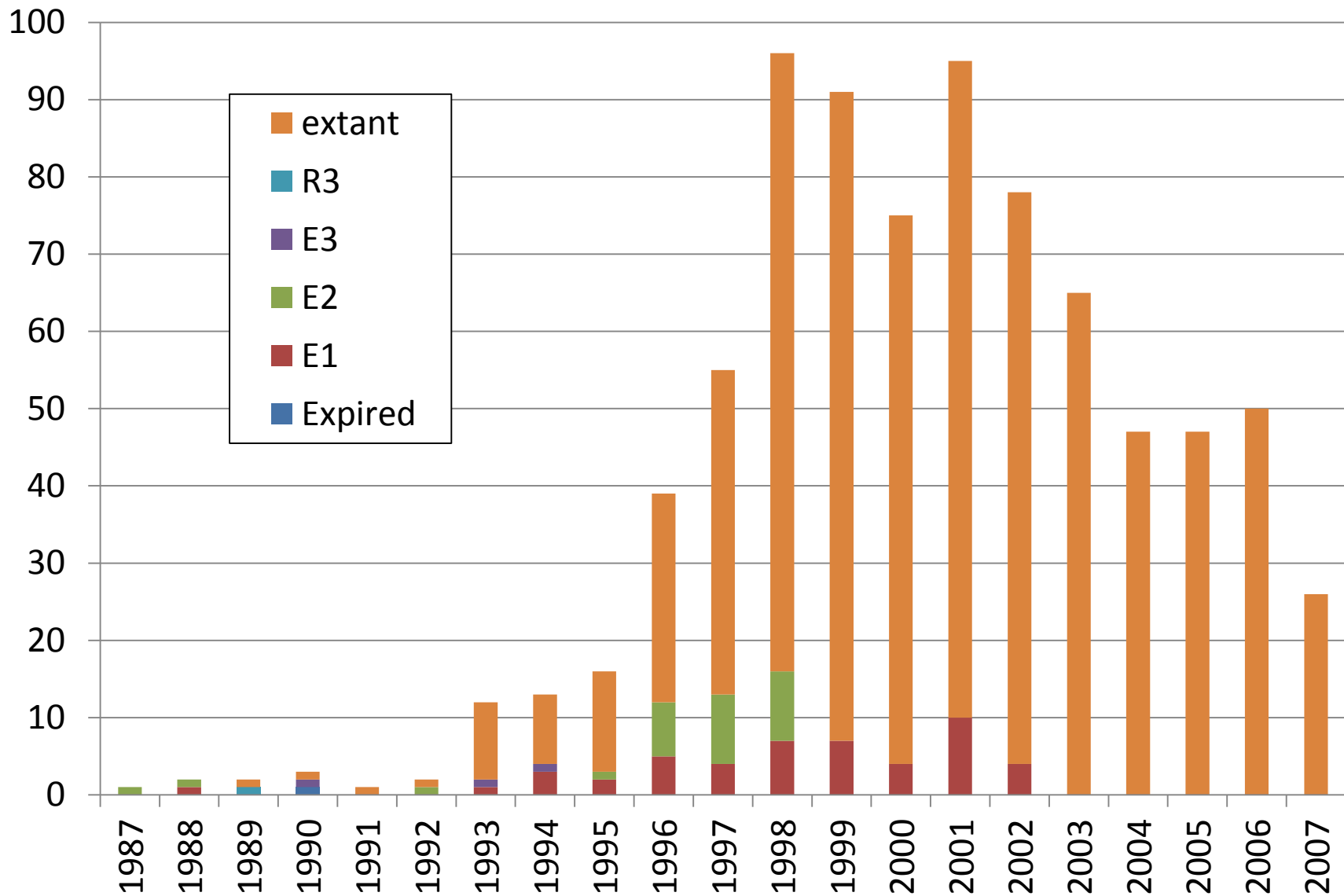
- Patent Claims Analysis
- Bibliometric & Scientometric Analyses
- Interviews
  - IKMC – 36
  - IMPC – 55
- Online Survey



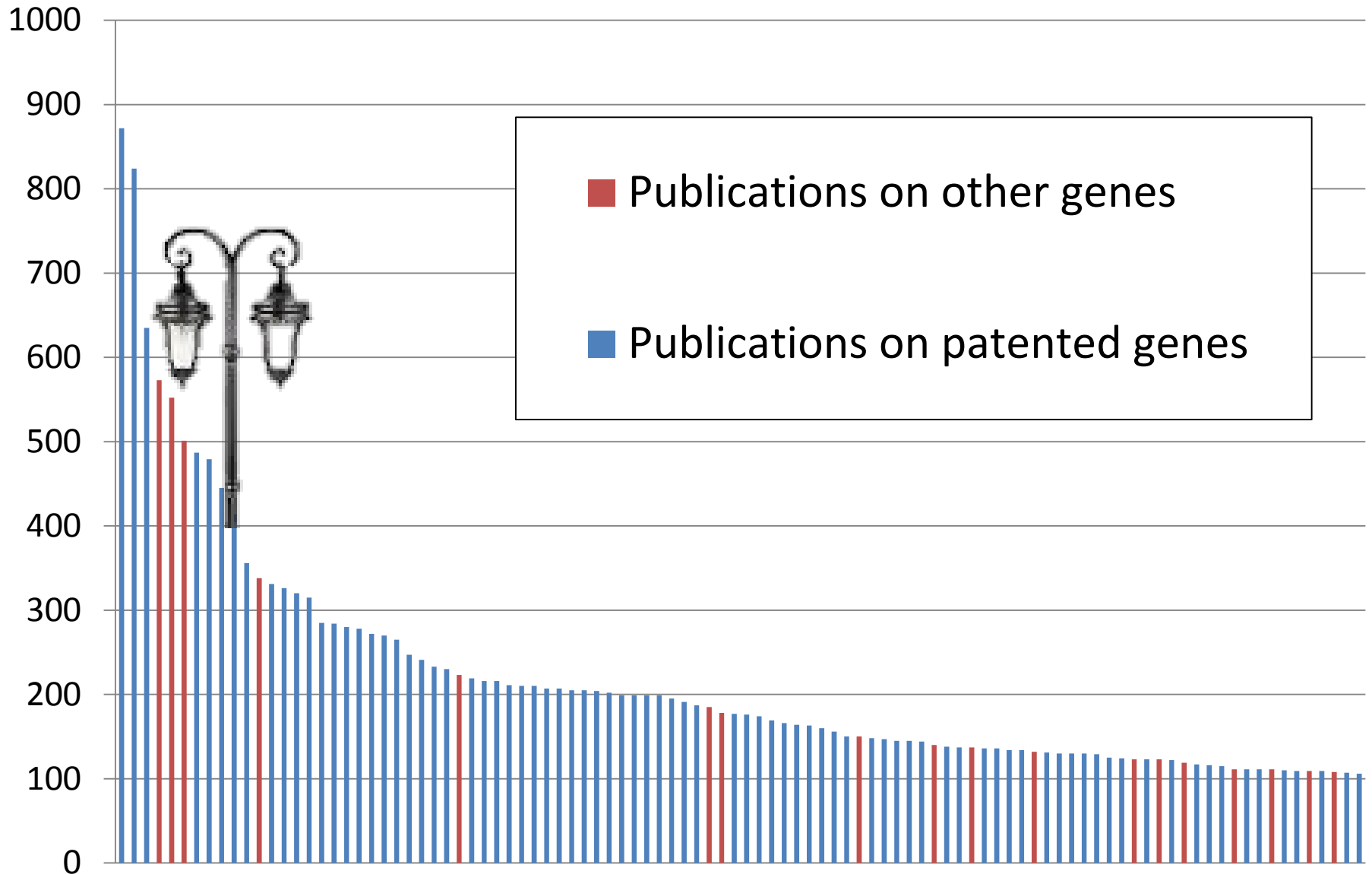


**Does the legacy of basic research patents created under current laws and practices hinder the establishment of mouse resources?**

## STATUS AND FILING DATE OF 816 MOUSE GENE PATENTS (US)



# PUBLICATIONS (>100) ASSOCIATED WITH PATENTED VERSUS UNPATENTED MOUSE GENES



# METHODS PATENTS

## Problematic for construction of resource

- Coding frame developed with experts
- Include product
- Broad/specific method

- BAC
- Positive/negative selection
- FLP/FRT Recombinase
- Isogenic DNA
- Recombineering
- Electroporation
- PhiC31

- Cryopreservation
- Gateway Technology
- Cre/Lox
- inverse PCR
- F0/F1mouse
- Vector
- Homologous Recombination

- Method used in Gene Trapping/Targeting
- **Total = 105 Patents coded**
- **New methods– zinc finger proteins, Talens, CRISPR**



# BACKGROUND IP IMPACTS HIGH-THROUGHPUT RESOURCES

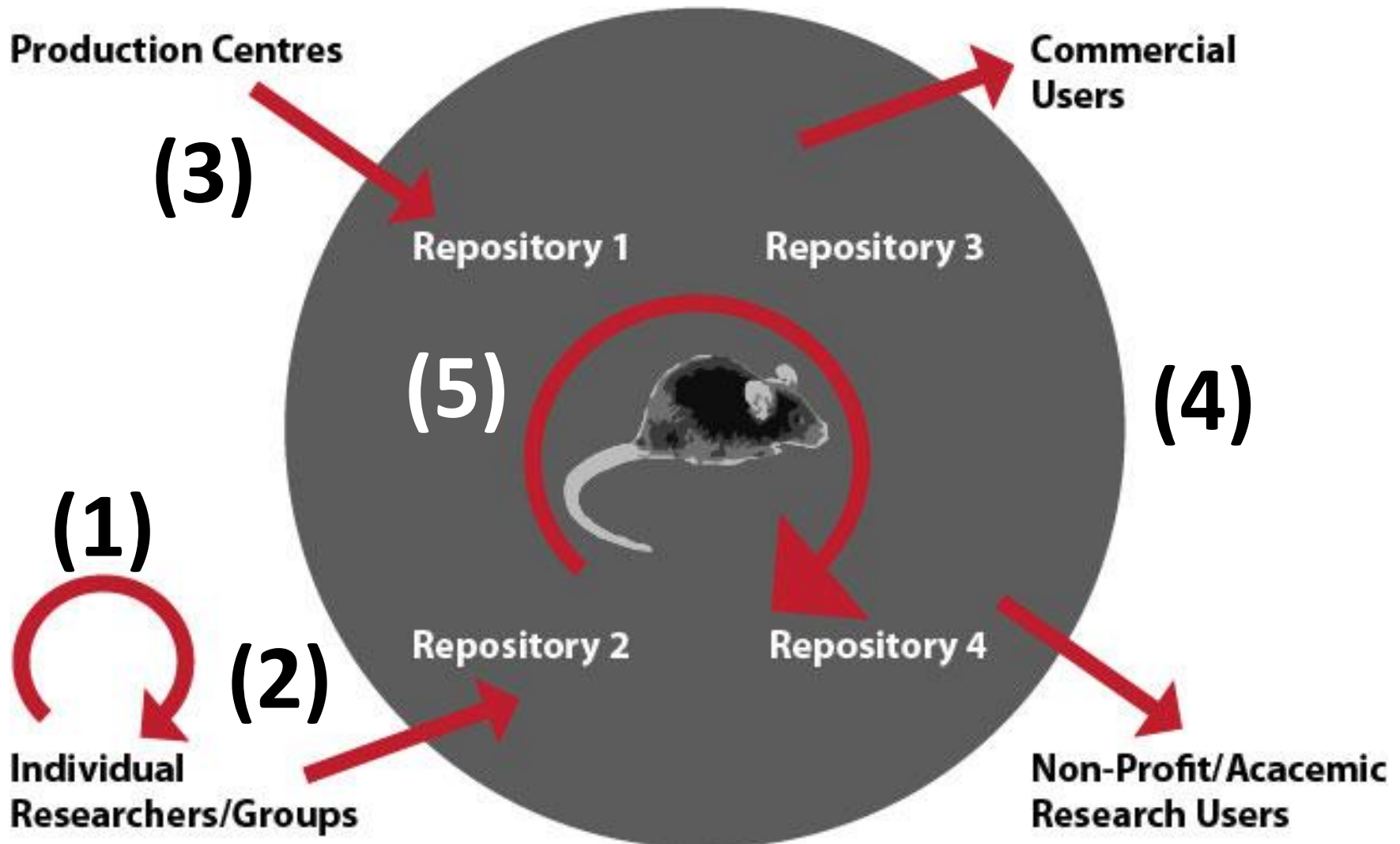


- Practising/non-practising entities.
- Post-hoc rent seeking behaviour.
- Drives behaviour of risk averse institutions.
- May discourage commercial users.
- But litigation Rare.
- Greater protections in US



**Does the management of  
Intellectual Property Rights  
hinder the distribution and use  
of mouse resources?**

# MTAs – central mediators of exchange



# INTERVIEWS & SURVEYS CONVERGE



- MTAs are substantial disincentive to accessing and providing materials.
- Problematic in context of research and funding timeframes.
- Delays not acceptable when no/little commercial value.
- Sharing facilitated through use of UBMTA/equivalent.
- **OR Simple Conditions of Use**



# COMPLEXITY NOT PROPORTIONAL



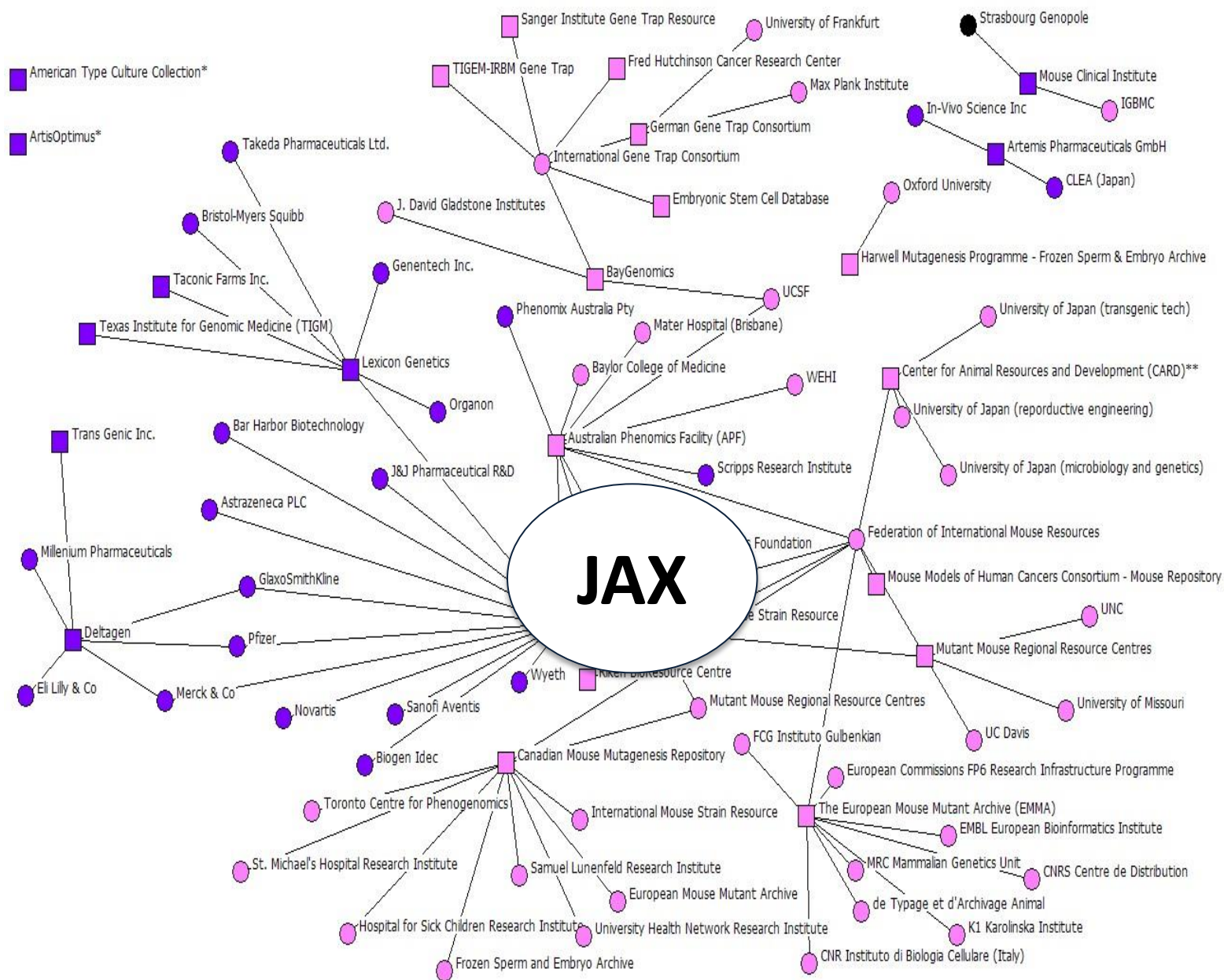
preparing for  
**complexity**

- Complexity of MTAs should be commensurate with potential commercial value.
- Institutions have limited ability to monitor terms.

# REPOSITORY MTAS



- Repositories support access to publicly generated research reagents.
- Encourage unrestricted donation, including **standard simple conditions** for distribution to nonprofits.
- **LEGAL INTER-OPERABILITY:** Highly variant MTAs hamper deposit of materials and create an administrative burden for repositories for distribution.
- Commercial restrictions.
- **Attribution important for the long-term sustainability of repositories.**



**Mouse Repository Network – Actors by Institutional Type**

**Public/Private**  
**Private**

# Best Practices



- Clear objectives
- Simple/Standard as Possible
- Commercial vs Non-commercial
- Non-exclusive
- Retention Of Rights
- Attribution
- Liabilities/warranties

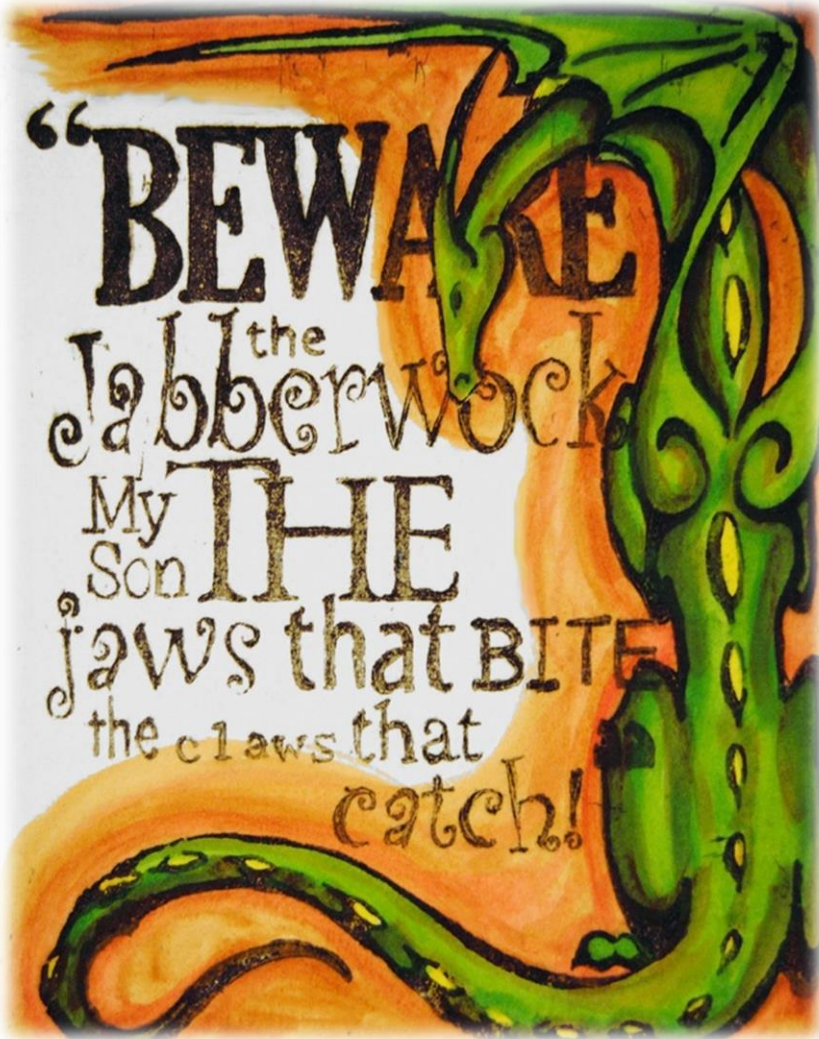


# Best Practices – No Reach Through



- No reach through regardless of reason.
- Reach through extends rights beyond what may fairly be attributed to originator of materials.
- Realistically unenforceable!

# Realistic Risk Management



- Base on realistic assessment of value, patent term and enforcement capacity.
- Focus on enabling objectives vs managing for all foreseeable risks.
- Litigation is an indicator of transactional value – virtually non-existent for MTAs.

# IMPC – CONSORTIUM MTAS



- IMPC directors agreed that standard MTAs could optimize the movement of materials and associated data between consortium members.
- Inertia stems from institutional risk aversion which may not reflect realities of the consortium's operational needs.
- Participants agreed that project MTAs need standard terms for overall efficiency.
- Distribution to commercial entities problematic but necessary for long-term sustainability?





**What do users think?**

# USER VIEWS



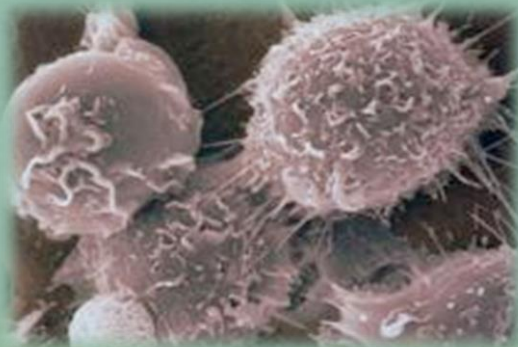
- Financial and time costs of depositing materials in bio-repositories are disincentives.
- Many users unaware of IKMC and IMPC.
- Awareness raising must be balanced against capacity to deliver.
- New tools may impact utility of resource.
- User trust takes time to establish—QC, timeliness, simplified transactions.



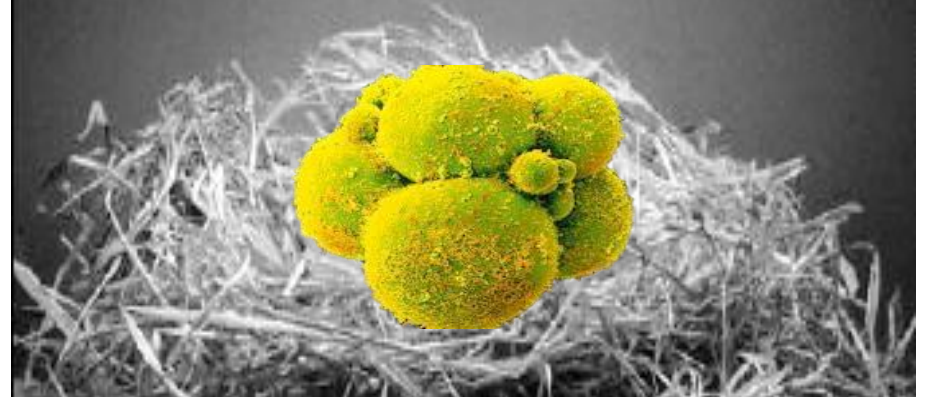
# CONCLUSIONS

- Material Transfer Agreements (MTAs) are central mediators in exchanges of data and materials.
- MTAs should embody policies and guidelines that incentivize data and materials sharing and foster related community norms.
- Complex MTAs and protracted negotiations frustrate sharing, create transactional bottlenecks and are unlikely to be monitored and enforced.
- Standard and simple agreements, decrease the administrative burden for repositories, institutions, and researchers and facilitate the creation of a research commons.

SCIENCE IS HARD



SHARING  
SHOULD NOT  
BE HARDER??





**THANK YOU**





# Acknowledgements

## Research Personnel

Amrita Mishra, Mark Bieber, Jenilee Guebert, Rhiannon Adams, Andreas Strotmann, Cami Ryan

## Key Collaborators

Paul Schofield, David Einhorn, Lauryl Nutter, Colin McKerlie



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