Requisites for Successful Precompetitive Collaboration between Industry and the Academic Community

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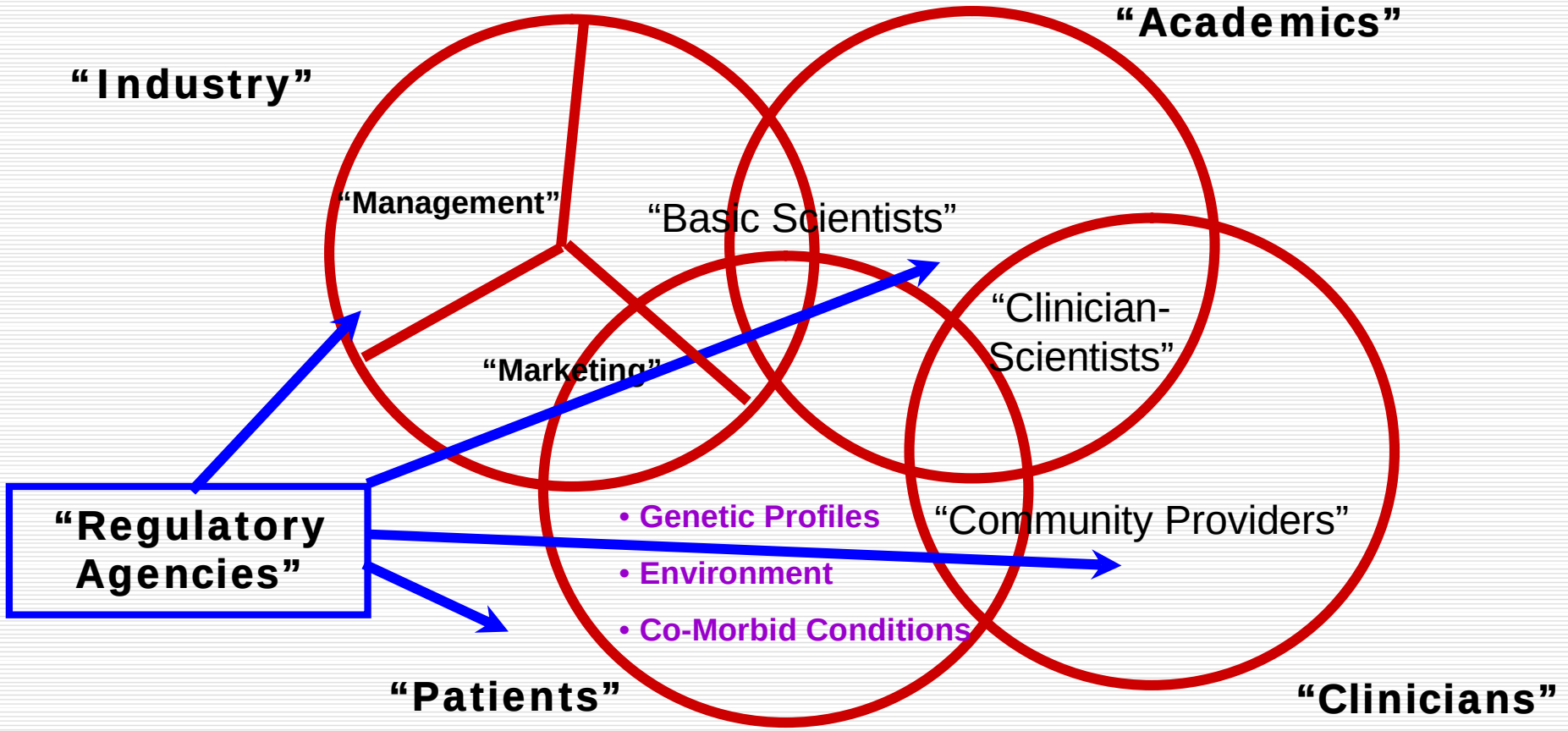
Requisites to Successful Precompetitive Collaboration

- **Describe the academic environment -- and its implications for collaboration**
  - **What is it?**
  - **The drivers for "success"**
- **Identify the current models for industry-academic relationships**
- **Describe potential barriers to broadening collaborations with industry – and how to overcome them?**
- **Propose some models to foster (precompetitive) collaboration?**

Understanding the Academic Environment

- **The academic environment is *heterogeneous***
  - **Undergraduate/graduate education**
  - **Diverse faculty**
  - **Basic science community**
  - **Clinicians, clinician scientists**
- **Goals and measures of success differ**
- **Collaborations with industry have been critical to the success within the academic community**
- **At the same time,**
  - **Value of collaborative relationships with industry is being questioned**
  - **Economics are influencing scientific inquiry**
  - **Industry competes with academic community for “talent”**

"Advancing Healthcare"



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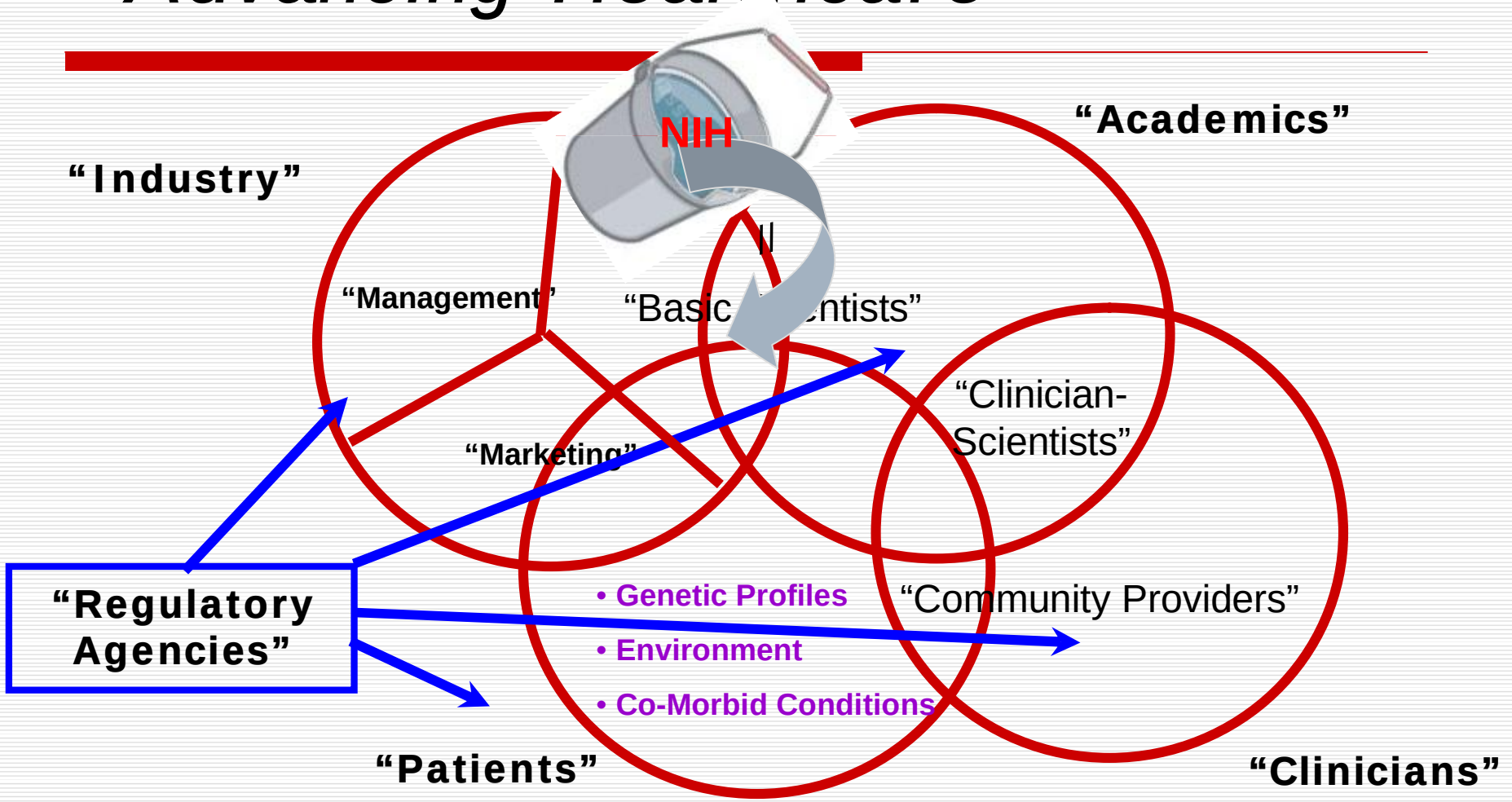

For Academic Communities, Traditional Models Are No Longer Sufficient

- **Current state of knowledge, skills inadequate to address some of the more complex methodologic and clinically important questions**
- **Mandate for more effective research paradigms**
  - **Increasing expectation that clinical care will be advanced by science**
  - **Personalized approaches to clinical management**
- **Federal funding for research is not sufficient – and comes at a cost**

Most Importantly…

Traditional Models Stifle Innovation

- **Most "collaborations" with industry are the result of individual academic-industry relationships ("siloed")**
- **Interdisciplinary research programs have been "undervalued"**
- **Each of the relationships has constraints that limit options**
  - **Conflicts of interest, commitment**
  - **Consulting relationships may preclude research opportunities**
  - **Industry support augments Federal grants and contracts – but doesn't necessarily advance science**
- **The existing models don't allow open access or sharing of critical resources and data**

So, What are the Alternatives?

- **There is no single new model that will address all issues**
- **Multiple opportunities to transform the relationships**
  - **Precompetitive collaboration**
  - **Shared scientific (and clinical) expertise**
  - **Integration of large databases, specimen banks that include diverse populations to establish meaningful relationships, associations**
  - **Engage the broader communities**
- ***but,* to do so, we have to understand existing barriers – and manage them**

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**

Academia-Imposed Barriers

- **Intellectual autonomy**
  - **Discovery valued for "advancing knowledge"**
  - **"Academic freedom"**
- **Compartmentalization of knowledge, skills**
  - **Lack of inventory of research focus, strengths, opportunities**
  - **Inadequate collaboration between basic scientists and clinicians**
- **Merit, promotion, tenure processes**
- **University policies and procedures**
  - **Contract negotiations**
  - **Technology transfer (royalty stream)**
  - **Economic autonomy**
- **Conflict of interest, conflict of commitment**

So, How Do We Convert These Challenges into Opportunities?

- **"Market" the importance of industry-academic collaborations**
- **Define the new (broader) strategic vision for collaboration**
  - **Scientific synergies, internal needs**
  - **Opportunity to establish relationship in other areas**
- **Identify alternative models for collaboration, including precompetitive collaboration**

Acknowledge the AHS as a critical link to fostering innovation

- **Identify potential collaborators *throughout* the academic community**
  - **Basic and clinician scientist relationships**
  - **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**
  - **Build on CTSA model**
- **AHCs train future generations of health care professionals**

Share Information and Resources

- **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)**
- **Develop non-exclusive consortia, alliances, networks, particularly in *precompetitive* areas of research**
- **Create incubators within the AHS**

Manage Collaboration as an "Enterprise-Wide" Investment Portfolio

- **Manage projects as a portfolio to capitalize on synergies and eliminate redundancies**
- **Identify key partner(s)**
- **Negotiate Master Agreements**
  - **Clarify goals and scope of collaboration(s)**
  - **Predefine terms and conditions**
  - **Minimize delays**
- **Think beyond the traditional academic models**

Redefine Collaborative Relationship

- **Define oversight structure for these relationships that promotes exchange of knowledge and collaboration**
  - **Strategic Planning Board**
  - **Coordinating Committee to "manage" collaboration**
  - **Advisory Board**
- **Address potential sources of conflict**
  - **Confidentiality**
  - **Ownership and commercialization of jointly developed biologics**
  - **Publication "delays" (patent filing)**
  - **Intellectual property rights**
  - **Budgeting to support the research collaboration**

Model for Industry-Academic Collaboration

Outstanding Questions

- **What are the best model(s) for successful collaboration?**
- **What will be the measures of success?**
- **Is "precompetitive" collaboration sufficient to generate breakthrough technologies?**
- **Can we effectively overcome the concerns about COI in these collaborative relationships?**