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Managing the pre-competitive research environment:

Evidence and Outcomes

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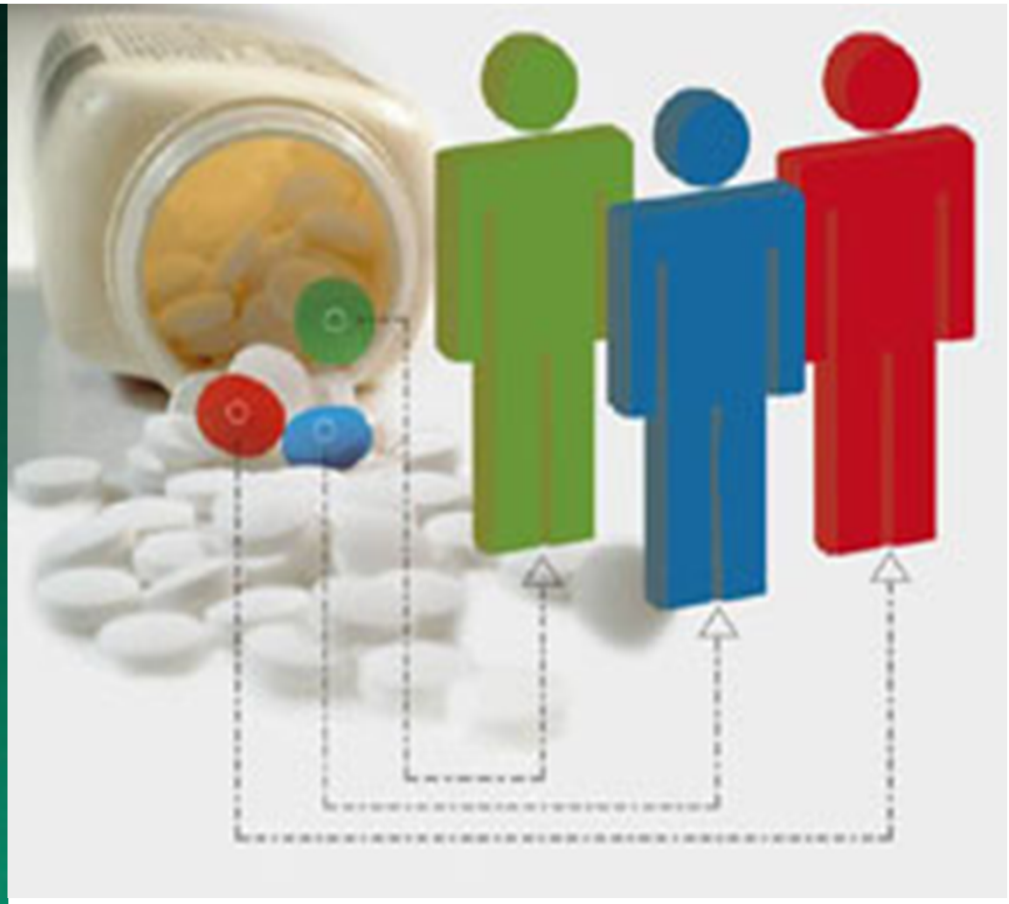
Precompetitive Research

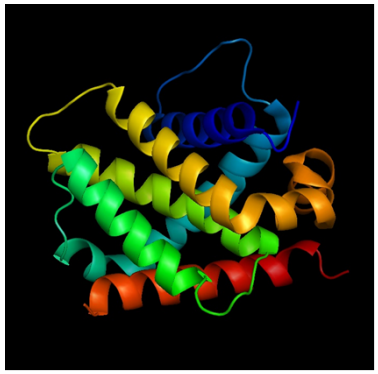
- ***improving the tools and techniques for successful translational research*** **(Woodcock, 2010)**
- **Current institutional and rule-based impediments to collaborative innovation models**
- **Incentives, Metrics, and Missing Data**
- **2 Empirical Studies:**
  - **Stem Cell Research**
  - **Mouse Models for Human Disease**

Statement of Problem - Therapeutics



PATIENTS AND PATIENT ADVOCACY ORGANISATIONS

raises the level of knowledge for all R&D actors without limiting their ability to appropriate knowledge and innovation that is closer to practical application



For Example – Research 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)


BOUNDARIES OF PRECOMPETIVE SPACE??
-needs tools & study
Parks Canada - Banff National Park

Rules in Use: (Focus on IP and Sharing)

- **FORMAL LAWS (IP, animal welfare, FDA)**
  - Often out of sync with new capabilities, community norms and technology
- **POLICIES AND GUIDELINES**
  - E.g., funding agencies, universities, journals, repositories, creative/science commons
- **INFORMAL RULES/ COMMUNITY NORMS/ PRACTICES**
  - Citation, attribution, reciprocity and sharing, publication,

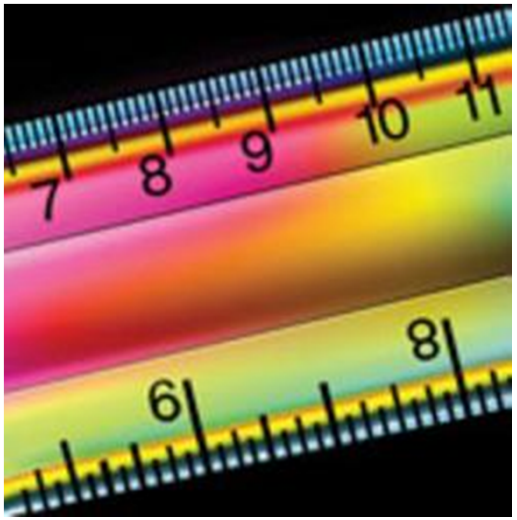
The Problem with Current Rules in Use

- No doubt of increasing commercialization pressure on publicly funded research institutions and their researchers
- Mediated through technology transfer offices
- Patenting as a proxy for commercialization and a signal of changing values and norms of a community (of users)
- Impact on community norms and trust?
- Impact on sharing/willingness to contribute to and use a resource?

Metrics aligned with commercialization objectives

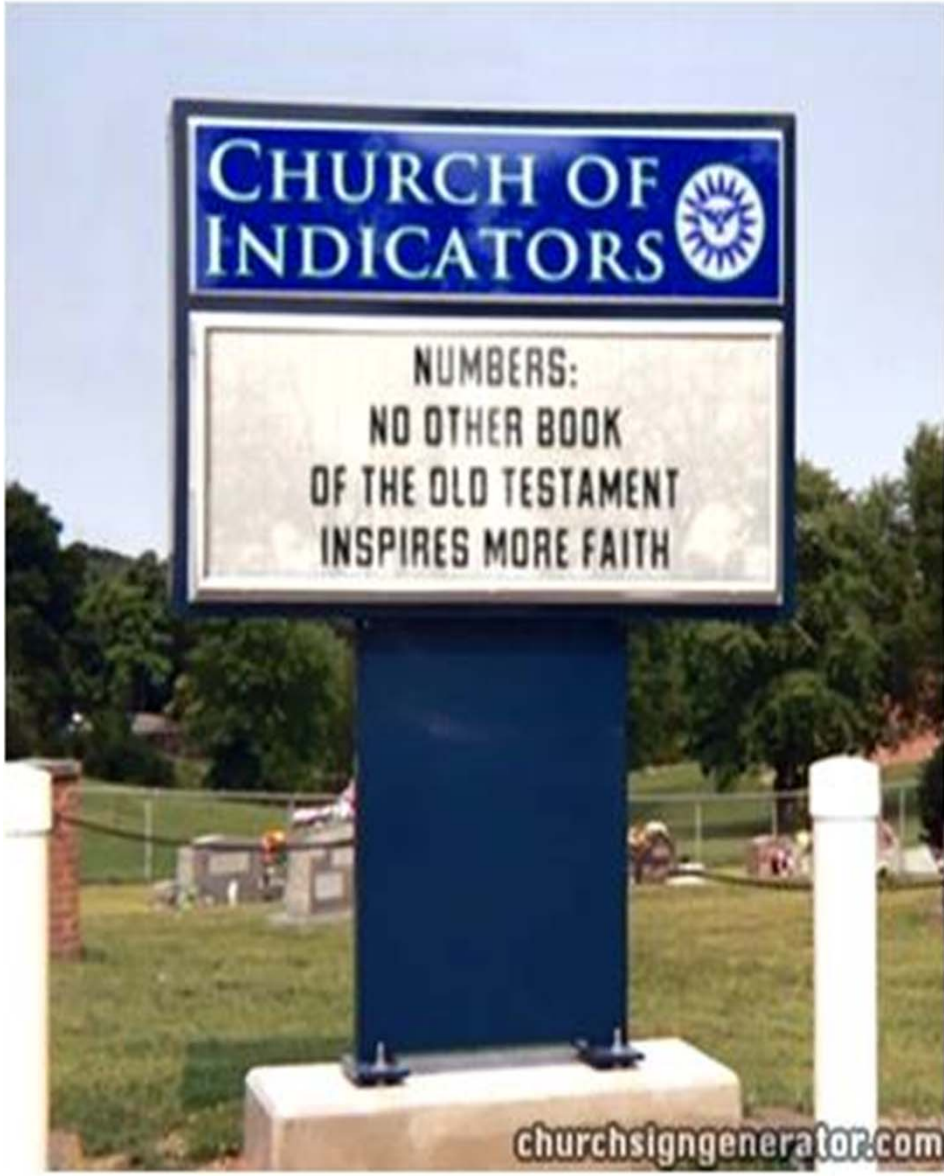
- **Matched to commercialization-based outcomes**
- ***You get what you measure. Measure the wrong thing and you get the wrong behaviors.“***

- John H. Lingle



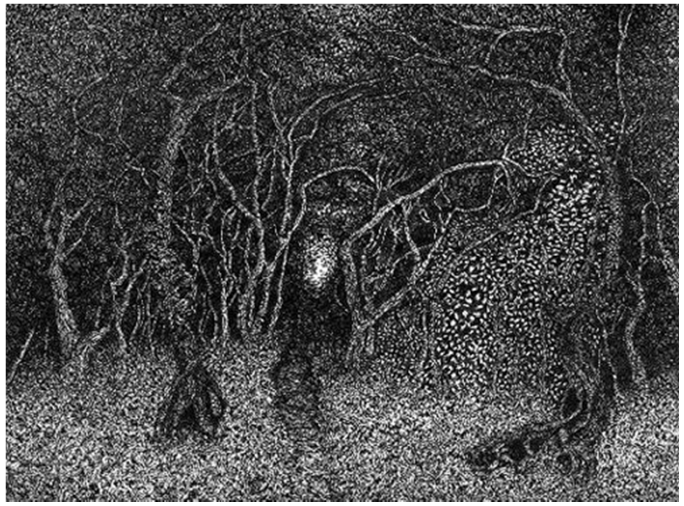
Current Metrics

- Economic
  - (OECD,
  - National Stats Offices)
- Aggregated
- Input/output
- Direct vs. indirect
- Correlation
- Simplistic
- Based on pipeline model



Encouraging Behaviours?

- Patenting
- Licensing for revenue generation
- Start-up Creation



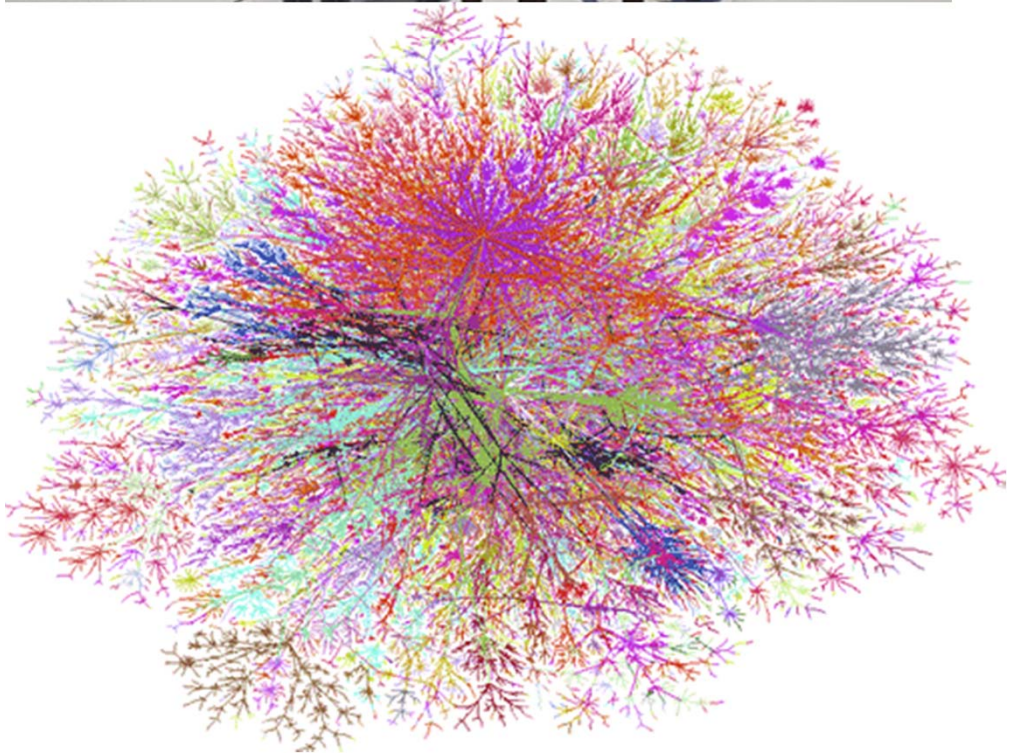
Impacts?

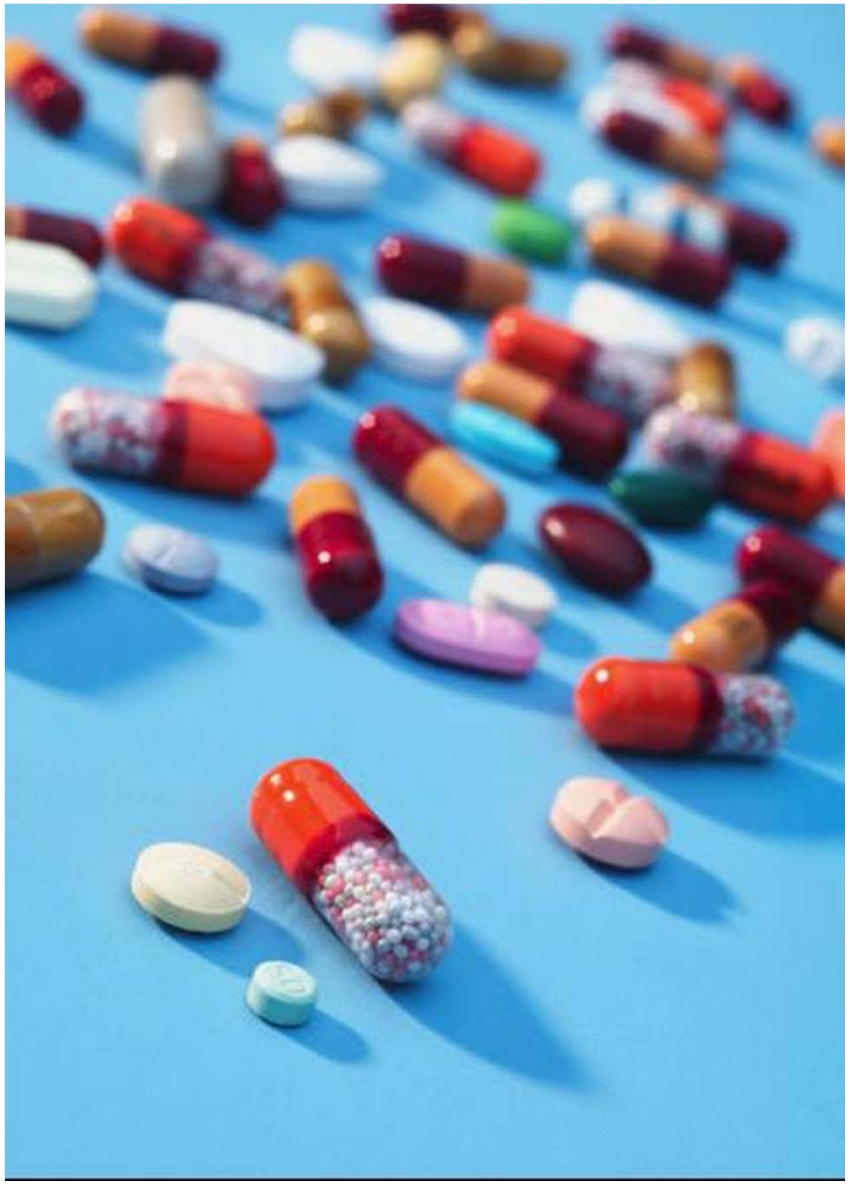
- Patent Thicket
- Culture of Science
- Access / Clinical Application

= Institutional and systemic inertia


Life Sciences Patenting
-Universities are actively patenting research tools
(Langford et al., 2006)
-Most patents are worthless and useless
(Kirsten, 2005)

Shift in Metrics






TRUST

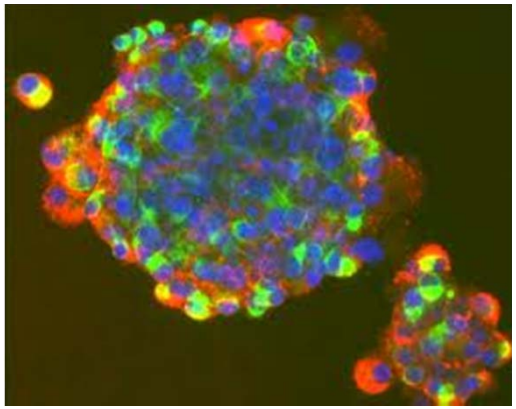
PUBLISHED AND PRELIMINARY EMPIRICAL STUDIES

ILLUSTRATE NEW METHODS IN NETWORK ANALYSIS AND BIBLIOMETRICS

Missing Data

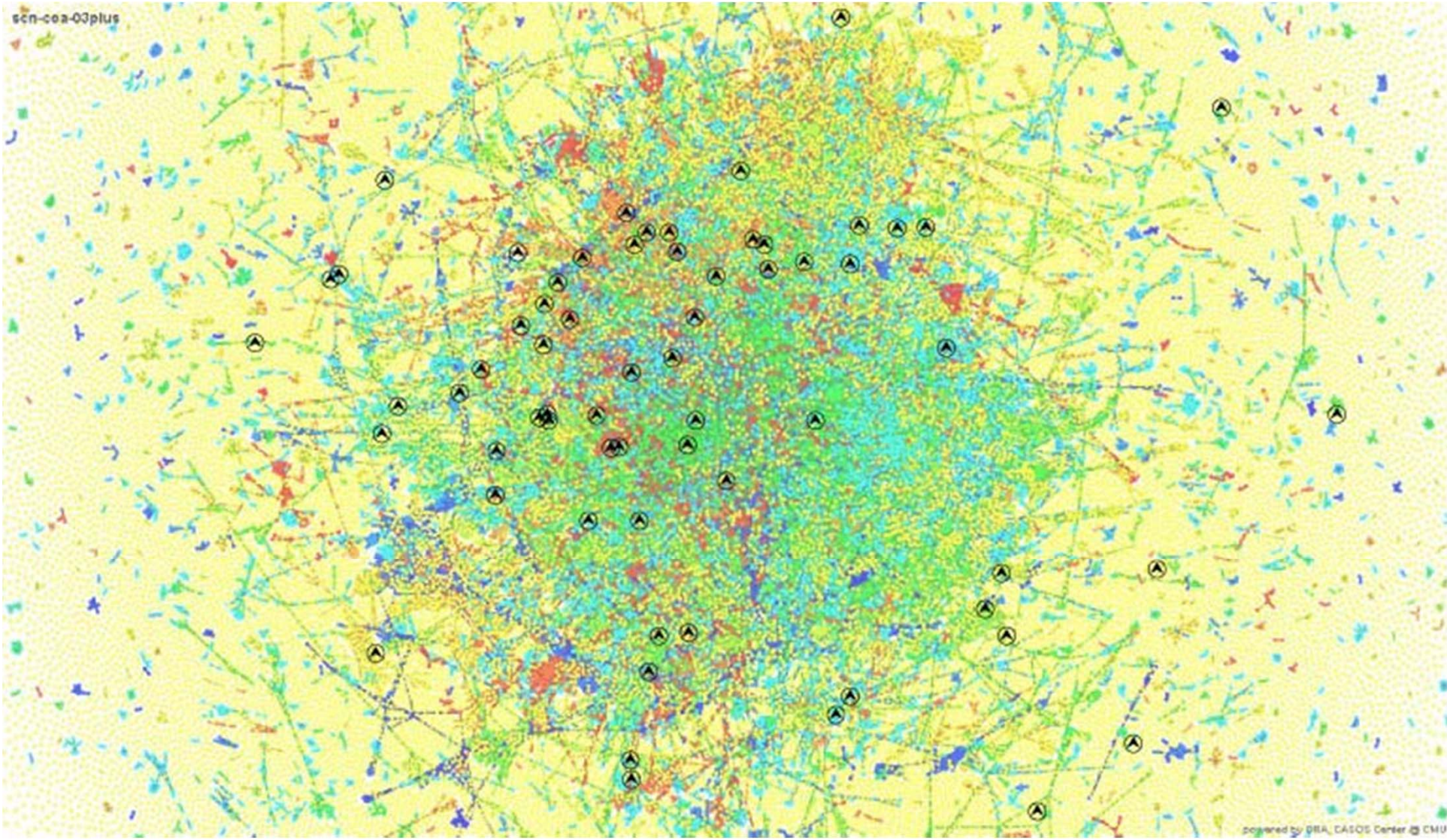
CASE 1: Stem Cell Network

(Bubela *et al.* Cell Stem Cell, 2010)

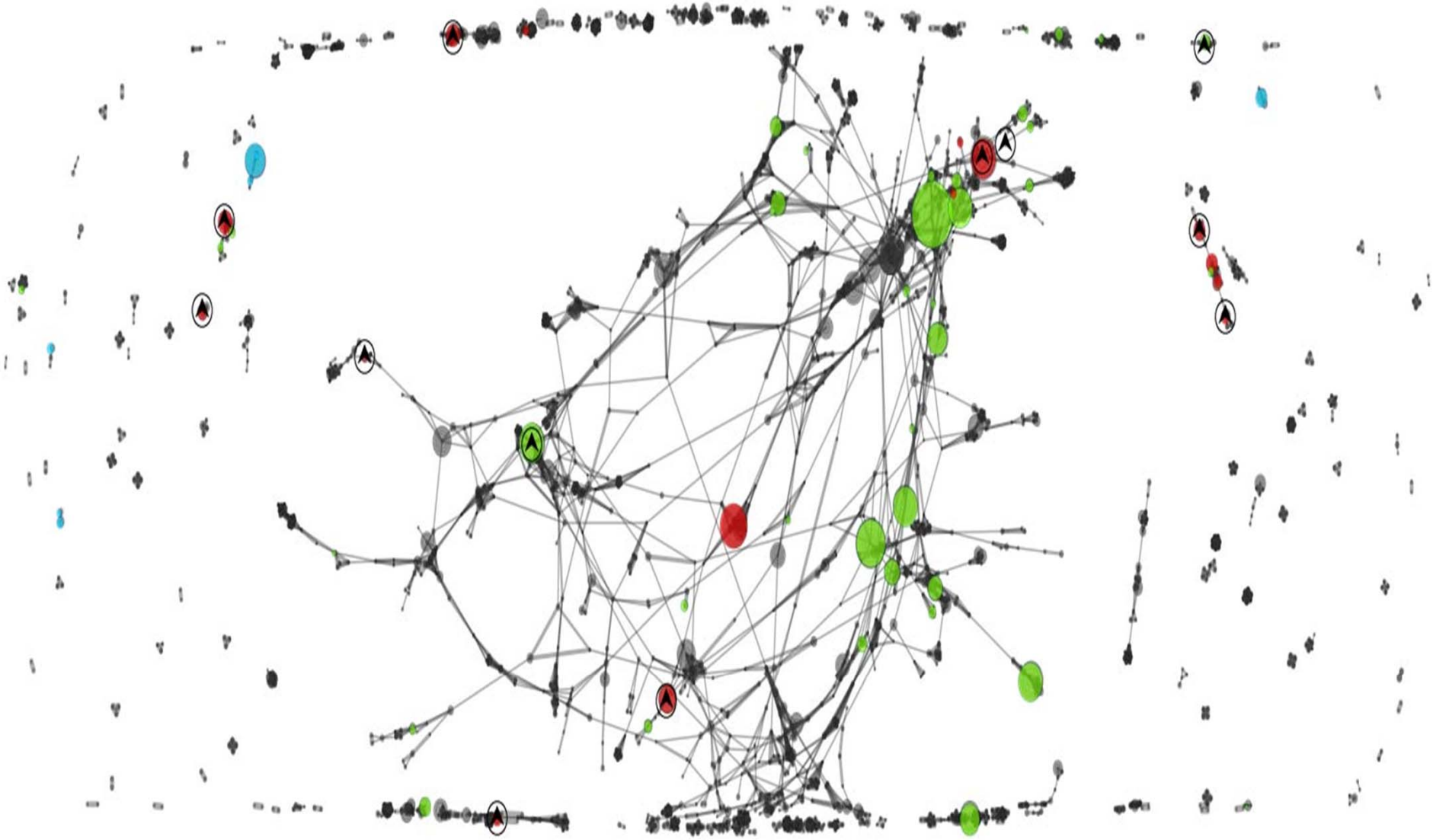


- **Networks of Centres of Excellence (NCE)**
- **RESEARCH GOAL:**
  - **impacts of SCN research,**
  - **the degree to which a collaborative research network has been established, and**
  - **conflicts between the mandates of the network - networking and commercialization mandates.**
- **New bibiolmetric methods**

International collaboration of stem cell network researchers

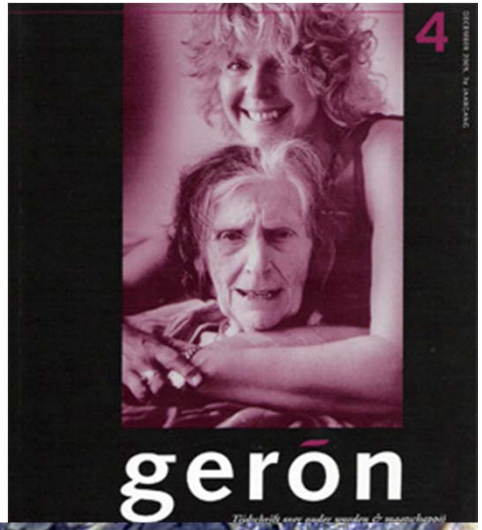


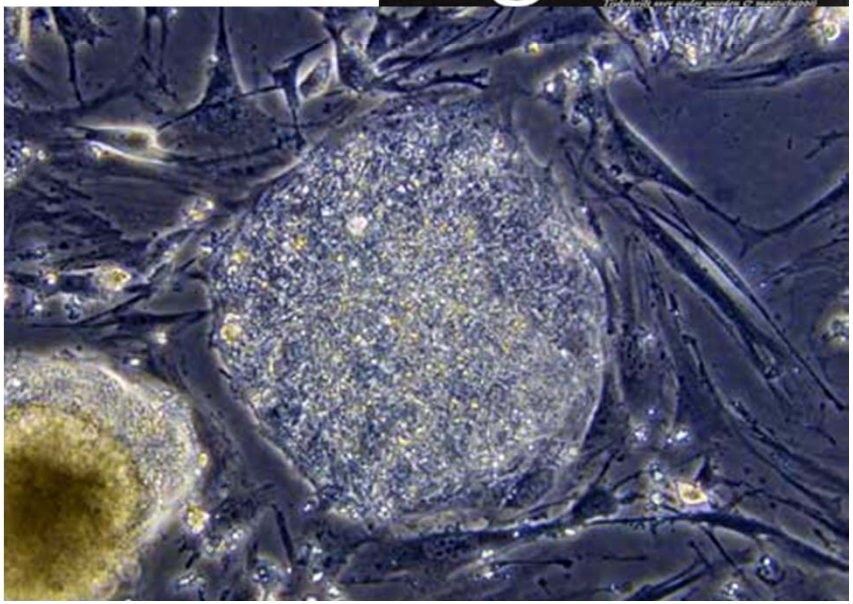
Co-authorship Network



NEW STUDY: Global Landscape of Translational Stem Cell Research

- Companies
- Patents
- Publications
- Clinical Trials
- Regulatory Environment
- Media Coverage





NEW STUDY: Methods

- Content Coding
- Keyword Analysis (OMNIVIZ)
  - Trends: time, space, document type
- Network Analyses
  - co-authorhip, co-inventorship and inventor-assignee
- Geographic Information Systems
  - Tacit and formal knowledge flows
- Statistical Modeling

NEW STUDY: Some Preliminary Findings

- **MAJOR DISCONNECTS:**
  - **Clinical trials / media coverage**
- **COMPANIES:**
  - **Rise of reagent companies (research grade)**
- **PATENTS:**
  - **Mainly non-human**
  - **Mainly process/methods**
  - **Rise of iPS**

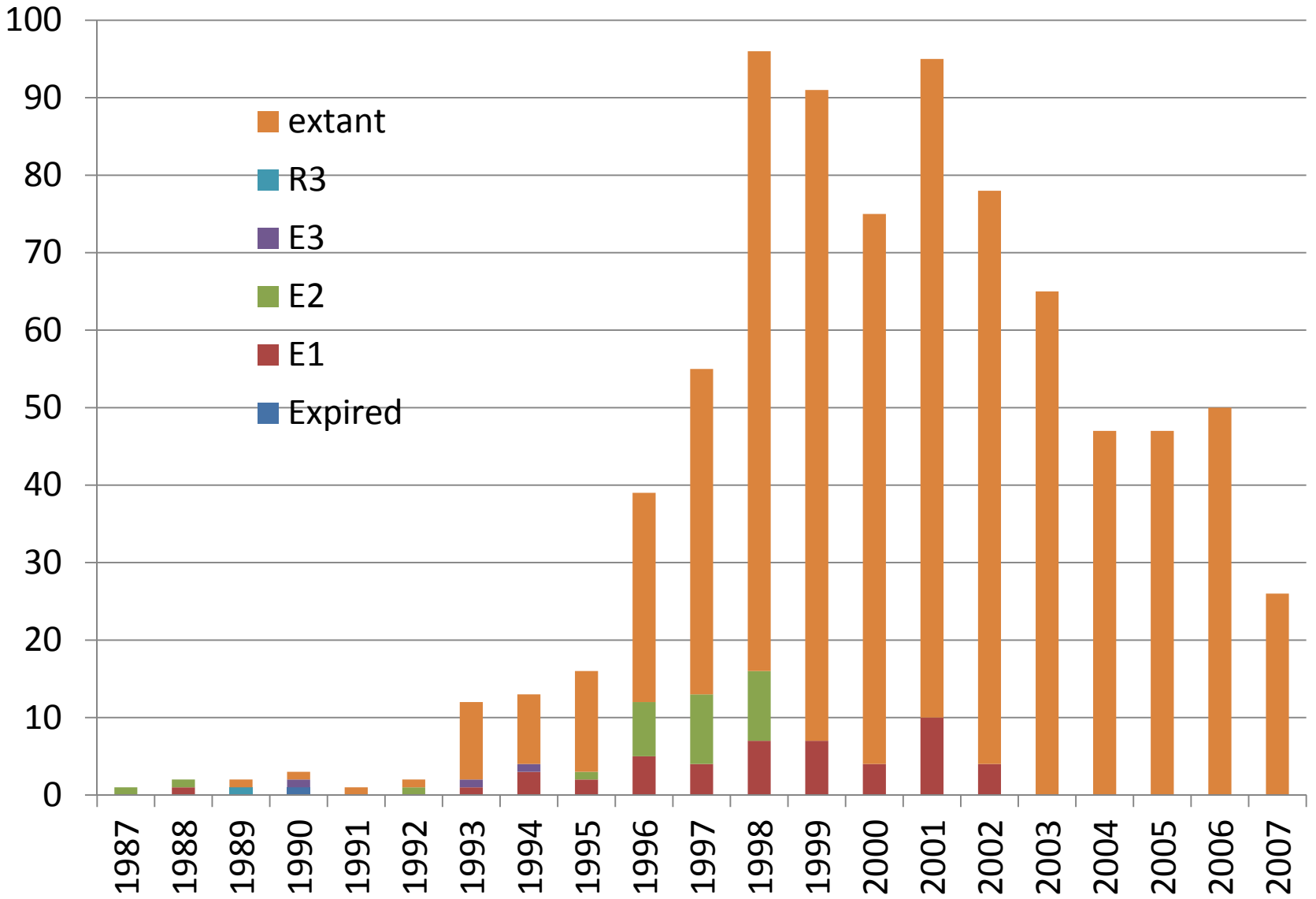
CASE 2: Creating Research Infrastructure

- **Public Resources established to provide public and private research communities with a source of Knockout Mice and Embryonic Stem cells**
- **EuCOMM, KOMP, NorCOMM**

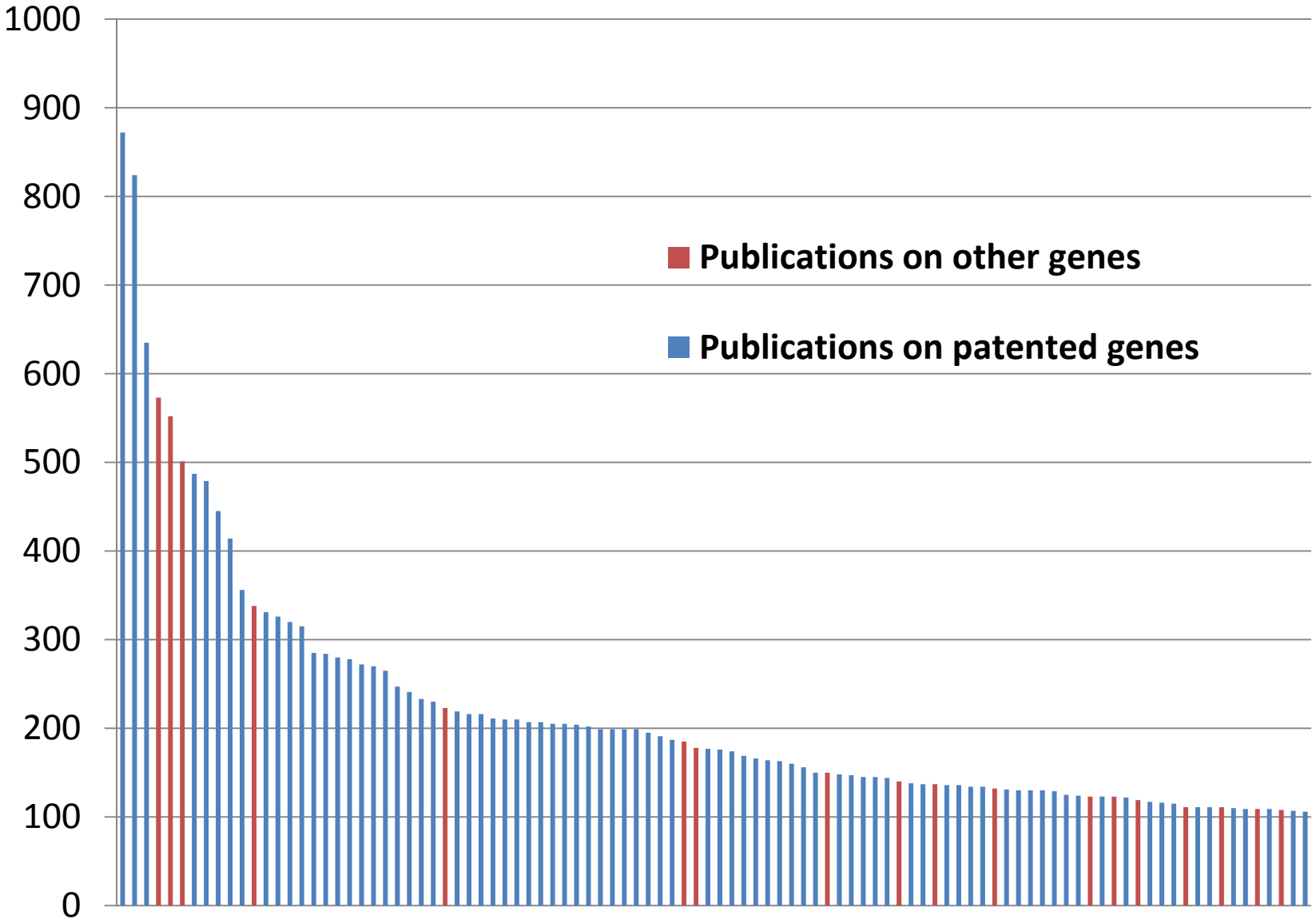
Research Question

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

Status and filing date of 816 Mouse Gene Patents (US)



Publications (>100) associated with patented versus unpatented mouse genes



METHODS PATENTS CODING
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

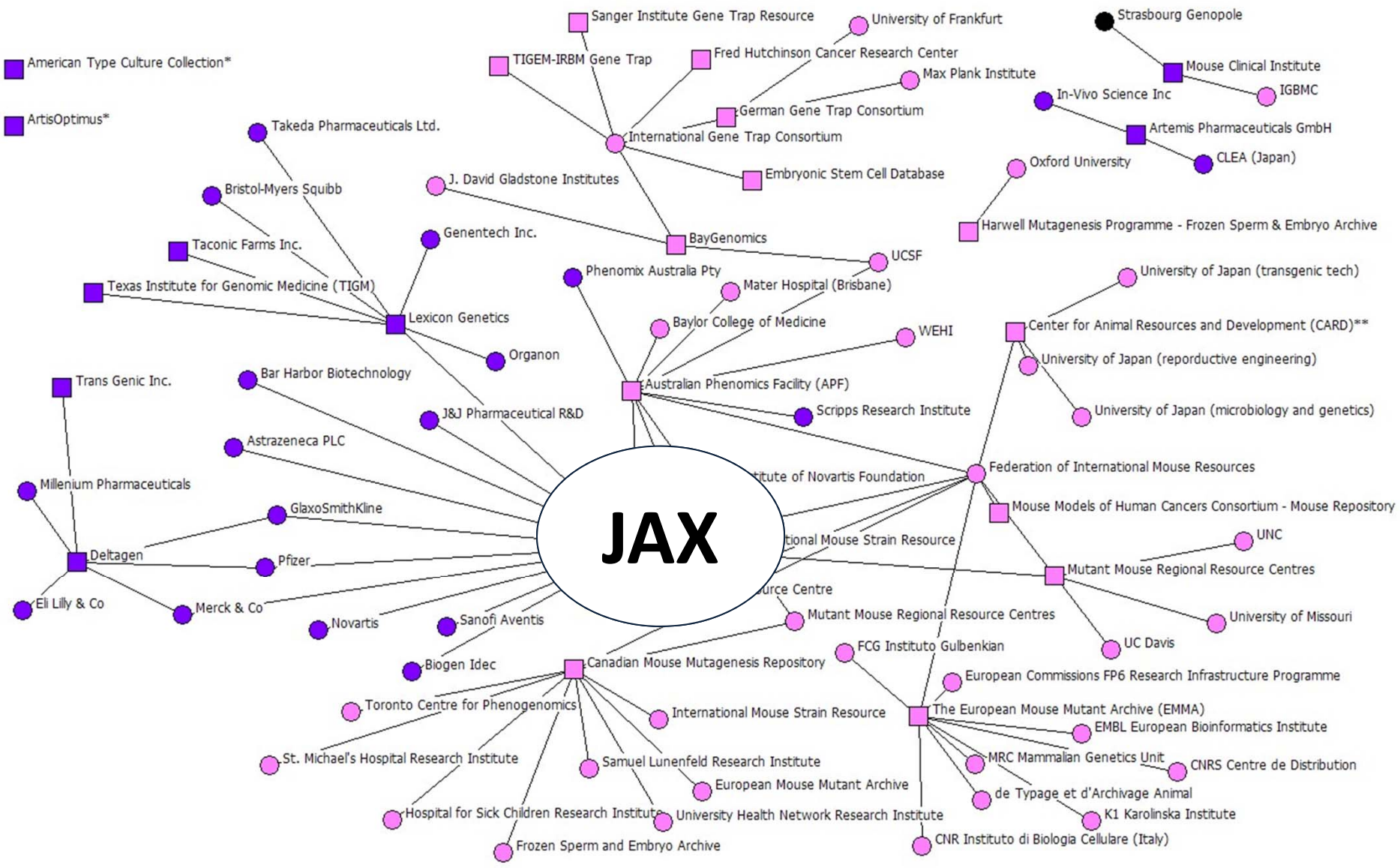
- Method used in Gene Trapping/Targeting
- **Total = 105 Patents coded**

Litigation: A sure way to destroy trust

- 2010 Markman Hearing: THE CENTRAL INSTITUTE FOR EXPERIMENTAL ANIMALS, a Japanese corporation, (Plaintiff) v. **THE JACKSON LABORATORY**, a Maine corporation (Defendant)
  - **"NOD/Shi Mouse" and "NOD/Shi-scid Mouse“**
- Alzheimer’s Institute of America, Inc (Plaintiff) v. Elan Corporation, PLC, Eli Lilly and Company, ANASPEC Inc, Immuno-Biological Laboratories, INC., Invitrogen Corp., **The Jackson Laboratory**, and Phoenix Pharmaceuticals (Defendants)
  - **Swedish Mutation**

Community identified problems with rules in use

- **Material Transfer Agreements**
  - **Substantial disincentive to accessing and providing materials**
  - **Increases transaction costs**
  - **Minimal value**
- **Researchers should be free to breed mice for research purposes and cross-breed them to produce new strains**
  - **Rome Agenda *Schofield et al. 2009 Nature***



4. Mouse Repository Network – Actors by Institutional Type

Public

Private

Public/Private

Conclusions

- New Collaborative Research Models gaining momentum.
- Need to build community norms, rule development, incentive structures, and adequate enforcement.
- Funding Agencies require tools to manage and enforce
- Influencing the other actors in the game, the funding agencies, research institutions, TTOs and journals is the next major challenge.
- Empirical research required to examine efficacy of new models
  - Case approach and systems approach
  - Increase transparency on deals

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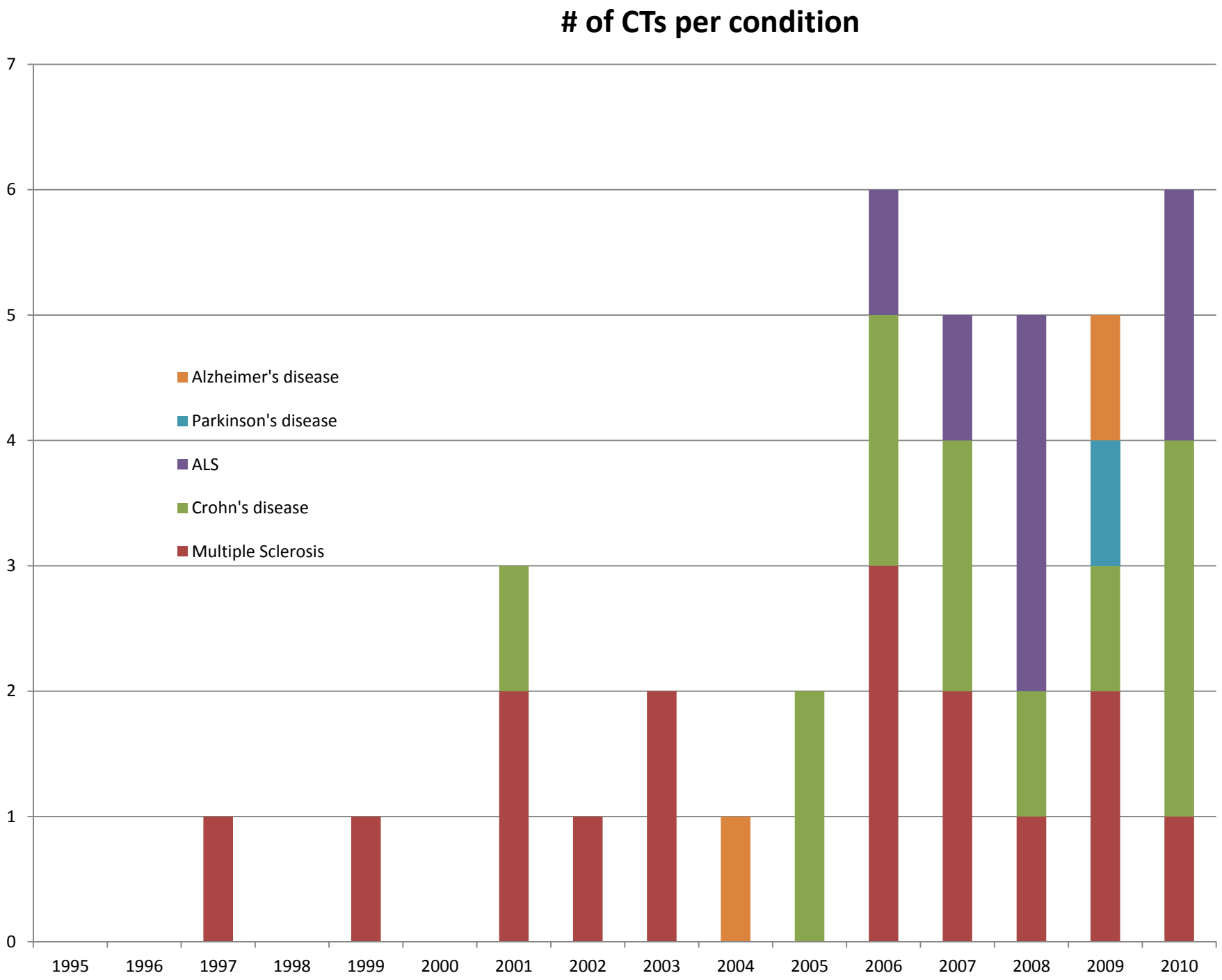
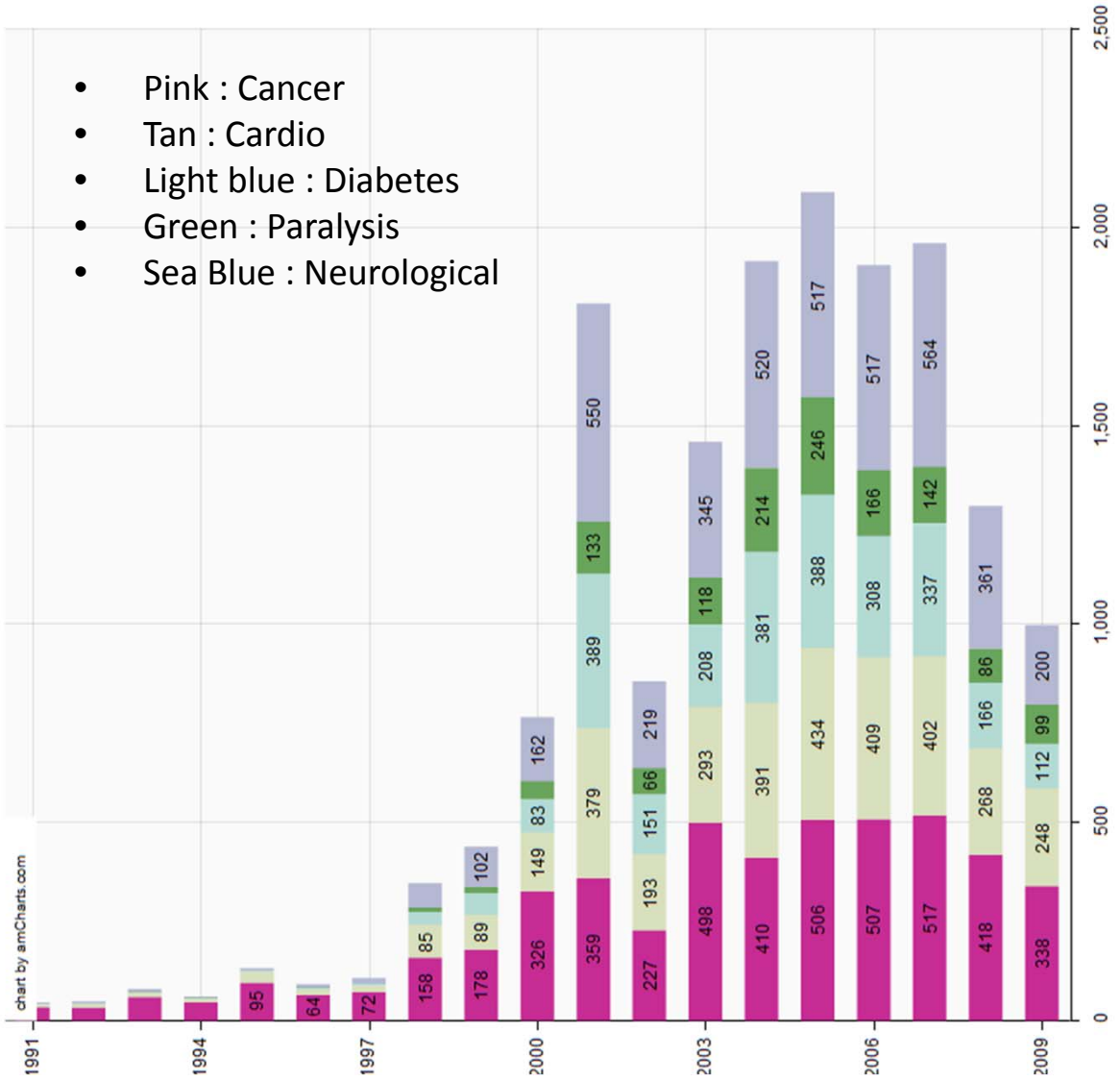
THANK YOU
QUESTIONS ??


# of CTs per condition
7
6
5
4
3
2
1
0
Alzheimer's disease
Parkinson's disease
ALS
Crohn's disease
Multiple Sclerosis
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010

Major Disease Types in the News



Specific Disease Types in the News

- Pink : Parkinson
- Tan : Alzheimer
- Light blue : ALS
- Green : Multiple Sclerosis
- Sea Blue : Crohns
- Yellow : Lupus