

ADEPT 2011

“An Industry Perspective on Collaborations” *

March 25, 2011

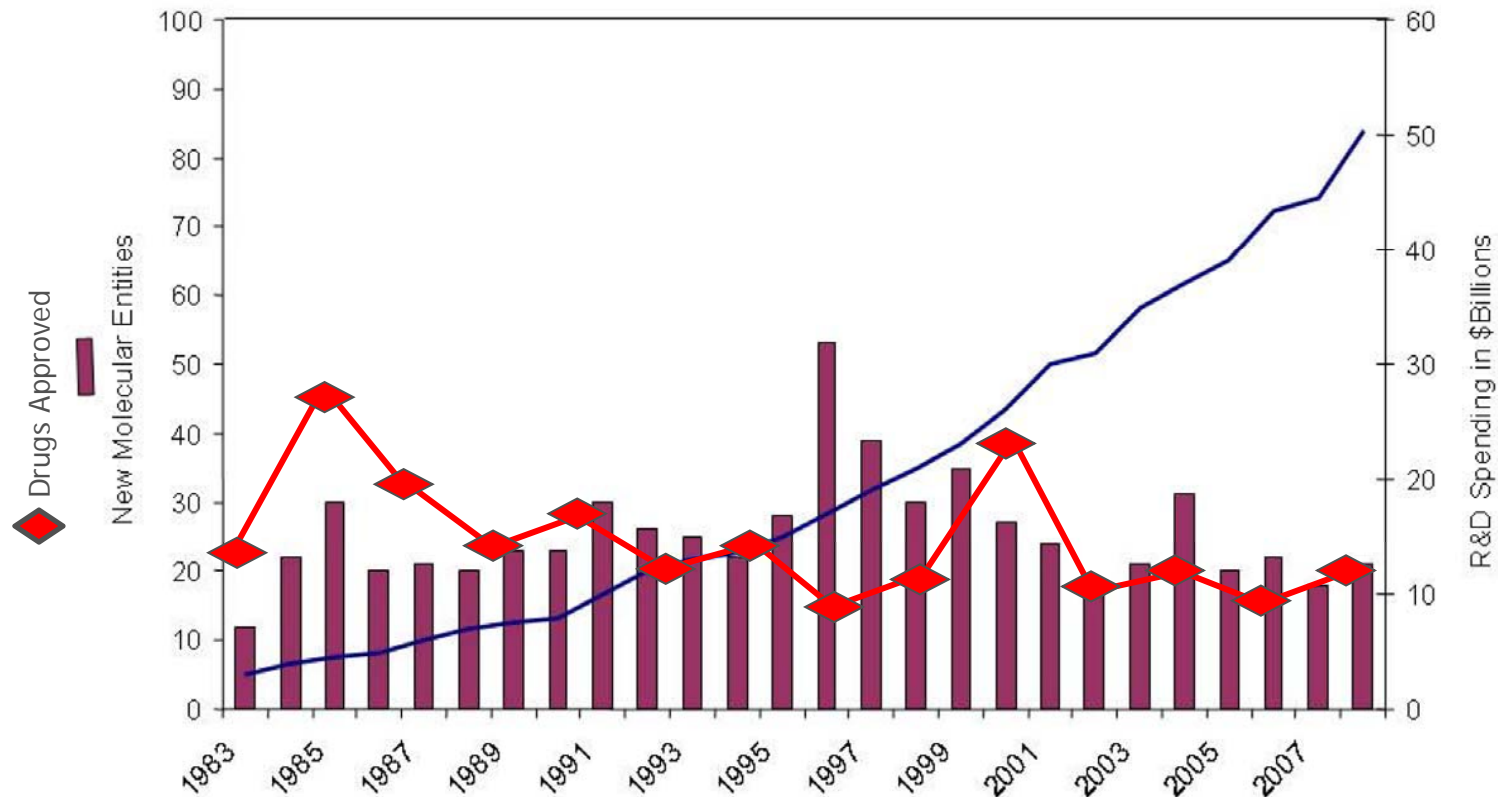
Christine Rauschkolb, MD, PhD

* This presentation reflects the personal views of the presenter,
and not the views of her employer or its affiliates

Points Considered for an Industry Perspective

- Why Collaboration?
- Perspective on Collaboration
- What Collaboration?
 - Academia
 - Other Pharma Companies
 - Government
 - Charity
- Hurdles
- Path to Success
- How to Measure Success?

Productivity of the Pharmaceutical Industry¹ and Regulatory Approvals

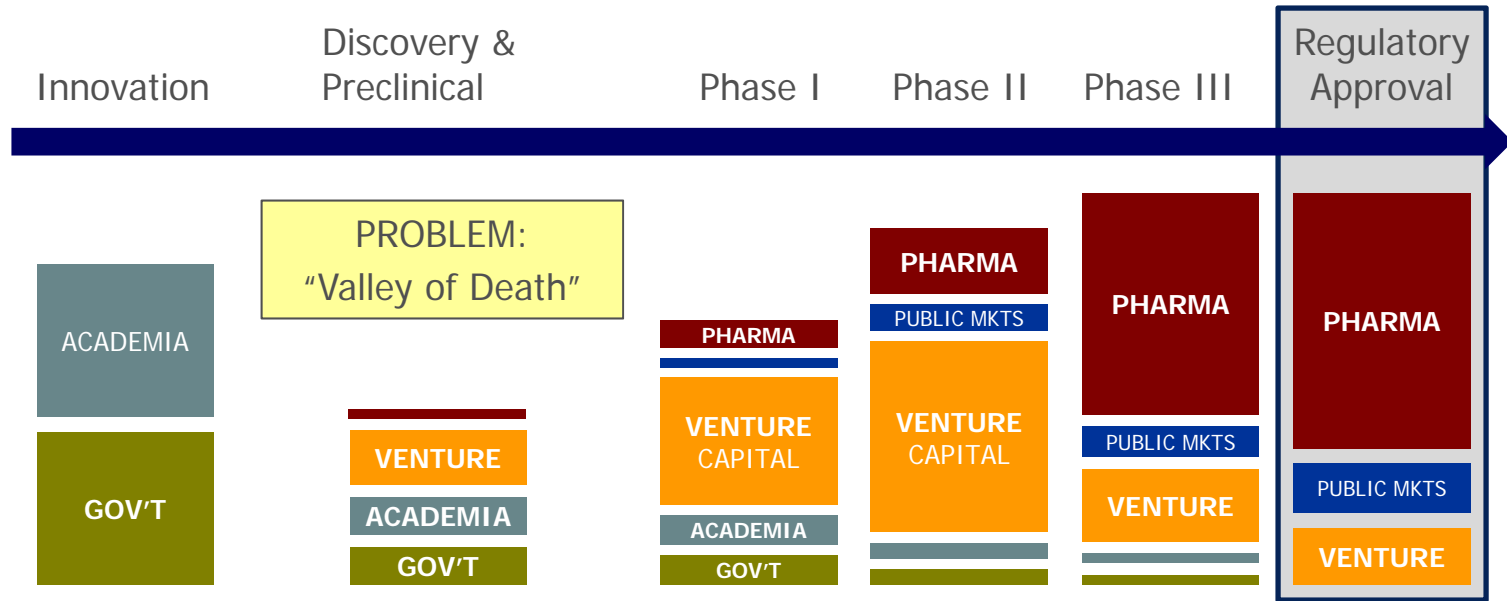


Novel Medication Success Rates Decreasing.

[Reuters](#) (2/14/2011, Berkrot) ...from early stage Phase I clinical trials to FDA approval between 2004 and 2010. ... **overall success rate is about one in 10**, down from one in five to one in six seen in reports involving earlier years.

¹Sources: PhRMA, BIO, Burril & Co, modified

The Current State of Drug Development



Graph courtesy of Daniel Perez, Ph.D., Bay City Capital, modified

Epecially true for Neuroscience / Pain???

Washington Post, Jan 27, 2011:

<http://www.washingtonpost.com/wp-dyn/content/article/2011/01/27/AR2011012702860.html>

Obama's call for innovation follows slowdown in most sectors, Innovation scholars say and point to a "valley of death" where new technologies go to die...

"Most of what you see are 'me too' drugs," said Leshner, a former head of two institutes at NIH. "What we need are new drugs."

The problem: Grand new ideas where we need them most - in energy, transportation and **health care** - bang up against the old ways of doing things.

MAYDAY – SOS

Passengers (Patients) in Need

The “Titanic Effect”

Unless new strategies of collaboration are created that align the interests and capabilities of all members of our ecosystem, we risk entering a prolonged period of dwindling new drug approvals, patients suffering, and industry decline

Statistics ...

- Science & Engineering Indicators 2008
 - Chapter 6. Industry, Technology, and the Global Marketplace
<http://www.nsf.gov/statistics/seind08/c6/c6s6.htm>
 - **Industry Collaboration in Publications**
Both in the United States and worldwide, a **major increase in collaboration across sectors and countries on S&E publications** has been evident during the past decade. (For a more complete discussion of collaboration patterns, see "[Coauthorship and Collaboration](#)" and "[Trends in Output and Collaboration Among U.S. Sectors](#)" in [chapter 5](#).)
 - **Changing Emphasis on Basic Research**
Industrial publications tended to shift away from basic research between 1988 and 2005. After peaking at 26% in 1995, the percentage of articles with an industrial author published in basic research journals declined to 22% by 2005 ([figure 6-28](#)). [\[36\]](#) This **declining emphasis on basic research in industry publications** has been especially strong in the biological sciences (from around 50% in the early 1990s to 39% in 2005), in physics (from 31% in 1988 to 20% in 2005), and in the **medical sciences** (from **10%** in the early- to mid-1990s to **5%** in 2005).

A Different Perspective on Collaboration ...

- The **principle of shared value creation cuts across the traditional divide** between the responsibilities of **business** and those of **government or civil society**. From society's perspective, it does not matter what types of organizations created the value. What matters is that **benefits are delivered by those organizations, or combinations of organizations, that are best positioned to achieve the most impact for the least cost**. Finding ways to boost productivity is equally valuable whether in the service of commercial or societal objectives. In short, the principle of value creation should guide the use of resources across all areas of societal concern.
- ... The right kind of government regulation can encourage companies to pursue shared value; the wrong kind works against it and even makes trade-offs between economic and social goals inevitable. Regulation is necessary for well-functioning markets, something that became abundantly clear during the recent financial crisis. However, the **ways in which regulations are designed and implemented determine whether they benefit society or work against it**.



European Efforts ...

- Road Map to 2015
 - Adopted by the Agency's Management Board on 16 December 2010
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000292.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac05800293a4
 - The agency proposes that **changes in the regulatory procedures** surrounding the approval process for medicines catering for unmet medical needs, rare diseases, and neglected diseases could be made, so that the **administrative burden could be eased and the process speeded up**, which could have positive benefits for health in the EU and beyond.
 - [Innovative Medicines Initiative](#), a **collaborative effort sponsored by the European Commission and EU-based pharmaceutical companies**. €1billion for five years, matched by companies with €1billion of in-kind contributions. Every year an independent committee determines the most important areas for research, and the academic-industry consortium that submits the best proposal wins funding.

Government Research US ...

Federal Research Center Will Help Develop Medicines

The New York Times
By Gardiner Harris
23 January 2011

"The Obama **administration has become so concerned** about the slowing pace of new drugs coming out of the pharmaceutical industry that officials have **decided to start a billion-dollar government drug development center to help create medicines.**"

"The National Institutes of Health has traditionally focused on basic research, such as describing the structure of proteins, leaving industry to create drugs using those compounds. But the **drug industry's research productivity has been declining for 15 years**, "and it certainly doesn't show any signs of turning upward," said Dr. Francis S. Collins, director of the institutes."

"The job of the new center, to be called the National Center for Advancing Translational Sciences, is akin to that of a home seller who spruces up properties to attract buyers in a down market. In this case the center will do as much research as it needs to do so that it can attract drug company investment."

Existing PPP... ADNI, ACTION, et. al.



The screenshot shows the header of the ACTION website. The logo features a stylized bridge over the word "ACTION". The main title is "Analgesic Clinical Trial Innovations, Opportunities, and Networks". A navigation menu includes links for Home, News, Organization, Meetings, Publications, Membership, Links, and Contact Us. The main content area contains two paragraphs of introductory text and a bulleted list of key objectives.

Home News Organization Meetings Publications Membership Links Contact Us

The Analgesic Clinical Trial Innovations, Opportunities, and Networks (ACTION) public-private partnership is aligned with the Food and Drug Administration's (FDA) recently launched Initiative for the Advancement of Regulatory Science. For the benefit of the public health, ACTION is designed to streamline the discovery and development process for new analgesic medications and to more generally accelerate the development of pain treatments with improved efficacy and safety. This multi-year, multi-phase initiative will initiate and foster strategic collaborations among a broad spectrum of stakeholders — including, but not limited to, academia, industry, professional organizations, patient advocacy groups, foundations, philanthropic organizations, and other government agencies — with the well-defined goal of sharing data, best practices, and innovative thinking.

Under the auspices of ACTION, it is anticipated that stakeholders will leverage their resources (e.g., data, scientific and clinical expertise, infrastructure, and financial support) to foster dialogue and develop specific projects that will advance the understanding and development of analgesic treatments so that improved interventions can be identified and made available in an expedited and efficient manner.

Key objectives include:

- Establishing relationships with key stakeholders, industry, professional organizations, academia, and government agencies;
- Coordinating scientific workshops with experts in the fields of anesthesiology, neurology, rheumatology, pain medicine and other specialties involved in the treatment of pain;
- Initiating and supporting a series of research projects and other activities; and
- Conducting in-depth and wide-ranging data analyses of analgesic clinical trial data to determine the effects of specific research designs and methods of analysis.

- **Alzheimer's Disease Neuroimaging Initiative (ADNI)**. Established in 2004, ADNI is a public-private partnership supported with **\$40 million from the National Institutes of Health (NIH)** and **\$27 million from the pharmaceutical and related industries and not-for-profit organizations**.
- ADNI developed a test to help diagnose the beginning stages of AD sooner and more accurately ... expected to help establish methods for AD clinical trials and identify the best imaging and biomarker methods. ... produced more than 100 articles and many more abstracts. **All data collected through ADNI are available to the research community.**

Academia-Industry-VC Collaboration

Best Practices on Academia-Industry Collaborations

- Presented by [Johnson & Johnson](#) and the New York Academy of Science
<http://www.nyas.org/publications/EBriefings/Detail.aspx?cid=a937b74a-a986-4bff-9633-9afd6d046e85>

On December 8, 2009, prominent representatives from higher education, industry, and government led a symposium exploring how academia and industry can partner more successfully, and what public policy measures could facilitate collaboration. Panelists offered examples of successful public-private partnerships, such as those between the Johnson & Johnson company, Janssen, and Vanderbilt University; ...

Eli Lilly funds aim to share research costs

Financial Times
By Andrew Jack in London
February 14, 2011

“Eli Lilly is seeking to raise up to \$750m through three funds that will share drug development costs and potential benefits with venture capitalists and external researchers.”

“The company will put up to \$50m into each of three mirror funds containing up to 20 experimental medicines from different therapeutic areas, designed to take them through the high risk phase from a year before testing in humans until the mid-stage clinical trials.”

Industry – Charity ...

TB Alliance Portfolio

Discovery			Preclinical Development	Clinical Development		
TARGET OR CELL-BASED SCREENING	LEAD IDENTIFICATION	LEAD OPTIMIZATION		CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III
Natural Products IMCAS	Whole-Cell Hit to Lead Program GSK	Mycobacterial Gyrase Inhibitors GSK	Nitroimidazoles U. of Auckland/ U. Ill Chicago		PA-824 Novartis	Moxifloxacin (+ H, R, Z) Bayer
Protease Inhibitors IDRI	Malate Synthase Inhibitors GSK/TAMU	InhA Inhibitors GSK	Preclinical TB Regimen Development JHU/U. Ill Chicago		TMC207 Tibotec	Moxifloxacin (+ R, Z, E) Bayer
TB Drug Discovery Portfolio NITD		Diarylquinolines Tibotec/U. of Auckland			PA-824/Pyrazinamide	
Topoisomerase I Inhibitors AZ/NYMC	Gyrase B Inhibitors AZ	Riminophenazines IMM/BTTTRI			TMC207/Pyrazinamide	
	Folate Biosynthesis Inhibitors AZ	Pyrazinamide Analogs Yonsei			PA-824/TMC207	
	Whole-Cell Hit to Lead Program AZ				PA-824/ Moxifloxacin/ Pyrazinamide	
	RNA Polymerase Inhibitors AZ					
	Energy Metabolism Inhibitors AZ/U. Penn					
	Phenotypic Hit to Lead Program U. Ill Chicago					
	Menaquinone Biosynthesis Inhibitors CSU					

■ Novel TB regimen development

Current first-line TB treatment consists of isoniazid (H) + rifampicin (R) + pyrazinamide (Z) + ethambutol (E)

OUR R&D PARTNERS

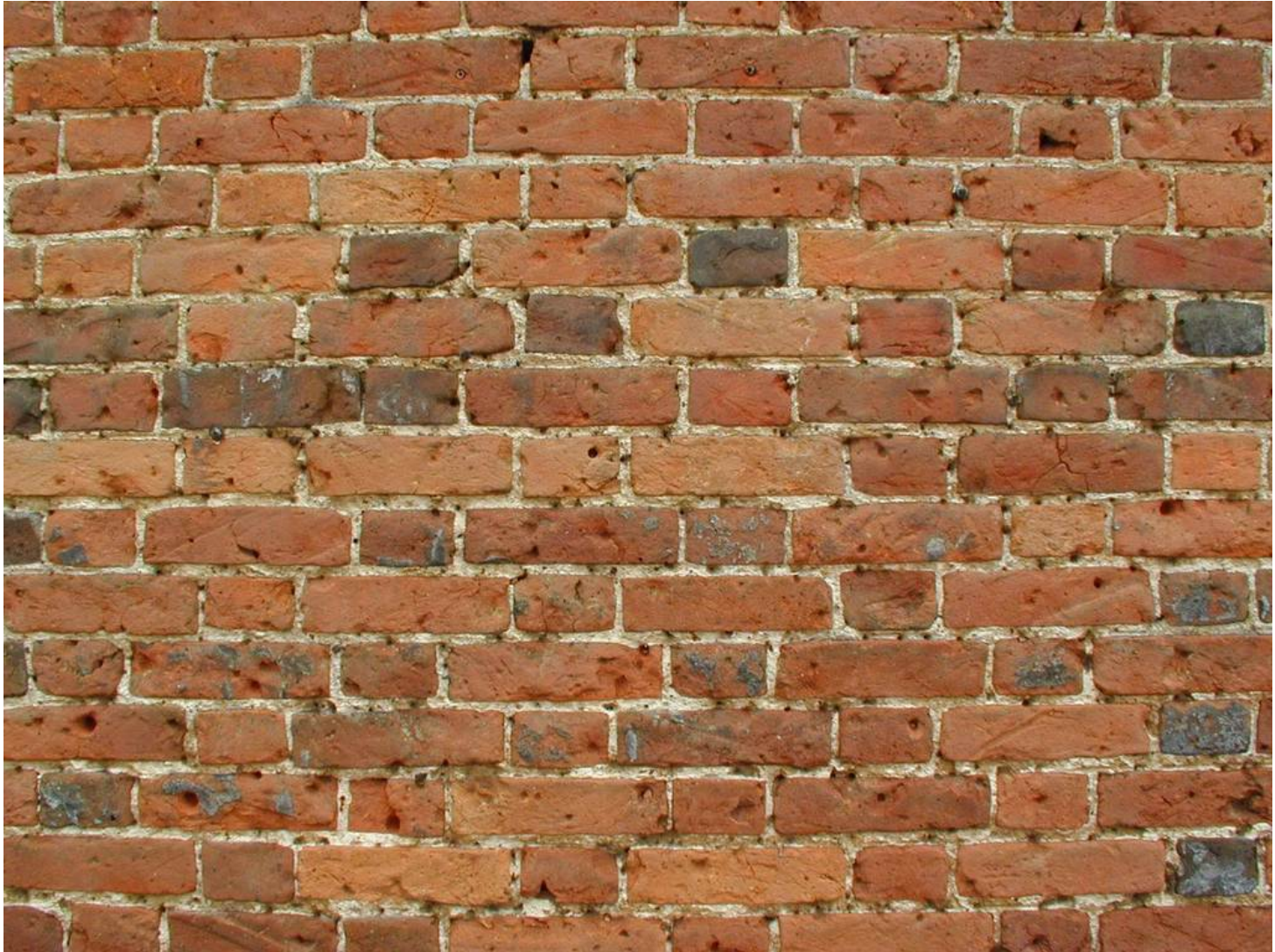
- AstraZeneca (AZ)
- Bayer Healthcare AG (Bayer)
- Beijing Tuberculosis and Thoracic Tumor Research Institute (BTTTRI)
- Colorado State University (CSU)
- GlaxoSmithKline (GSK)
- Infectious Disease Research Institute (IDRI)
- Institute of Materia Medica (IMM)
- Institute of Microbiology, Chinese Academy of Sciences (IMCAS)
- Johns Hopkins University (JHU)
- Johnson & Johnson / Tibotec (Tibotec)
- New York Medical College (NYMC)
- Novartis Institute for Tropical Diseases (NITD)
- Novartis Pharmaceutical (Novartis)
- Texas A&M University (TAMU)
- University of Auckland (U. of Auckland)
- University of Illinois at Chicago (U. Ill Chicago)
- University of Pennsylvania School of Medicine (U. Penn)
- Yonsei University (Yonsei)



TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

February 2010

Barriers ...



Translational Partnerships with Academia

... Yet Cultures Still Clashing???



- Shared concerns
 - Who owns the intellectual property?
 - How can productivity and success be measured?
 - How can two very different incentive and compensation systems be aligned?
- Academia's perceptions/concerns
 - Research can lead to commercialization, but it also is about learning for its own sake
 - Academics speak the language of science, not business
 - Industry doesn't value basic research
 - Industry collaborations don't contribute to academic promotion
 - Industry is bureaucratic
- Industry's perceptions/concerns
 - Academics believe industry has limitless funds
 - The goal of research is to commercialize a product
 - Academia don't see the effort it takes to commercialize a product
 - University overhead charges are too high
 - Academics don't understand Good Laboratory Practices (GLP)
 - Universities are very bureaucratic

Conflicting Interests (?!)

University-industry Collaboration: The United States Experience

By J. H. Reichman, Bunyan J. Womble Professor of Law, Duke University School of Law, Durham, N.C., U.S.A. WIPO Conference Paper, June 23, 2005

“Collaboration between universities and industry in the United States has ... usually been a two-way street. ...

Moreover, while university patents increasingly do support some important technology transfers, they remain only a part of the United States innovation system. **The role of non-IP interaction between universities and industry is much greater overall, and experts warn that there are growing risks for U.S. universities from too much intellectual property protection. ...**

On the whole, the evidence reveals a growing need to balance the economic incentives of researchers with the research needs of the scientific and technical communities.

This concern **elicits interest in new types of intellectual property, such as open-source licensing strategies and especially, potential uses of liability rules instead of exclusive property rights in regard to government-funded research results,** which we are working on at Duke. Note in this connection that **federal funders may be able to impose sharing rules, non-exclusive licenses, and even ex ante automatic licenses (liability rules), if they want to, without federal legislation.”**

http://www.wipo.int/academy/en/meetings/iped_sym_05/papers/pdf/reichman_paper.pdf

Dinosaurs @ Work???

- ... Managers who hope to get the best out of their workers by fostering teamwork could be in for a shock: Many young workers now consider traditional teams to be dull, pointless and unnecessarily rigid.
- The **social-network generation expects collaborations and alliances to emerge organically from the huge number of colleagues and peers with whom they share their ideas and interests**, writes Karsten Jonsen.
- "Our challenge will be to ... find the right balance between established teams inside an organization and fluid open collaborative teams spanning across organizations, disciplines and boundaries".

[Management-Issues \(U.K.\)](#)

Creating a Culture of Collaboration / Open Innovation

Key Learnings

- The ship is turning, but there is way to go
- Must be driven from the top*
- Do not assume that everyone in your organization has embraced Collaboration/Open Innovation just because they say they have
- The fear that competitors will profit from Collaboration/Open Innovation can outweigh the promise it holds for your organization*
- Do not underestimate the organization's* capacity to mount an immune response
- Run pilot programs outside of the traditional organizational structure*
- On occasion, castles must be destroyed to break through entrenched behaviors and business practices
- Do not assume that all external stakeholders in your area/industry share your vision

*True for Academia, Government & Industry

Success Is ...?

- ... our findings suggest that university–industry relationships **constitute a two-way exchange rather than a one-way transfer of university-generated technology**... and emphasize the recursive nature of university–industry relationships where academics' access to industrial technology **generates learning in universities which in turn can lead to innovation in technology**

Success Is ...!

- ... our findings suggest that university–industry–government relationships constitute a multi-way exchange rather than a one-way transfer of university-generated technology... and emphasize the recursive nature of university–industry–government relationships where academics' access to each others technology and data generates learning in all constituencies which in turn can lead to innovation in technology

Modified after Perkmann and Walsh. The two faces of collaboration: impacts of university-industry relations on public research. *Industrial and Corporate Change*. 18:1033-65, 2009

Success is Finally Healing the Hurt

We understand

PAIN

And treat it
successfully