



INFRAFRONTIER / IMPC workshop

Promoting the international exchange of mouse mutant resources

May 8 - 9th, 2014

Peter Wells
Director Technology Transfer
The Jackson Laboratory



THE JACKSON LABORATORY

David Einhorn – big shoes to fill



**US
Size 13**

**EU 45
Jap 29.5
UK 11
Korea
279**



Two Questions:

1. What is the trend in patenting genetically modified mice (GMM)?
2. What is the value of a genetically modified mouse in a commercial license ?



Trend in Patenting Genetically Modified Mice

1. US Data only (but some filing from outside us)
2. Source of Data USPTO
 - US Patent Class 800 “Multicellular Organisms”
 - Sub Section 018 “Mouse”
 - Claims must include words “Mouse or Mice”

(87) PCT Pub. No.: **WO00/41561**
 PCT Pub. Date: **Jul. 20, 2000**

(30) **Foreign Application Priority Data**

| | | | |
|---------------|------|-------|------------|
| Jan. 14, 1999 | (JP) | | H11-007365 |
| Aug. 12, 1999 | (JP) | | H11-228282 |
| Oct. 29, 1999 | (JP) | | H11-309238 |

(51) **Int. Cl.**
A01K 67/027 (2006.01)

(52) **U.S. Cl.** **800/18; 800/3**

(58) **Field of Classification Search** 800/3,
 800/18, 22; 435/252.1
 See application file for complete search history.

(56) **References Cited**

OTHER PUBLICATIONS

Vacheron et al. Induction of interleukin 1 secretion by adjuvant-active peptidoglycans. Infection and Immunity, 1983, vol. 42, No. 3, pp. 1049-1054.*

immunity, vol. 9,
 Research for Evc
 Science and Tech

Primary Examiner
Assistant Examiner
 (74) *Attorney, Agent*
 Kinberg; Venable

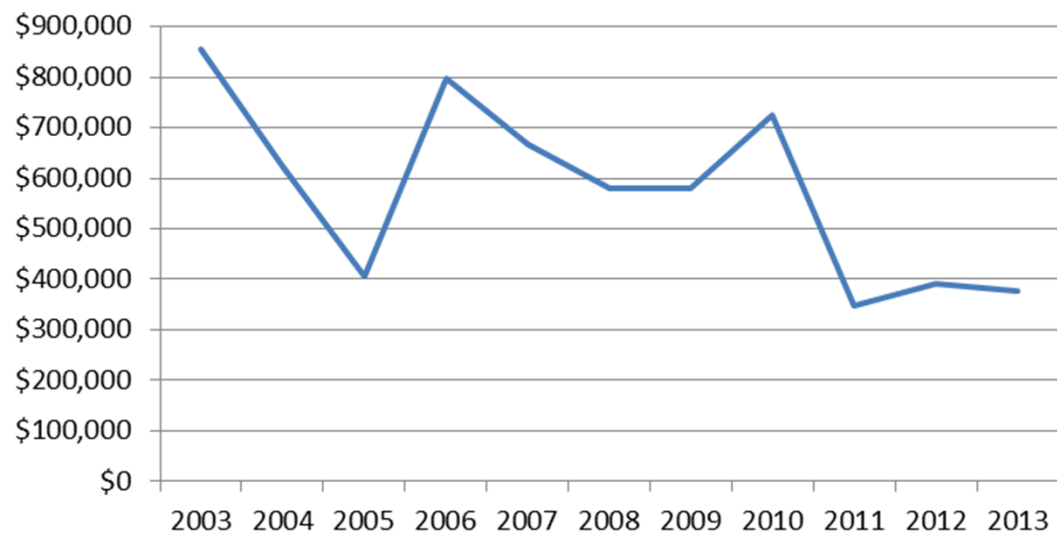
(57)
 A knockout mouse
 a lipoprotein/lipo
 elucidating the co
 TLR family to a
 components in vi
 MyD88 in vivo.
 knockout mouse i
 steps of: a target
 whole or a part
 containing a cyto
 and the like with
 marker gene; the
 embryonic stem
 having a homolog



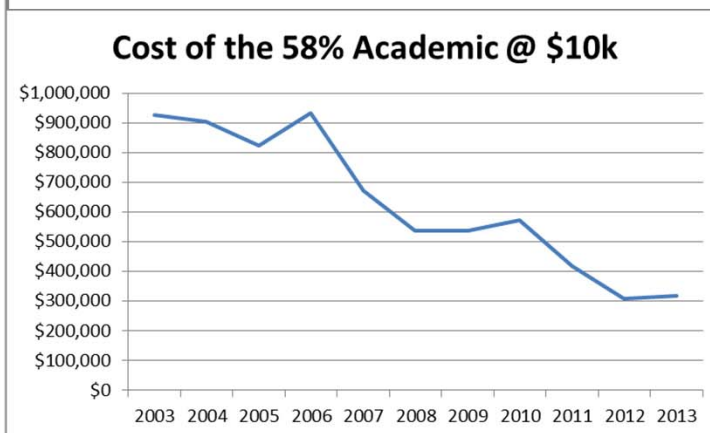
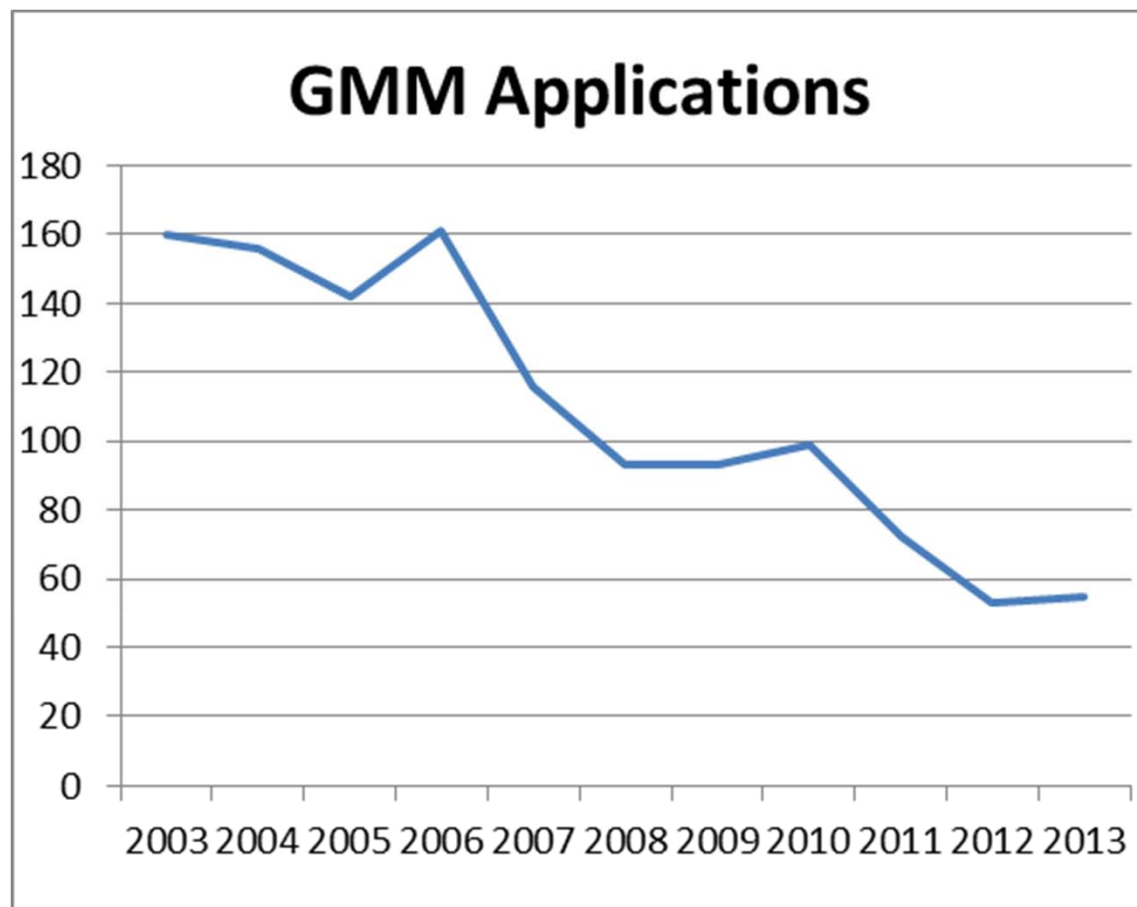
Issued GMM US Patents by Year



Cost to Issue @ 25k application



But could this be the result of tougher examination standards at the USPTO?

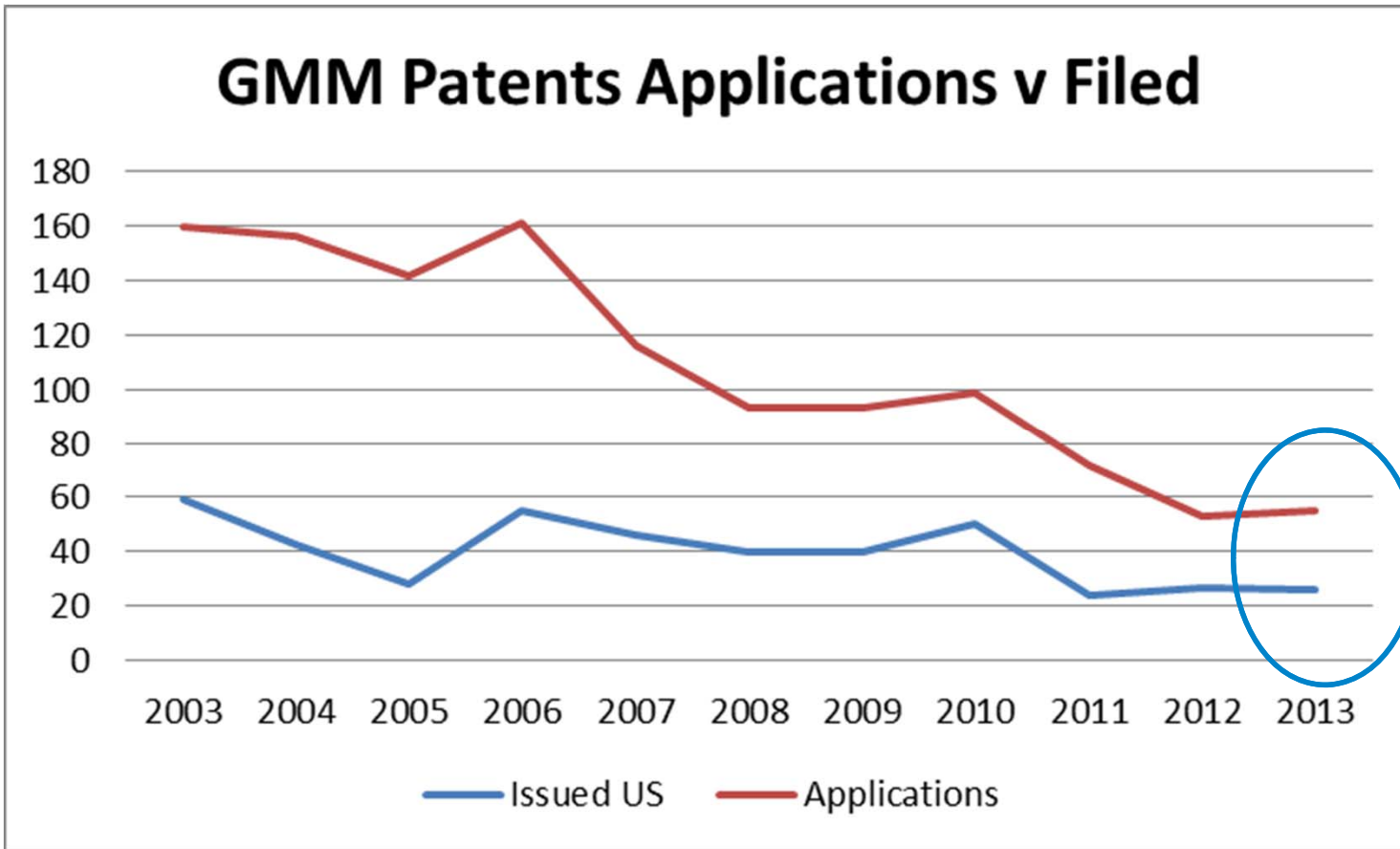


Applicants:
Academic: ~58%
Industry: ~42%

2005 – 2012
Academic
58% only
total:
\$4.8 m



Filing Less GMM Applications but better applications ?



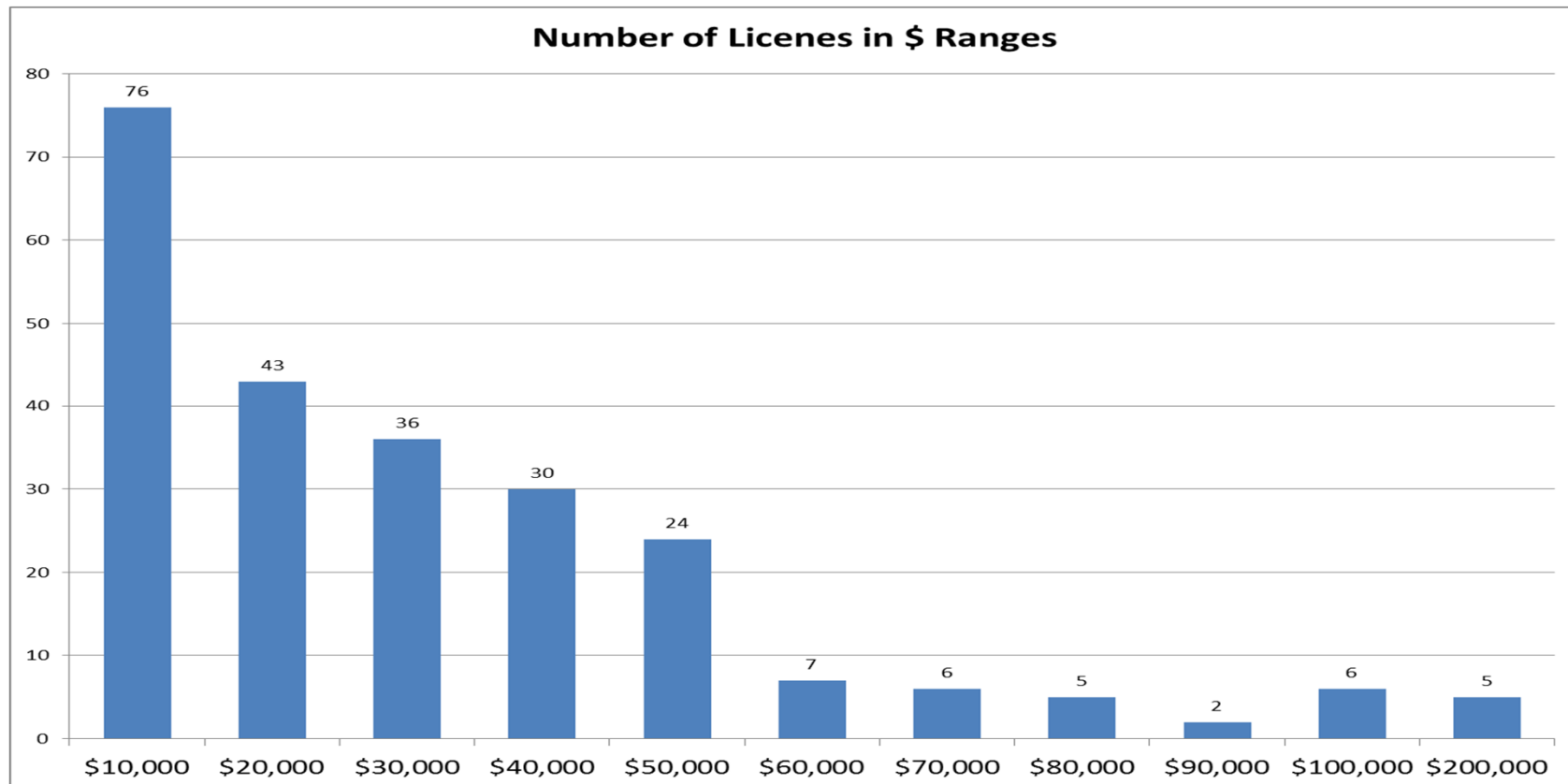
But there is still a 50% failure rate



What about licensing ?

- Simple annual survey
- 2005 – 2012 (Amalgamated Data) 240 licenses
- Most licenses are one time flat fee
- Some have annual maintenance – typically low fee

240 licenses
50% under
\$20k
Total Value
\$6.7m



Genetically Modified Mouse Patent Filing:

Trend Down

Flat Fee Mouse Licenses:

50% Under \$20k

Average \$~30k (but biased by a small number of high value licenses).

What makes a valuable mouse strain ?



Use in research ?

International Mouse Strain Resource (IMSR)

 [Search](#) [Repositories](#) [Participate](#) [Glossary](#) [Contact Us](#) [About Us](#) [Deposit Strains](#)

Summary

Search for: [Search](#) [Reset](#) [+ Show Options](#)

You searched for:
Query: Apoe
74 strains(s) match your unfiltered search.

Filters: [Remove All Filters](#) [Mutation: targeted mutation](#)

<< first < prev 1 **2** next > last >> 25 ▾

47 item(s) match after applying filter(s). Showing items 1 - 25 of 47

Apoe, targeted mutations, 47 versions various forms – MANY AVAILABLE



Grant Applications

Under Text Search “Apoe&knockout”

U.S. Department of Health & Human Services

NIH Research Portfolio Online Reporting Tools (RePORT)

Search

HOME | ABOUT RePORT | FAQs | GLOSSARY | CONTACT US

QUICK LINKS | RESEARCH | ORGANIZATIONS | WORKFORCE | FUNDING | REPORTS | LINKS & DATA

Home > RePORTER > Query Form

NIH RePORTER Version: 0.3.0

RePORTER Login | Register System Health: GREEN

ABOUT RePORTER DATA | FAQ | EXPORTER | RePORTER Manual | RSS of Newly Added Projects

QUERY | BROWSE NIH | MATCHMAKER BETA

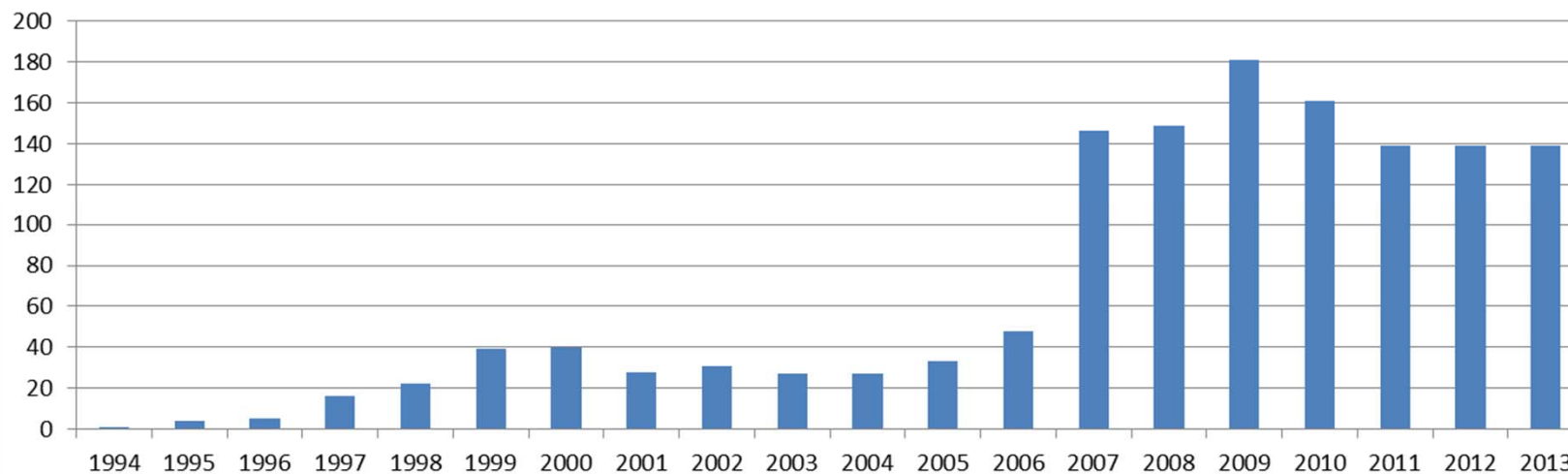
SUBMIT QUERY | CLEAR QUERY

Fiscal Year (FY): Active Projects

RESEARCHER AND ORGANIZATION

Principal Investigator (PI)

RePort Grant entries



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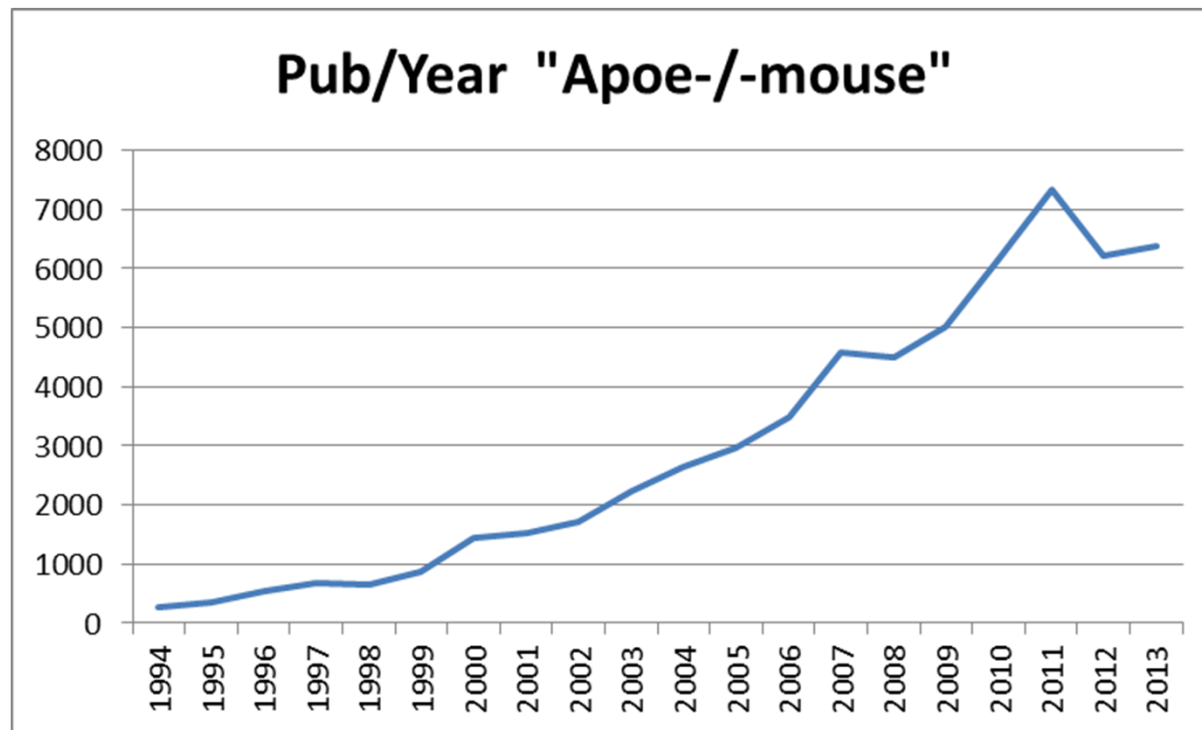
Publications ?

By Year x “ApoE-/-Mouse”

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☒ Articles ☐ include patents ☐ Case law



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Resource and data sharing

The Rome Agenda

NATURE, Vol. 461, 10 September 2009

The Rome Agenda

Access to data and materials

- The data on which publications are based should be made available immediately through public databases on publication. Journals should insist that mice or embryonic stem cells are deposited in a public repository within a specified time frame.
- It should become mandatory for publications to explain where and how to access data and materials generated during the investigation. Publications should acknowledge any other data or materials used, the originating sources and availability.
- Grant reviewers should be provided with clear guidelines to assess data and material sharing plans and whether these have been met in the application, and whether the mechanism of sharing proposed would meet appropriate

goals if the work was to be funded or ultimately published.

- Funding organisations should be willing explicitly to cover the costs of deposition of materials arising from projects as part of the project budget.

Licensing and patenting

- The public sector should patent mice as research tools only under exceptional circumstances.
- Licensing terms for mouse resources or research methods should promote the establishment of a mouse 'research commons'.
- Materials and data should be shared under the least restrictive terms possible. Material transfer agreements for sharing materials between academic and not-for-profit institutions should be avoided or simplified.
- Researchers should be free to

breed shared mice for internal research purposes and to cross-breed to develop new mouse models.

- Licensing of mice or methods for commercial use should include a broad reservation of rights for academic and not-for-profit institutions.
- Licensing terms should not include inappropriate royalty reach-through or product reach-through on subsequent inventions, and institutional policy should reflect this.

Data and resource-sharing infrastructure

- Further dedicated sustainable investment in public databases and repositories should be encouraged.
- Funding agencies should provide researchers with clear direction on

expectations for data/resource/publication sharing, and should ensure appropriate data-sharing plans at the outset of projects and facilitate sharing as data and resources are generated.

Standards and tool development

- Data structure and semantics need standardizing and adopting.
- Metadata should be consistently attached.
- Investment is needed in computational tools to make use of standards and interoperability for data sharing and reuse.

Attribution and reward

- Attribution of data or resources should be enforced by journals and databases.
- A system for measuring attribution is needed to provide rewards for data sharing.

Paul N. Schofield, Tania Bubela, Thomas Weaver, Lili Portilla, Stephen D. Brown, John M. Hancock, David Einhorn, Glauco Tocchini-Valentini, Martin Hrabe de Angelis, Nadia Rosenthal and CASIMIR Rome Meeting participants.

