

Research Teams in Industry and Academia

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GREAT Group Annual Meeting
Seattle, Washington
October 4, 2008



Relevant Career Experiences

- **1981-94** **Professor and Chairman, Department of Pharmacology, University of Pennsylvania**
- **1995-2001** **Vice President, Neuroscience and Genitourinary Drug Discovery, Bristol-Myers Squibb**
- **2001-03** **EVP Research and Development, Palatin Technologies**
- **2003-2006** **Vice Provost for Research, University of Pennsylvania**
- **2006-present**
 - **Professor of Pharmacology, University of Pennsylvania**
 - **Consultant/Board Member**
 - **Palatin Technologies**
 - **Cypress Bioscience**
 - **Galleon Pharmaceuticals**
 - **Advinus Therapeutics**



Missions are Different

- **Academic Institutions**
 - Creation of knowledge
 - Answers inevitably generate new questions
 - Translational research and technology transfer
 - New institutional models are emerging
- **Industrial Organizations**
 - Development of products
 - A marketed product is an end point
 - Generate a return on investment
 - Need access to intellectual output of academic medical centers



Critical Questions

- **Academic Research**

- Is it known
- Would it be interesting/important to know
 - Subject only to availability of funds

- **Industrial Research**

- Is it known
- Is the knowledge necessary to proceed
 - Cost of unnecessary research can be enormous



Teams in Academia

- Investigator initiated research
- Collaborations are entirely voluntary
 - Can be situational or long-term
- Entrepreneurial – if you have the grant you can do the work
- Multiple factors increasingly encourage collaborative research
 - Expensive shared instrumentation
 - Translational research
 - NIH Roadmap - building new teams
 - Eg. Genes and the environment - geneticists and experts in Environmental Health Sciences

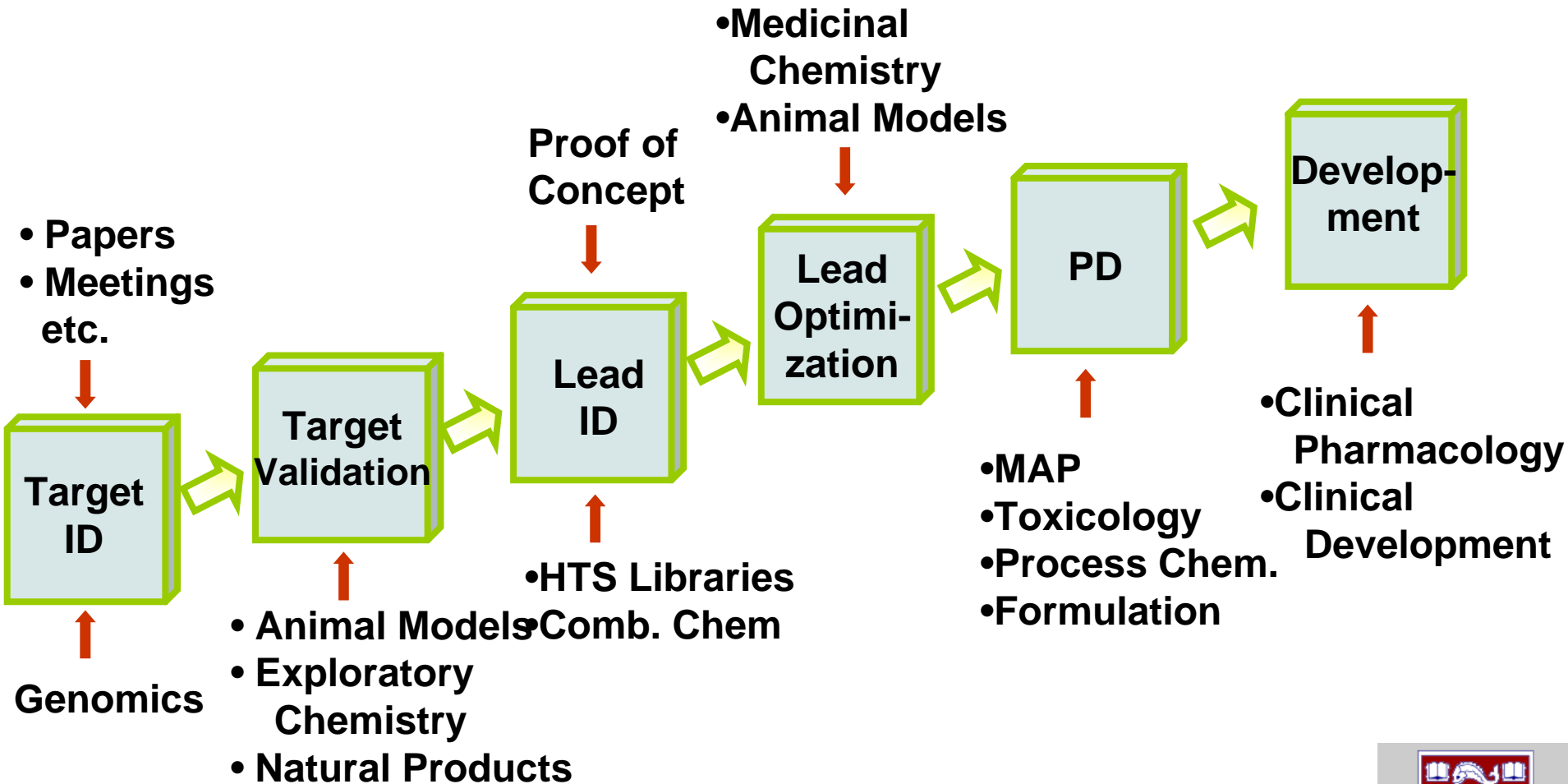


Teams in Industry

- Everyone is in the same boat
- A willingness to collaborate is assumed/expected
- Multiple types of expertise are required as a program progresses
- Panel of required expertise changes as a program moves through development
- Virtual teams outsourcing of drug discovery and development,



Steps in Drug Discovery



Discovery versus Development

• DISCOVERY TEAM*

- Medicinal Chemistry
- HTS
- Biological Science
- POC in Animals
- PK
- Toxicology

*Scientific lead

• DEVELOPMENT TEAM**

- Process Chemistry
- Formulations
- Toxicology
- MAP
- Clinical Trials

**Often business lead



Silos and Handoffs in Industry

- Target identification(TI) and target validation(TV)
hand off
 - High throughput screening(HTS)/lead identification
hand off
 - Compound selection and animal proof of concept
hand off
 - Clinical development
- NB: Licensing
- Increasing outsourcing of research
 - Virtual teams and Research Alliances
 - Involves targets, leads, and clinical candidates
 - The NIH syndrome



A Problem of Integration

- Project oriented distribution of personnel
- A finite number of projects with dedicated biologists
- Problems
 - Difficult to staff new or exploratory programs
 - Uneven distribution of work



A Matrix Solution

- Departmental Structure
- Departmental heads responsible for staffing decisions
- Permitted a more flexible utilization of resources
- Result
 - Increased number of active programs
 - Increased number of approved clinical candidates

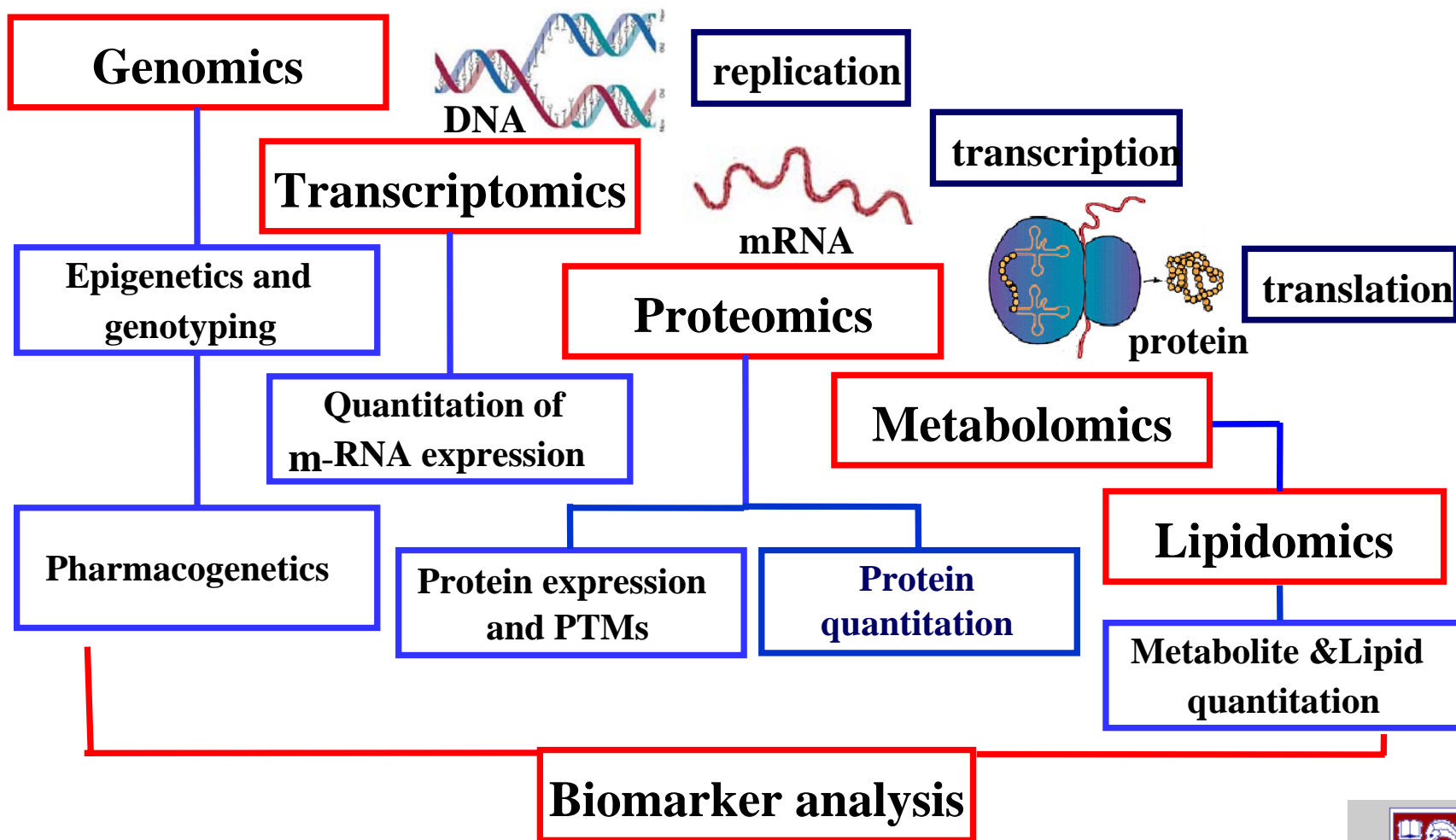


New Approaches to Academic Research

- Multidisciplinary approaches are increasing - collaborative research involving scientists with different sets of expertise
- “OMICS”
 - Genomics
 - Proteomics
 - Metabolomics
 - Lipidomics
- Increasing interest in translational research
 - CTSA
 - University/Corporate alliances
- Transinstitutional Initiatives
 - NIH neuroscience microarray consortium
 - HTS centers



Molecular Profiling



New Aspects of “OMICS” Research

- Highly collaborative
- Highly specialized
- Equipment is expensive and of restricted availability
- Critical dependence on bioinformatics
- Varying levels of expertise are required
 - Service core – routine assays. Usually fee for service
 - Research core – Trouble shooting/validating a system
 - Cutting edge research



Issues in “OMICS” Research

- Potential for an overwhelming number of collaborations
 - Fee for service versus a collaborative model
- Funding of research core activities is hard to identify – data is usually required to get funding
- Funding of high cost equipment
 - Leasing vs purchase
- Integration of “OMICS” technology with biology



CTSA (Clinical & Translational Science Awards)

- Awarded to Penn after first round
- Collaborative program
 - University of Pennsylvania
 - The Children’s Hospital of Philadelphia
 - The University of the Sciences in Philadelphia
 - The Wistar Institute
- Followed the establishment of the Institute for Translational Medicine and Therapeutics (ITMAT)
 - Inclusion of the GCRC - Integration of facilities at PENN and CHOP
 - Dedicated “wet” and “dry” bench space for translational research
 - Robust educational programs - Masters in Translational Research
 - Fosters interdisciplinary research



University/Corporate Alliances

- **Traditional model**
 - Individual research contracts
 - Usually includes existing and to be developed intellectual property
 - Negotiation between a company and the office of technology transfer - ? role of investigator
- **Objectives of new model**
 - Build relationships with the corporate community
 - Identify and develop new business opportunities
 - Improve institutional processes

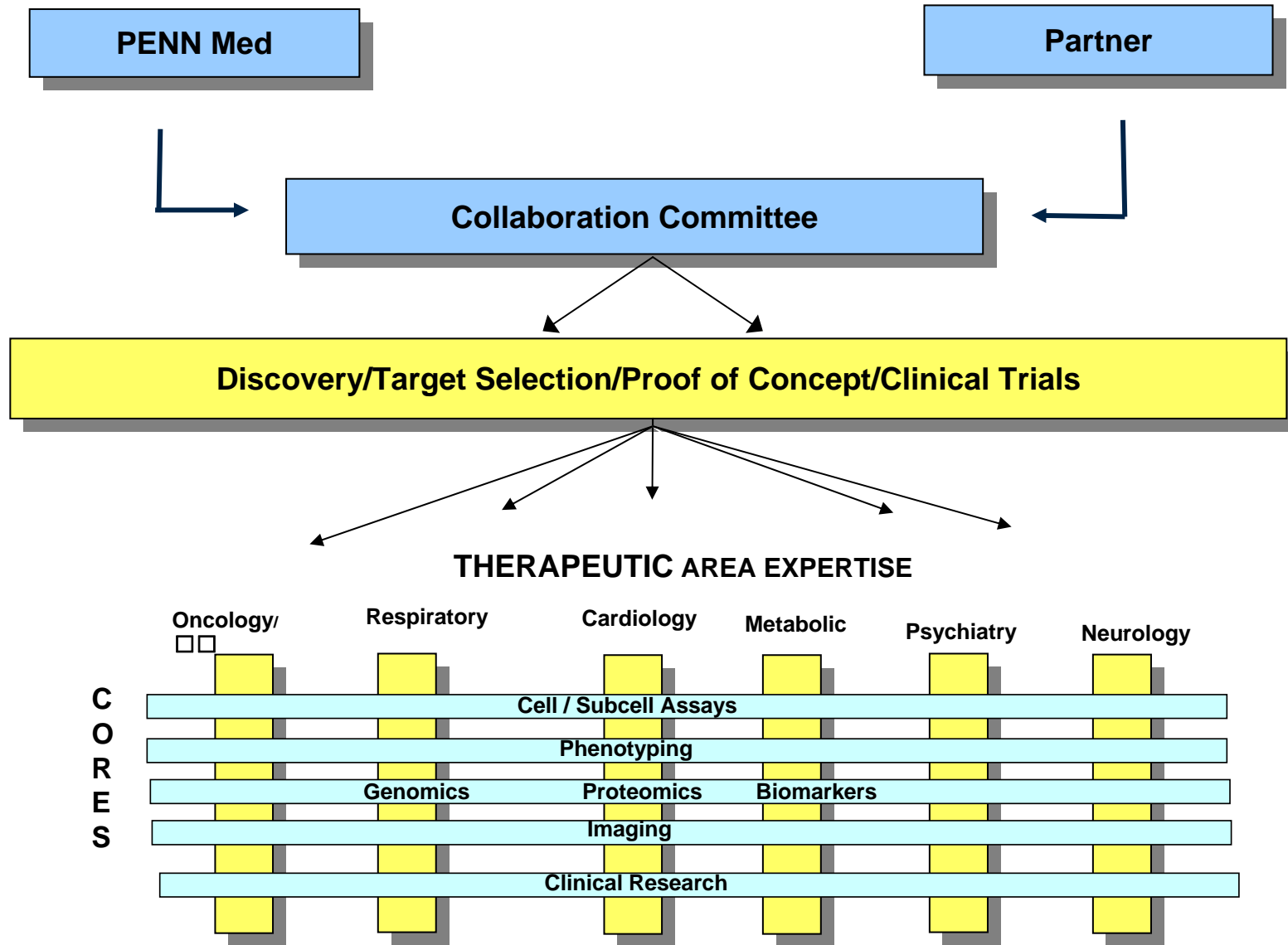


Corporate Alliances: Operating Principles

- Umbrella agreements - Specific projects are jointly developed between Penn faculty and company counterparts
- Agreements are prospective - ie, WORK TO BE DONE
- Projects compete for funding and have defined goals, objectives, and timelines
- Target identification and testing in defined clinical areas, coupled to enhanced early phase clinical optimization
- Ownership of intellectual property (ip) is not predetermined - company may receive an option to license university owned ip



Structure of Partnerships



Alternative Models/Solutions

- **Affiliated foundation/institute**
 - Can do fee for service research
 - Restrictions on results
 - Publications/Presentations, eg. DOD
 - Limitations on participation
- **Blanket assignment of intellectual property**
 - Assign ip before research is done
 - Predetermination of value
- **Right of first refusal or first right to negotiate**



Conclusions

- Differences in mission and approach
- Teams are increasingly important in the academic sector
 - Changes in mechanisms of research support
 - Changes in capability and opportunity
- Outsourcing in industry - teams being redefined
 - Industry is supporting an increasing percentage of university based R&D
 - Industry is putting less emphasis on internal research and is outsourcing both research and development
 - Biotech companies
 - Alliances, eg. India and China

