The Role of Knowledge Markets in Reducing Drug Development Costs and Improving Clinical Care

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Knowledge Markets in Life Sciences

- New disease or treatment paradigms will require increased collaboration between parties—not only on molecules—but on the approach and methodologies for development and regulatory approval.
- Partnerships, consortia and entirely new constructs—all designed to increase the flow of information and foster innovation will be needed.
- Examples of collaborative research have been seen mainly in areas such as oncology, but are expanding to other disease areas as well. Will a collaborative approach be critical in developing new clinical and regulatory pathways in the future?
- What are the benefits, pitfalls and alternatives?

Remaining Competitive in Challenging Times

- Recognize importance of incremental innovation
- Ensure budget forecasting models reflect today's realities
- Provide marketplace rewards for innovation
- Revise policies that stifle innovation
- Expand access to information
- Implement & utilize knowledge markets

Partnerships & Innovation = Commercial Success

How can innovation be characterized?

- Depends on knowledge and strong intellectual property (IP) protections
- Generally progresses as a series of small, incremental steps
- NOT limited to R&D Process

Sustaining Commercial Success

How can innovation be sustained?

- Proper rewards for innovators
- Appropriate global IP framework, given complex interdependencies
- Discussion of meaning of healthcare, its worth, and society's willingness to support it
- Stronger partnerships between governments, payers and industry
- Access to and transparency of information

Pfizer Inc – a Snapshot

- Currently largest funder of research on new medicines
  - Spending more on R&D than any other company, regardless of industry
- In 2007, invested more than $7 Billion in discovery, development and post-approval research
- Wide breadth of research efforts
  - More than 200 novel compounds in development, spanning multiple disease areas of unmet medical need
- Roughly 800 alliances with diverse partners
  - Span entire spectrum of research, development and commercial
  - Forward integration across markets is huge asset to global economies, patients and citizens, with multiple benefits in many sectors

Pfizer Philosophy on Partnering

- Essential to continued innovation
- Across industries, academia, non-profit and public sectors
- Across full-spectrum of research, development and commercial activities
- Rely on trustful relations across all parties involved in healthcare in order to manage significant challenges that aging populations pose to budgets, medical practice and continued innovation
- Develop strategic alliances designed to share risk and cost of drug development—with the potential of bringing more medicines into expensive late-stage testing

Consortia – a Snapshot

- Just how big is the boom in pharmaceutical precompetitive consortia?
- What is driving it—and what models are emerging?
- Ingredients for success……..and risk factors for failure
- Where will all this take us?
- How will we measure success?

Consortia by the Numbers

<10	Number of pharmaceutical consortia 7 years ago
1.7m	Number of Google hits when searching for 'pharmaceutical consortia'
>40	Over 40 consortia and public-private partnerships focused on discovering and developing new medicines
>1b	Estimate of total annual budget (USD) for major consortia

Why do We Need Consortia?

Key Topics Consortia are Addressing Today

Productivity	**Increasing productivity challenges remain as drug development timelines increase due to complexity, efficacy and safety concerns, regulatory requests, ↓ NMEs/R&D$$**
Cost	**Cost of developing innovative new medicines continues to rise due to need for new technology, biomarkers and validation of clinical endpoints in safety**
Risk	**As pharma companies downsize and blockbuster drugs come off patent, the fiscal risk of drug development grows. Is a financial burden to maintain resources no longer needed**
Acceptance	**Greater need of acceptance from regulators and practitioners on standardization and use of new technologies and endpoints**

Critical need for consortia to share cost & resource in developing approaches and methodologies for development and regulatory approval

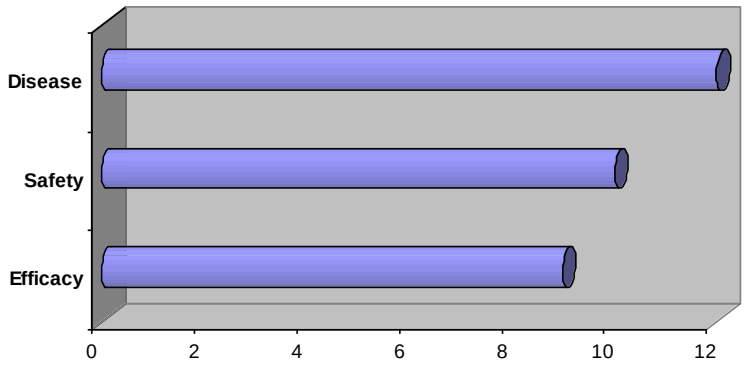
Consortia Landscape Today

Consortia available for a variety of needs today

Consortia focus by Disease Area

	All	Gastrointestinal	Genitourinary and Sex Health	Allergy and Respiratory	Inflammation	Dermatology	Pain	Infectious Disease	Opthalmology	Cardiovascular / Metabolic Disease	Neurosciences	Oncology
US Biomarker Consortium	■											
UK Medical Research Council	■											
EU Framework 7, Innovative medicines initiative				■	■		■	■		■	■	■
GAIN					■	■				■	■	
Top Institute Pharma (Netherlands)								■		■	■	■
BioWin (Belgium)					■						■	■
Canceropôles (France)												■
Medicamentos Innovadores (Spain)	■											
HUPO	■											
Standardization and Harmonization of Imaging for Clinical Trials	■											
ADNI - Alzheimer's Disease Neuroimaging Initiative											■	
Ostoearthritis Initiative							■					
Cardiac Saefty Research Consortium (CSRC)	■											
Imaging Consortium for Drug Development (ICD)							■				■	
Mass Insight Collaborative Imaging Research Center (CIRC)	■											

Consortia focus by need

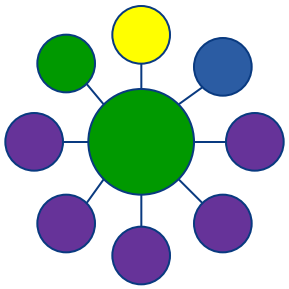


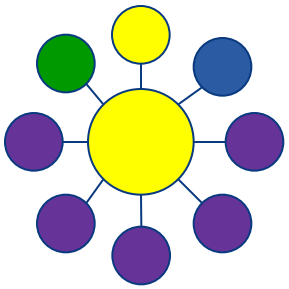
Consortia funding needed
(by company/government per year)

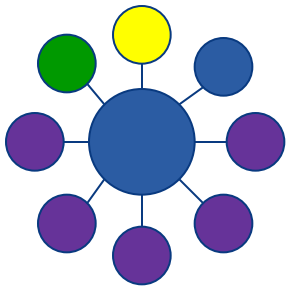
Common Challenges to Consortia

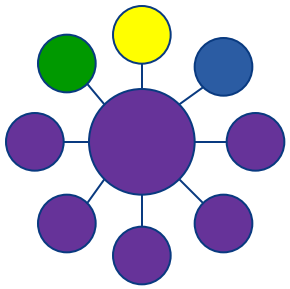
- Intellectual Property Rights
- Governance and Decision-making
- Liability
- Anti-trust Regulations
- Logistics and Operations – delivering the data
- Evaluating Continued Utility

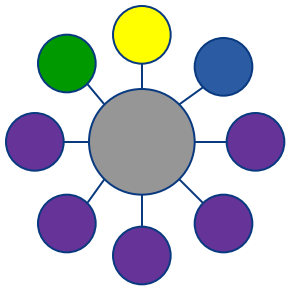
Consortia Models











Driver	Academia & Foundations	Regulators	Government	Industry (Pharma)	Company (Solution Provider)
Examples	SNP Consortium	Predictive Safety Testing Consortium	Innovative Medicines Initiative	International Serious Adverse Events Consortium	High-Risk Plaque Initiative
Description	Independent 3rd party to coordinate effort and provide data for public access	Identify the most informative tests and tools with regulatory acceptance built in	Support faster discovery and development of medicines through coordination and funding	Collaboration between companies to share cost and resource for individual use	Development of novel biomarkers and tools to license

Academia/Foundations

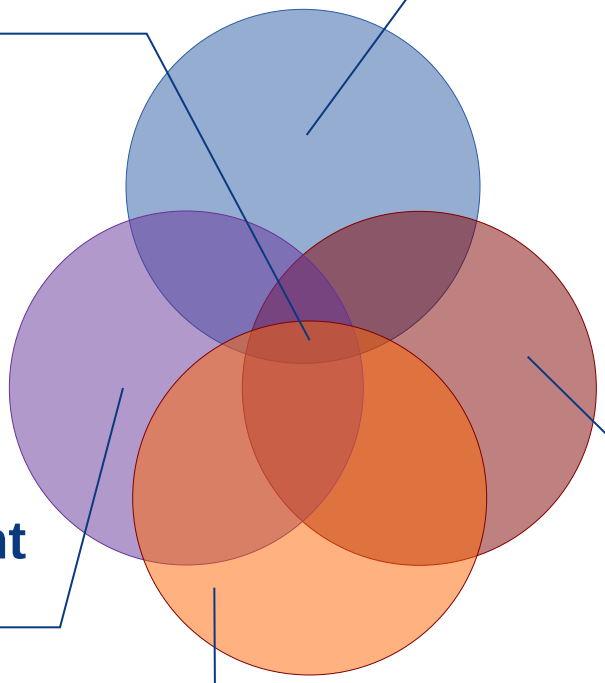
Regulators

Government

Industry (Pharma)

Industry (Solution Providers)

Converging & Diverging Interests



Industry

- Increase speed of drug development
- Lower costs
- Increase acceptance
- Focus on unmet medical need

Academia

- Research funding
- Publications
- Explore science
- Rare disorders are interesting

Government

- Economic stimulation
- Support education and research enterprise

Patient Organizations

- Transmit Patient Feedback
  - Real-life experiences
  - Needs of patients
  - Acceptance of Rx

- Speed the flow of new medicines

The Path Forward – Reducing Drug Development Costs

- Aggressive application of shared science knowledge to drug discovery and development over the next five years
  - Strong collaborations between industry and academia to drive customized therapy solutions
  - Novel and collaborative clinical trial designs that incorporate best of new molecular and biology data
- Development of methodologies that allow for safe sharing of data between health care providers, industry and regulatory authorities to speed the conduct of clinical trials and faster routes to the approval of safe and effective drugs
  - Risk-sharing partnerships that facilitate a greater number of experimental compounds to be moved into Phase III testing
  - Out-licensing of assets and knowledge markets
- Collaborative relationships with regulators that strengthen patient safety but also speed path of novel biomarkers application and acceptance

The Path Forward - Better Clinical Care

- Pooling knowledge helps to identify areas of medicine needing attention
- Provides research on the fundamental aspects of disease/condition
- Provides learnings on how to leverage research to bring new medicines to patients more quickly
- Provides insights from clinicians on what types of medicines patients need

Consortia in R&D

Improving R&D Efficiency

- Innovative Medicines Initiative (EU Framework 7)
  - Participants: Academia, Pharma, Biotech, Regulators, Patients
  - Aims: Overcome R&D bottlenecks, e.g., predictive pharmacology and toxicology, identification of biomarkers, patient recruitment

Customizing Medicines

- International HapMap Project
  - Participants: SNP Consortium, International research groups
  - Aims: Exchanging and building individual and population-based knowledge critical to drug discovery, development, use and benefit

Improving Toxicity Predictions

- Predictive Safety Testing Consortium
  - Participants: Critical Path Institute, Pharma
  - Aims: Identify most informative tests (i.e., animal, in vitro or clinical) for predicting toxicity

Consortia in R&D (cont.)

Identifying Gene Associations

- Genetic Association Information Network
  - Participants: NIH Institutes and Centers, Foundation for NIH, Pfizer Inc, Affymetrix Inc, Perlegen Sciences, Inc and Abbott Laboratories
  - Aims: Perform whole gene scanning of common diseases to identify gene associations relevant to disease and disease pathways. Combine the resources and expertise of several public and private entities to streamline the genetic research process

Developing Animal Models

- Animal Models Working Group
  - Participants: Pharma, Biotech, FDA, Research Institutes
  - Aims: In short term, facilitate development of medical countermeasures (i.e., medicines and vaccines) for bioterrorism. In long term, develop animal models more reflective of human disease.

Consortia in Commercial Area

Bolster Medicine Supply Network

- Rx Response
  - Participants: Pharmaceutical and biotechnology companies, pharmacy and drug store and hospital associations, American Red Cross
  - Aims: Ensure U.S. pharmaceutical supply system can continue flow of medicines to patients during severe public health emergencies

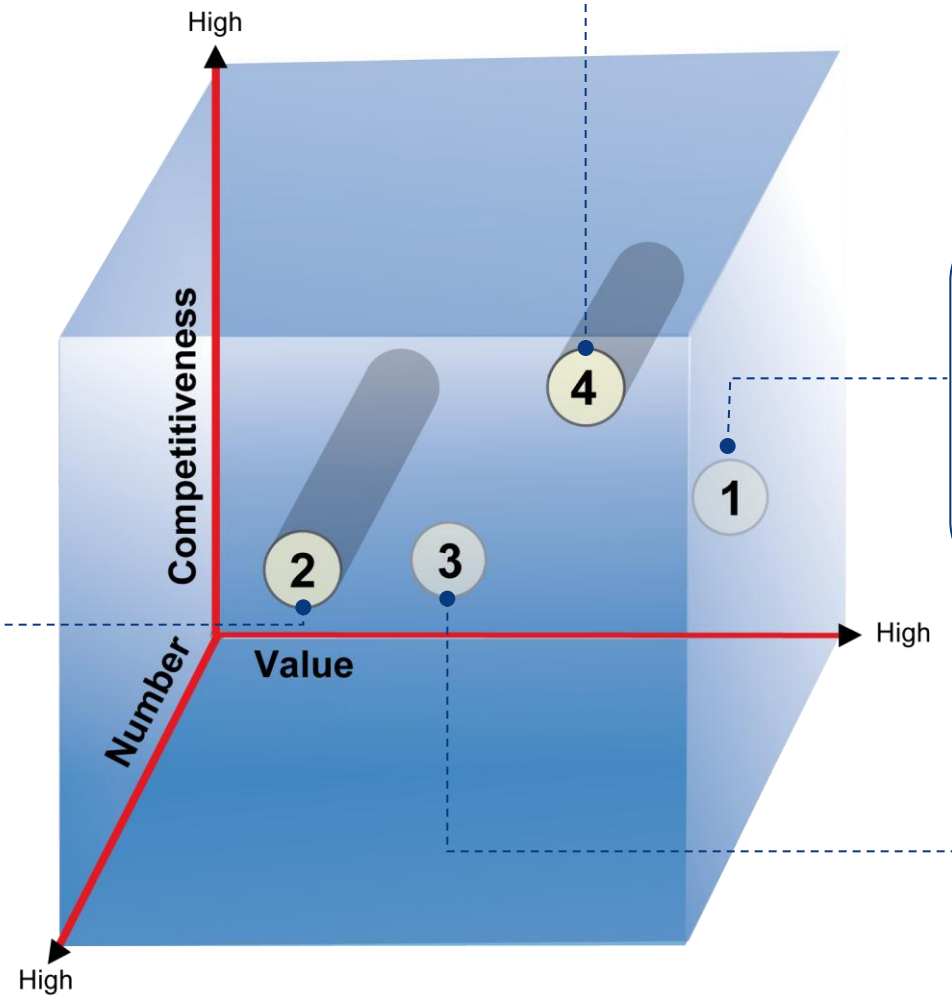
Build Sustainable Healthcare Delivery Models

- Grameen Health/Pfizer Partnership
  - Participants: Grameen Health and Pfizer Inc
  - Aims: Identify ways to improve healthcare delivery systems and primary care clinics in Bangladesh. Replicate successful business models in other developing countries.

Where Are We Going with Consortia? Potential Scenarios

Status quo – 'as is'

Too many consortia that do not deliver and lack specificity



Pre-competitive space becomes bigger and redefines the industry and the way we develop drugs

Standardize the industry with fewer competitive elements

Policy Considerations for Success of Knowledge Markets

- Foster collaboration between industry and public, academic and non-profit organizations
  - Recognize the essential role biopharma companies can play
- Recognize importance of incremental innovation in improving health
- Identify mechanisms for enticing parties to participate in consortia
- Address “free rider” issue
- Revise policies that stifle innovation
- Expand access to information
- Ensure predictable regulatory pathways, preferably across markets