

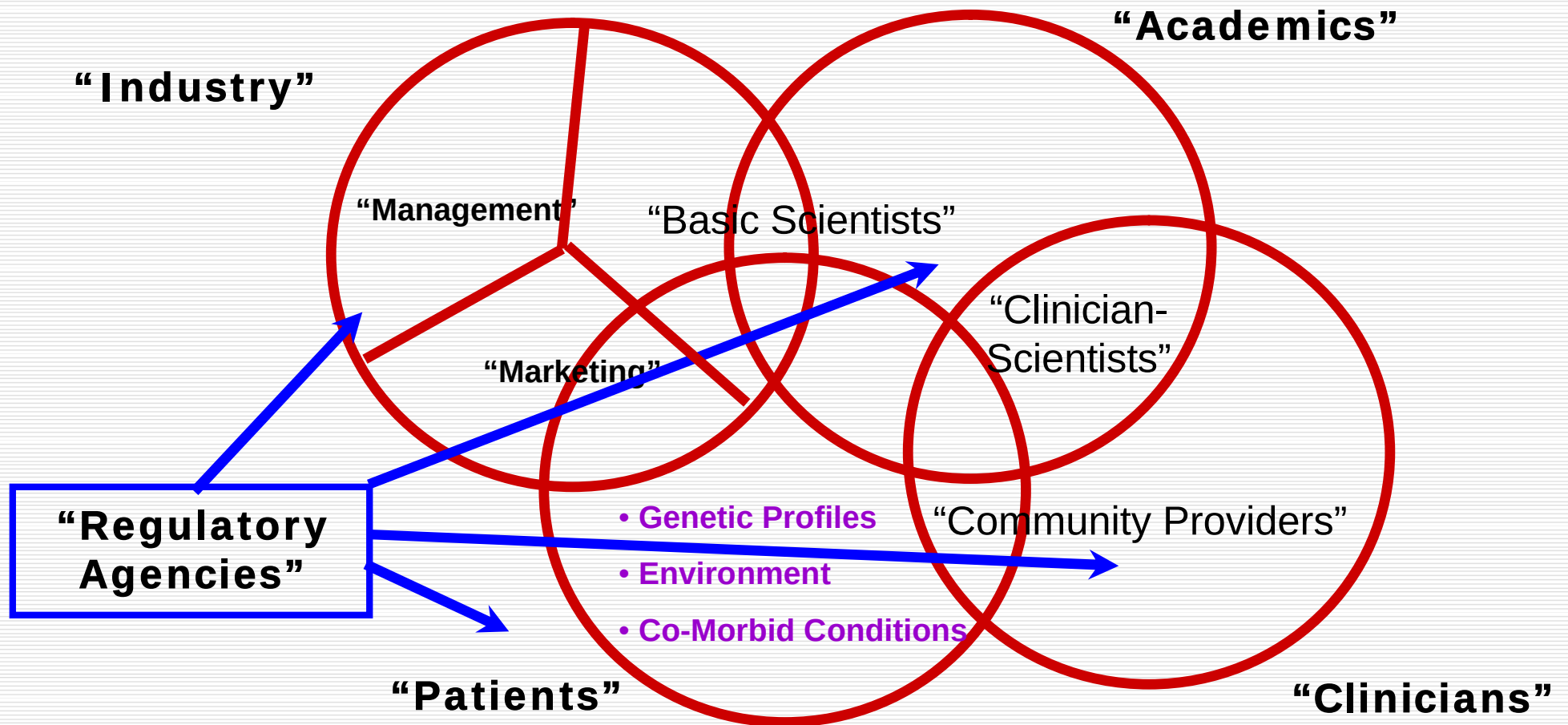
Open Innovation Networks: An Imperative for Breakthrough Therapies

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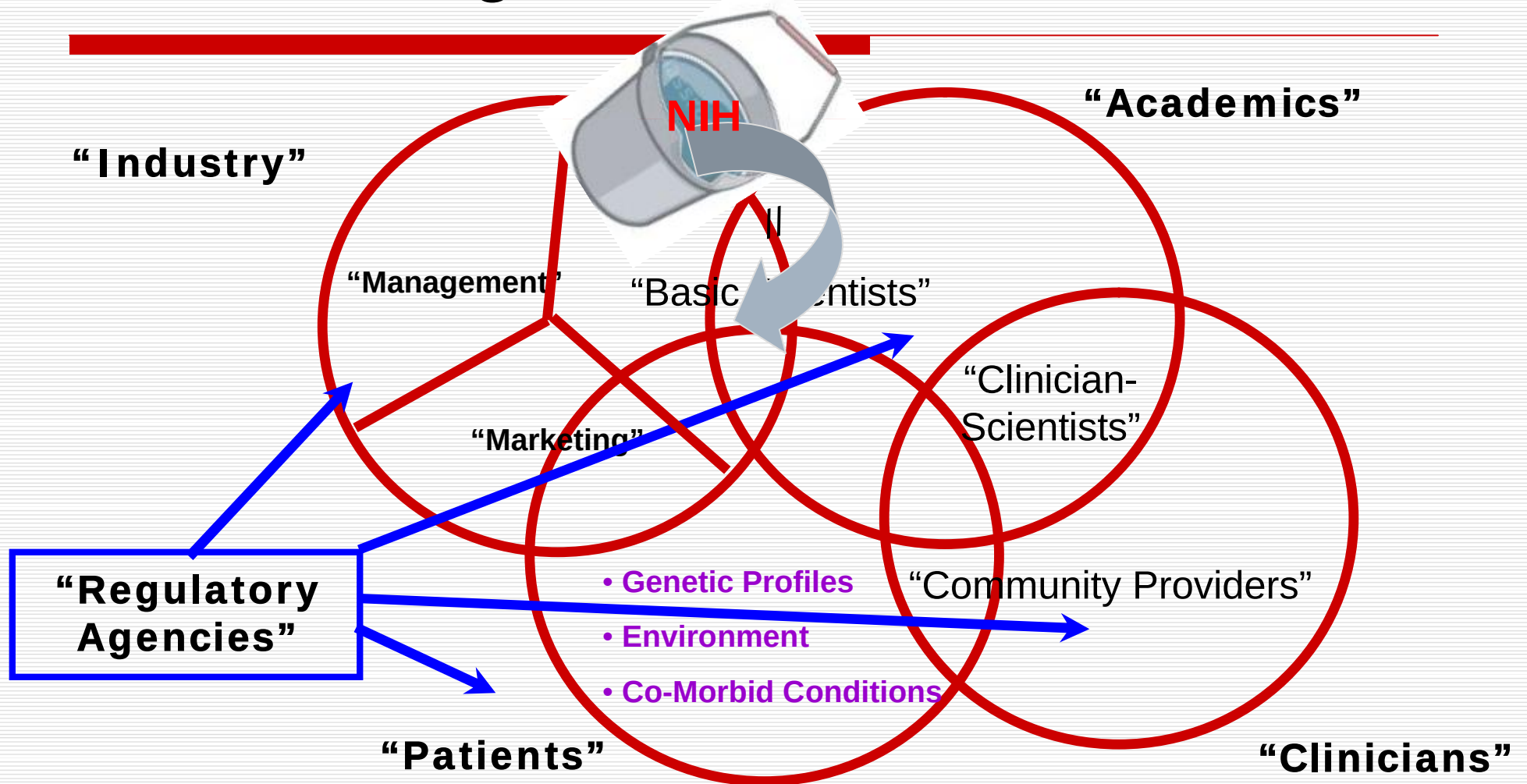
Creating Breakthrough Technologies

- § Why aren't existing models sufficient?**
 - § What are the barriers that undermine new scientific breakthroughs?**
 - § How can industry and academia collaborate to more effectively address them?**
 - § What are “Open Innovation Networks” and “Precompetitive Collaboration” and are they viable alternatives?**
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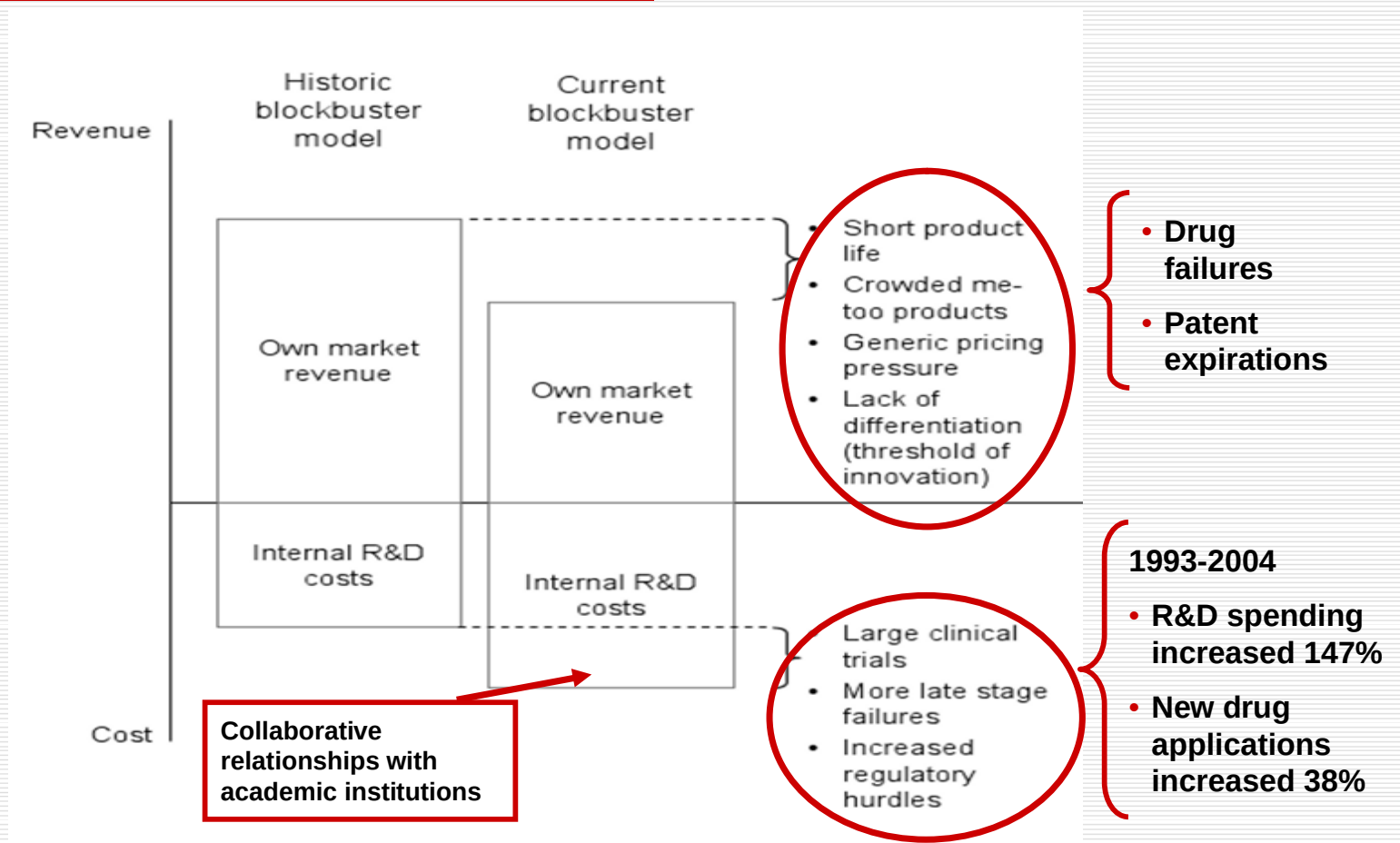
“Advancing Healthcare”



“Advancing Healthcare”



Models for Biopharmaceutical Innovation



Traditional Models No Longer Sufficient

§ Current state of knowledge, skills inadequate to address some of the more complex methodologic and clinically important questions

- Increasing complexity of research methodology
- Need for diverse expertise

§ Mandate for more effective research paradigms

- Evidence-based therapeutic interventions
- Comparative effectiveness studies to justify new treatments
- Personalized approaches to clinical management

§ Cost is only one contributing factor

- On average, 1-in-10 drugs that enter clinical trials will become a marketed product
 - Limitations are not due solely to “commercial” implications
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Most Importantly...

Traditional Models Stifle Innovation

- § Most “collaborations” are the result of independent (siloed) collaborations, based on individual academic-industry relationships
 - § Each has (appropriate) protections and limits
 - Conflicts of interest, commitment
 - Consulting relationships may preclude other research opportunities
 - For investigators, corporate funding augments Federal grants and contracts – but doesn’t necessarily advance science
 - § Multi-institutional relationships have been discouraged
 - § None of these models allow open access or sharing of critical resources and data
-

...and

Industry Is Recognizing These Realities

- § For many companies, it is now more cost effective to bring promising therapies from the *outside their own walls*
 - § “The days of a monolithic approach to ... research or commercialization are behind us” (Jeffrey Kindler, CEO, Pfizer)
 - Pfizer reducing R&D spending by \$3B by 2012 *without sacrificing future drug development*
 - Research hasn’t been worth the high levels of investment
 - Partnerships (and Wyeth acquisition) are filling the pipeline
 - AstraZeneca cutting research staff by 3500
 - Sanofi-Aventis cutting R&D spending by 20%
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“Open Innovation”

- § ***Economics of innovation*** is a key driver for companies to open their innovation process
- § **“...newly developing technologies and products benefit from *integrating knowledge and expertise from multiple sources*”**

Chesbrough, HW:HBS Press, 2003, 2006

What are the Key Elements of Change?

- § **Transformative therapeutics will require “creative” approaches, new rules**
 - Large databases including diverse populations required to establish meaningful relationships, associations
 - Diverse scientific expertise
 - Cross-disciplinary skills sets
 - Computational biology tools
 - Cores
 - Clinician-basic science collaborations
 - Clinical correlations
 - § **Existing barriers to communication, collaboration, cooperation must be understood and “managed”, if not overcome**
 - § **There is no single new model that will address all needs**
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Where are these “barriers”?

- § **Industry**
 - § **Academia**
 - § **The Public**
 - § **Government/Regulatory Agencies**
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Industry-Imposed Constraints

- § “Industry” is diverse
 - § Discovery valued based on benefit it brings to real world problem(s) – [commercial value]
 - § Scientific “autonomy”
 - § Economic realities
 - § Regulatory constraints
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Academia - Imposed Realities

- § **Discovery valued for “advancing knowledge”**
 - § **“Academic freedom”**
 - § **Intellectual autonomy**

 - § **Lack of inventory of research focus, strengths, opportunities**
 - § **“Compartmentalization” of basic scientists and clinicians**

 - § **Merit, promotion, tenure processes**

 - § **University policies and procedures**
 - **Contract negotiations**
 - **Technology transfer (royalty stream)**
 - **Economic autonomy**
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Other “Hurdles”

§ Potential conflicts between public good and shareholder value

- *Conflict of interest*
- Conflict of commitment

§ Historical “errors in judgment”

- Scientific misconduct
 - 90% of clinicians believe that ignoring certain entry criteria for a trial is acceptable if a patient *might* benefit from the trial
 - Lack of critical evaluation
 - Poor research design and execution
-

The Challenges Provide an Opportunity to Create New Relationships ...

- § **Categorize existing research relationships and assess its value**
 - Identify opportunities to expand relationship
 - § **Define the new (broader) strategic vision for collaboration**
 - Scientific synergies, internal needs
 - Opportunity to establish relationship in other areas
 - § **Consider alternatives**
 - Precompetitive Collaboration
 - Open Innovation Networks
 - Other “Translational” Opportunities
 - § **Evaluate strategy and outcomes**
-

Some Critical Elements

- § Recognize the *Value Proposition* of each collaboration
 - § Manage the industry-academic collaboration as an *Investment Portfolio*
 - § Adopt new approaches to *Information Sharing*
 - § Then define the most appropriate *Innovative Models* that will foster collaboration and overcome barriers
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Value Proposition

- § **All participants bring something of value to the collaboration**
 - Valuation of assets of collaborators must be “equitable” and “flexible”
 - § **Goals are more aligned than not *and* are compatible**
 - Academia values discovery that increases knowledge
 - Corporation values discovery that solves a real world problem
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Manage Collaboration as an “Enterprise-Wide” Investment Portfolio

- § **Manage projects as a portfolio to capitalize on synergies and eliminate redundancies**
 - § **Identify partner(s) that provide the synergies**
 - Clarify the roles and responsibilities of each partner
 - Be sure each partner values the relationship
 - § **Negotiate master agreements that define goals and scope of collaborations**
 - Predefine terms and conditions
 - Optimize “contractual” negotiations, minimize delays
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Acknowledge the AHS as a critical link to fostering innovation

§ Identify potential collaborators throughout the academic community

- **Basic and clinician scientist relationships longstanding**
- **Clinicians also provide keys to breakthrough technologies**
 - Understand mechanisms of disease
 - Monitor individual response to and compliance with therapies
 - Source for patient cohorts, biological specimen banks
- **AHCs train future generations of health care professionals**

§ Clinical and translational science initiatives (CTSA) are facilitating translation of bench science to the “bedside”

Share Information

- § **Develop “open” standards to allow validation, comparative analysis**
 - § **Create “Open Innovation” Research Networks to foster collaboration and innovation through shared resources (compound libraries, screening facilities, personnel sharing)**
 - § **Create non-exclusive consortia, alliances, networks, particularly in *precompetitive* areas of research**
 - **Examples**
 - RNAi Consortium
 - Biomarkers Consortium
 - Diabetes Genetic Initiative
 - § **Identify Collaborators within the Academic Community**
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Potential Models for Collaboration

- § **One company/one academic institution**
 - § **One company/several academic sites**
 - § **Consortium of industry and academic “members”**
 - § **Open access platforms**
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Define Scope of Relationship(s)

§ “Consultancy Phase”

- Define potential targets, drug candidates
- Provide “due diligence”

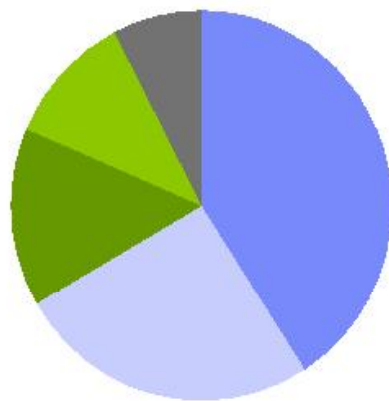
§ Pre-Clinical Collaboration

- Pre-competitive

§ Clinical Trials

Current Collaboration Management

Allocation by functional area with each responsible for managing its own collaborations

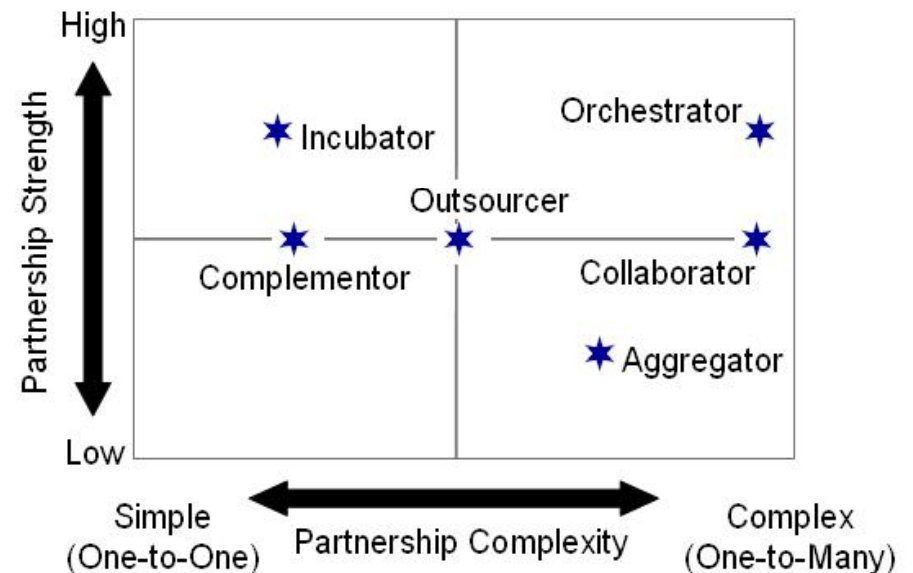


- Functional Area 1
- Functional Area 2
- Functional Area 3
- Functional Area 4
- Functional Area 5

Future Collaboration Management

Enterprise-wide portfolio management, utilizing diverse partnership models

Partnering Business Models



What Do “Open Innovation Networks” Provide?

- § **Create *coherent datasets* that capture the inherent complexity of human physiology**
 - § **Develop *robust representations of biology and disease* to more completely reflect the underlying complexity of physiologic systems**
 - § ***Harness the creativity* of the community of scientists**
 - § **Enable *more rapid progress* in refining the representations of biology and disease**
-

Open Innovation Models

§ InnoCentive (e.Lilly Division)

- Designed to foster innovation and efficiencies in research and development

§ Open Access Drug Companies

- Sector of corporate R&D designated for collaborative partnerships to focus on rare diseases

§ Sage Bionetworks

- Open access platform for sharing and disseminating complex data
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Open Innovation Models

§ Each of these approaches has a different structure, different goals, different financial expectations

§ Multiple approaches

- **Information Sharing**
 - **“Matchmaking”**
 - **Venture Capital**
 - **Incubators**
 - **Identify Potential Multi-institutional Collaboration Opportunities**
-

How Can We Optimize Chances for Success for These Collaborations?

- § **Define a oversight structure that promotes exchange of knowledge and collaborative development of milestones**
 - § **Prospectively acknowledge potential sources of conflict**
 - Organizational Issues
 - Culture
 - Funding challenges
 - § **Address key sources of controversy**
 - Confidentiality
 - Ownership and commercialization of jointly developed biologics
 - Publication “delays” (patent filing)
 - Intellectual property rights
 - Budgeting to support the research collaboration
 - § **Appoint “advisory board” to address COI issues**
-

Model for Industry-Academic Collaboration



Outstanding Questions

- § What will be the measures of success for these models?
 - § Is “precompetitive” collaboration sufficient to generate breakthrough technologies?
 - § Are “open innovation networks” and consortia the best models?
 - § Finally, are there other ways to create “out of the box” alternatives?
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*“Leap...
and the net will appear”*

Zen Proverb