Defining the Expertise for the 21st Century Neuroscience Workforce

James E. Barrett, Ph.D.
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Department of Pharmacology and Physiology

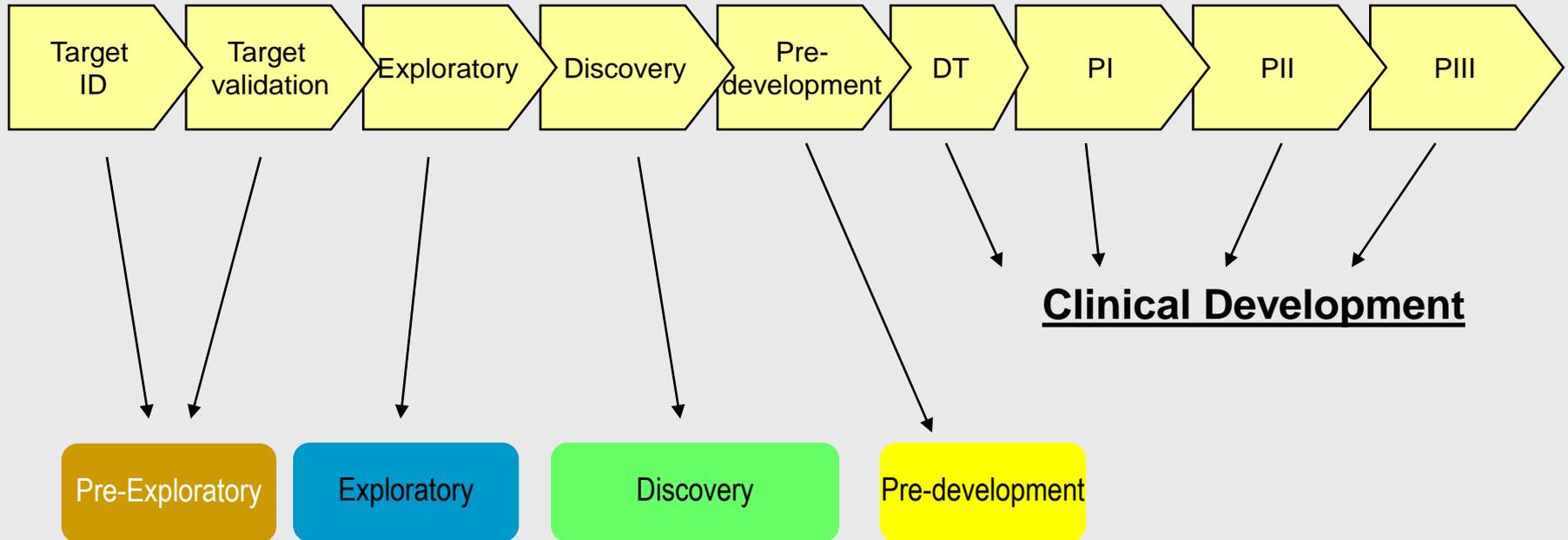**Drug Discovery and Development Program at Drexel University College of Medicine**

A new comprehensive program offering a Master of Science in Drug Discovery and Development.

Learn more about the program at: **www.drexelmed.edu/drug-discovery-development**

Phases of Drug Discovery Research and Development

| Target ID | Target validation | Exploratory | Discovery | Pre-development | DT | PI | PII | PIII |

Clinical Development

| Pre-Exploratory | Exploratory | Discovery | Pre-development |

M.S. Program in Drug Discovery and Development

Basic >	Translational >	Clinical >

Provide the rigorous scientific and technical training necessary to succeed in the complex field of drug discovery and development and facilitate a smooth transition to an enduring and productive career in industry or academia.

Key components

- **Core Curriculum** incorporates multiple biomedical disciplines to establish a solid scientific foundation

- **Customized course of study** with numerous options at Drexel's Graduate and Professional schools
  - Medicine, Business, Law, Public Health, Biomedical Engineering
  - **Extensive network of industry professionals** provides experience, depth, specialized training and real world insights

DREXEL UNIVERSITY
College of
Medicine
Department of Pharmacology and Physiology

Foundation Courses

- **Drug Discovery**
  - Introduction to the Drug Discovery and Development field
  - Comprehensive overview of the drug discovery process
  - Developed and taught by experienced professionals
  - Topics range from target identification to IND submission

- **Drug Development**
  - Comprehensive overview of the drug development process
  - Topics range from Clinical Trials to Marketing and Commercialization
  - Project Management and Project Team Formation
  - Includes illustrative case studies

Topics

- **Drug Discovery**
  - High Throughput Screening
  - Medicinal Chemistry
  - Computer Aided Drug Design
  - Lead Optimization
  - Pharmaceutical Profiling
  - **Animal Models**
  - Safety and Toxicology
  - Biologics
  - **Pharmacogenetics**
  - **Translational Medicine**
  - Peptide Therapeutics
  - Vaccines
  - IND Application
  - **Case Studies**

- **Drug Development**
  - Phase I – Safety and Tolerability
  - **Biomarkers**
  - Phase II – Proof of Concept
  - Phase III – Efficacy and Safety
  - Pharmaceutical Manufacturing
  - Formulation
  - Role of the FDA
  - New Drug Application
  - Medical Writing
  - **Pharmacoepidemiology**
  - Business Development
  - Commercialization and Marketing
  - Intellectual Property
  - **Case Studies**

ELSEVIER

Something's got to give: psychiatric disease on the rise and novel drug development on the decline

Daniel J. Chandler

Drexel University College of Medicine, Department of Neurobiology and Anatomy, 2900 Queen Lane, Philadelphia, PA 19129, USA

Research and development of drugs for psychiatric disease is currently in a state of decline. Despite the increasing prevalence and healthcare costs of psychiatric disease, the costly and unpredictable drug development process has led to decreased public and investor confidence in the abilities of companies to develop safe and efficacious drugs. Industrial research in this disease area is therefore being scaled back owing to various scientific, corporate, financial and legal factors. This review will consider how these factors contribute to the current status of psychiatric drug development and offer several avenues forward to spur reinvestment in this type of research. Such a shift is needed to reduce the burden psychiatric disease imposes on the healthcare system and its patient populations.

"Valley of Death"

CNS Drugs
Valley of Death

Academic – Industry Collaborations
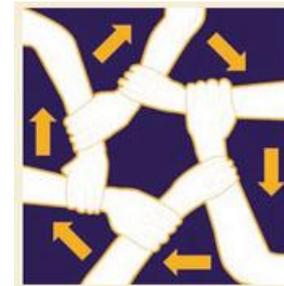
Finding improved medicines: the role of academic–industrial collaboration

Jaye Chin-Dusting, Jacques Mizrahi, Garry Jennings and Desmond Fitzgerald

Drug discovery: new models for industry–academic partnerships

Cathy J. Tralau-Stewart, Colin A. Wyatt, Dominique E. Kleyn and Alex Ayad

Drug Discovery Centre and Business Development, Imperial College London SW7 2AZ, UK

Helping Science and Drug Development to Succeed through Pharma-Academia Partnerships

Yale Healthcare Conference 2013
Daniel X. Yang, BS* and Yunsoo A. Kim, AB

More pharma–academia R&D collaborations

NIH encourages translational collaboration with industry

A meeting that marks a new effort to promote collaboration between academic institutions and industry on translational research took place at the US National Institutes of Health (NIH) in February.

Drug Discovery Gets an Academic Push

Drug discovery through industry-academic partnerships

Nathanael S Gray

Translational research in academia is extending beyond the traditional involvement in clinical trials to the early phases of the drug discovery process. Examples of successful academic-industrial partnerships illustrate the ways in which they can enable the discovery of new medicines.

Academic – Industry Partnerships
## A Growing Trend

Driving Drug Discovery:
The Fundamental Role of Academic Labs

B. Michael Silber

Published 5 May 2010; Voume 2 Issue 30 30cm16

Academic labs have been responsible for virtually all of the basic science discoveries that translate into the discovery and development of innovative new medicines. There is a growing concern that large pharmaceutical and biotechnology companies are not able to sustain research pipelines that bring new compounds into drug development that translate into innovative new medicines, especially in areas with high unmet medical need. To address the needs of patients, caregivers, and society, academic labs have played and can continue to play an important role at one or more stages in the development of innovative medicines, both directly and through collaborations with researchers in pharmaceutical and biotechnology companies. Collaboration is in the best interests of patients and society if it accelerates the translation of basic science discoveries to new medicines that address unmet medical needs.
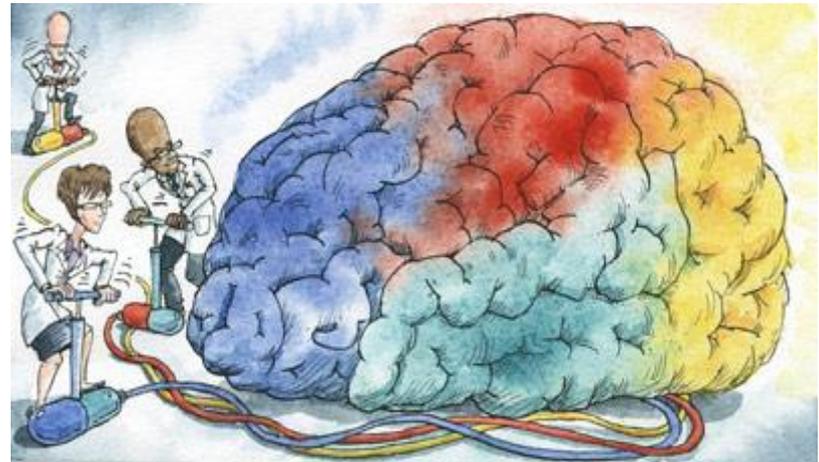
Drug discovery goes back to school: changing ecosystem of drug discovery and the rising role of academia

B Slusher[1,2,3,4]

[1]*Department of Neurology;* [2]*Department of Psychiatry;* [3]*Department of Neuroscience; and* [4]*NeuroTranslational Drug Discovery Program, Brain Science Institute, Johns Hopkins School of Medicine, Baltimore, MD, USA*

Challenges facing the pharmaceutical industry:

- Costs of bringing new drugs to market
- Patent loss – generics -by 2016 the "patent cliff" will impact 57% of overall 2010 sales – a potential loss of over $130 billion
- Costly, late-stage clinical failures
- Decreased productivity
- Recent downsizing in pharma of over 100,000 jobs
- Reduction of efforts in drug discovery

Contributions from academia

While the pharmaceutical industry is facing highly challenging times, the academic drug discovery sector has the potential to contribute meaningfully to the discovery of novel drug targets and to the development of new mode-of-action therapeutics against a range of diseases, including rare and neglected diseases.

Industry 53%   Non-industry 47%
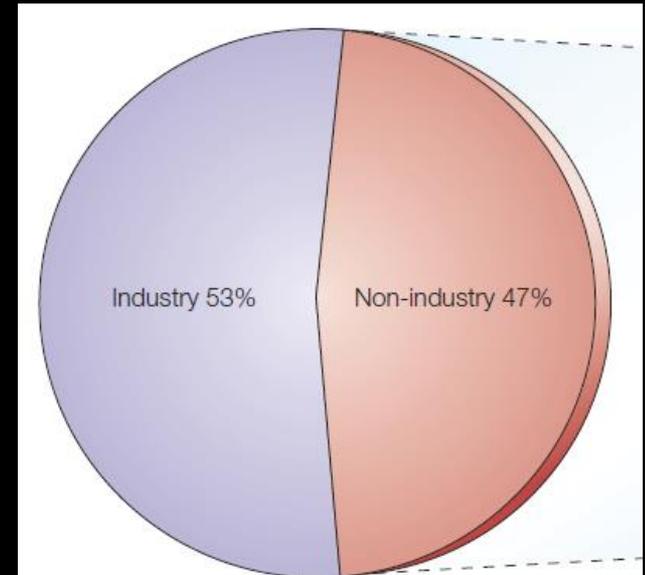
Team Science ⟹

bioentrepreneur
from **bench** *to* **boardroom**
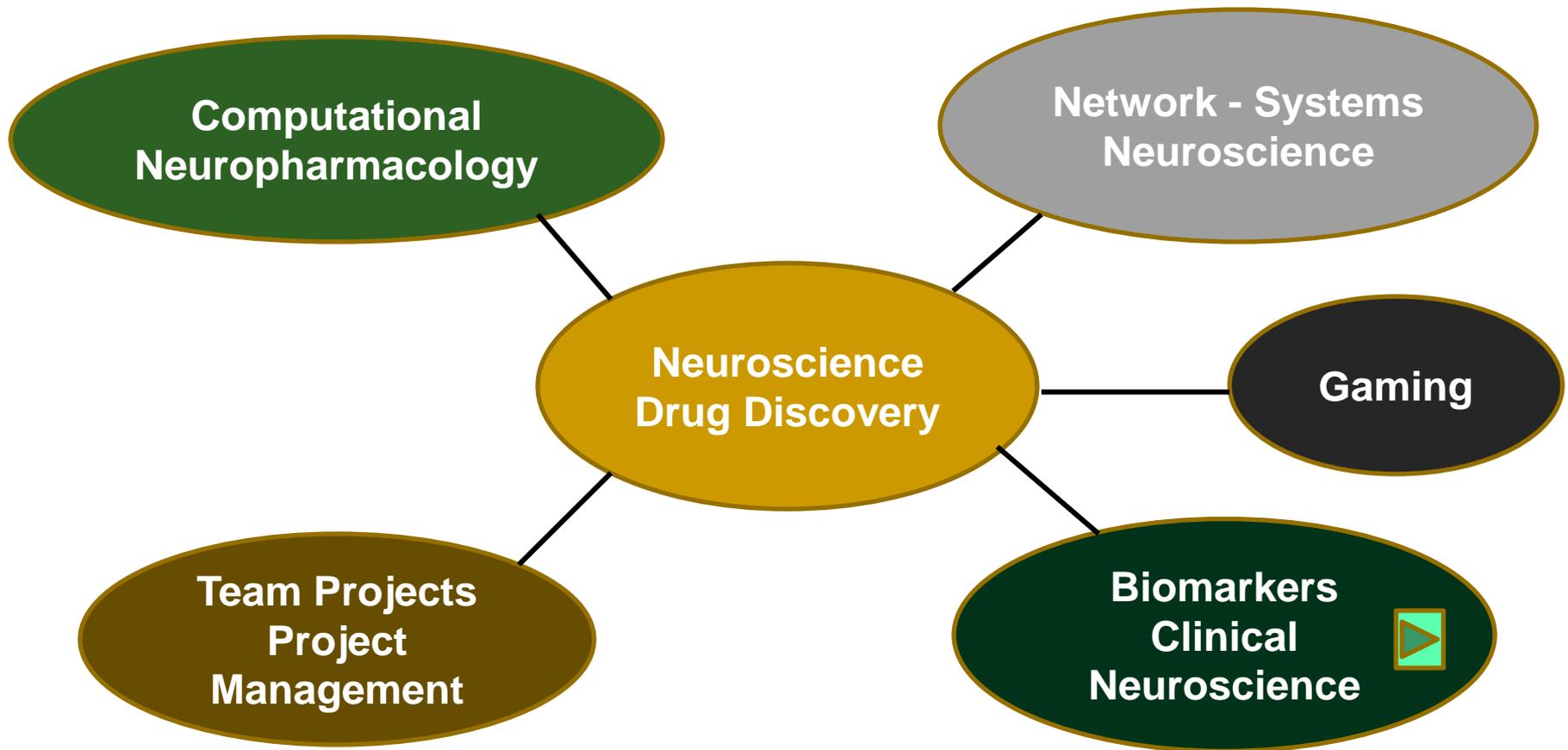
BUILDING A BUSINESS

From academic solos to industrial symphonies

Gwen Acton, Alicia Gómez-Yafal & Emily Walsh

Academic researchers often need to stand out to advance, but the corporate world calls for team players. Moving from one world to the other can be a culture shock.

Extensions and Additions Driven by Drug Discovery and Development Program

Basic and Clinical Research are Interdependent

| Basic Research | ⟷ | Clinical Research | ⟷ | Improved Health |

Translation from basic science to human studies

Translation of new knowledge into clinical practice

Adapted from Sung et al. (2003) JAMA, 289, 1278-89.
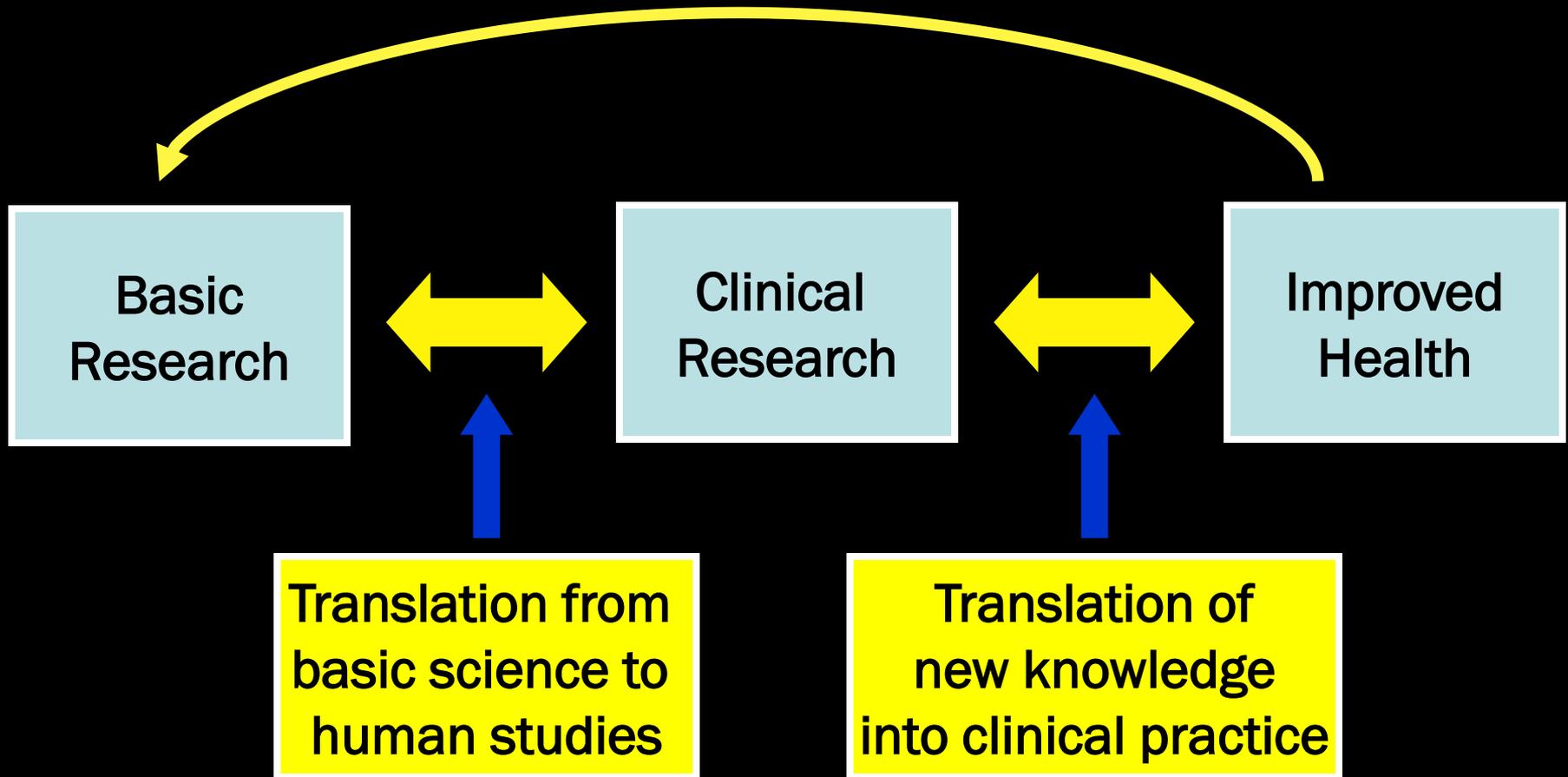
Features of Complex Regional Pain Syndrome
Edema, Color Change, Dystonia

Circos diagram showing the correlation of selected parameters and miRNAs
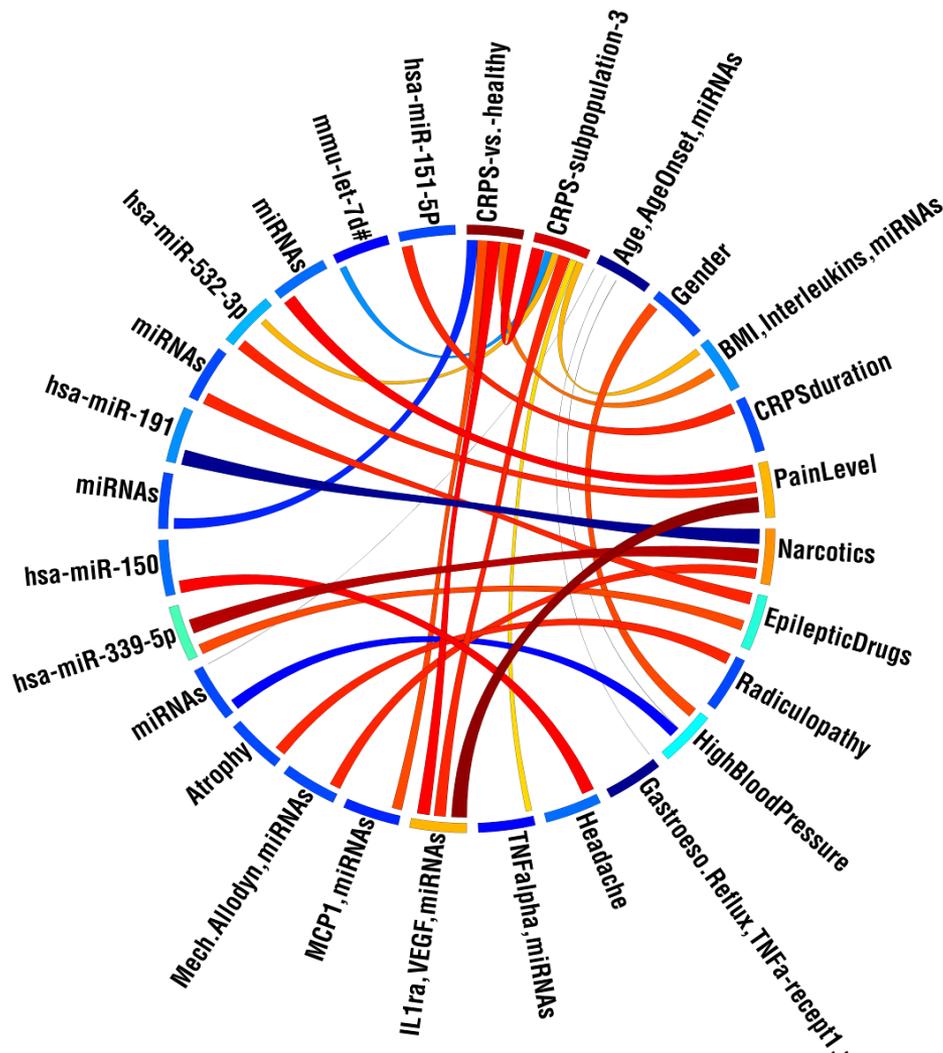
The nodes along the circle are colored by the total strength of correlation of the corresponding variable

Strong negative correlations shown in dark blue (e.g., narcotics vs. hsa-miR-191).

Strong positive correlations are shown in dark red (e.g., pain level vs. "IL1Ra, VEGF, miRNAs")
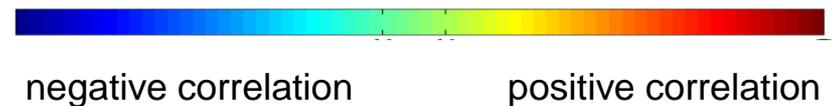
negative correlation   positive correlation

Orlova et al. 2011

Extensions and Additions Driven by Drug Discovery and Development Program

ISB platform complements the limitations of animal models

Placebo response

Differences in drug metabolism

Different drug affinities

Different neurotransmitter wiring

Absence of functional genotypes

Incomplete pathology in transgenic mice

Geerts 2009, CNS Drugs 23, 1

In Silico Biosciences
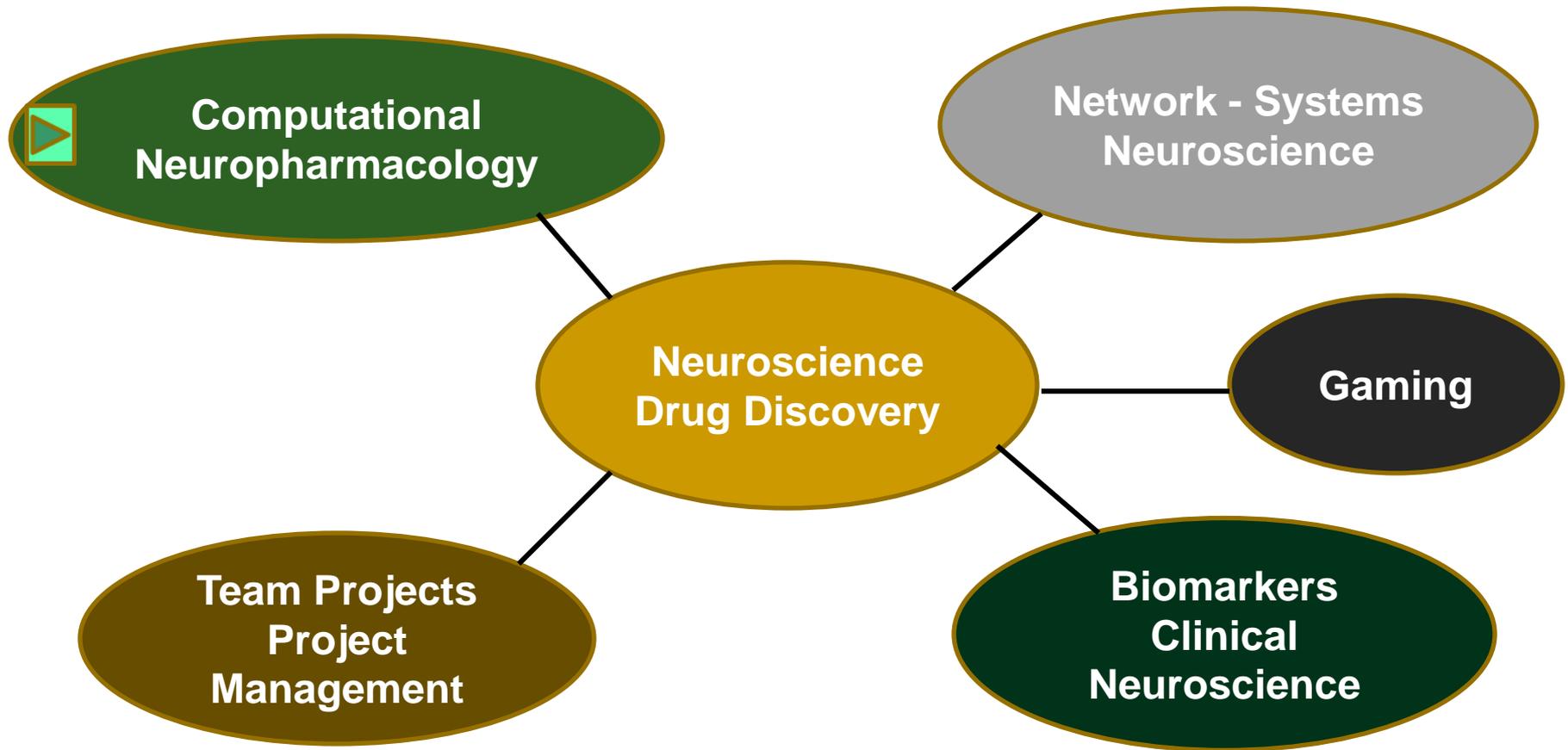
Areas Needed to Enhance Program

- Behavioral analysis, animal models in neuroscience and data capture and data analysis ▶
- Neurodevelopmental processes
- Clinical neuroscience – Physician Scientists
- Bioinformatics

Innovative Drugs to Treat Depression: Did Animal Models Fail to Be Predictive or Did Clinical Trials Fail to Detect Effects?

Catherine Belzung[*,1]

[1]INSERM 930 and Université François Rabelais Tours, UFR Sciences et Techniques, Parc Grandmont, Tours, France

REVIEW

Predictive validity of behavioural animal models for chronic pain

Odd-Geir Berge

AstraZeneca R&D, CNS&Pain IMed, Södertälje, Sweden, and Department of Surgical Science, Uppsala University, Uppsala, Sweden

The benefits and limitations of animal models for translational research in neurodegenerative diseases

Mathias Jucker

Research in Translation

Can Animal Models of Disease Reliably Inform Human Studies?

H. Bart van der Worp[1]*, David W. Howells[2], Emily S. Sena[2,3], Michelle J. Porritt[2], Sarah Rewell[2], Victoria O'Collins[2], Malcolm R. Macleod[3]

1 Department of Neurology, Rudolf Magnus Institute of Neuroscience, University Medical Centre Utrecht, Utrecht, The Netherlands, 2 National Stroke Research Institute & University of Melbourne Department of Medicine, Austin Health, Melbourne, Australia, 3 Department of Clinical Neurosciences, University of Edinburgh, Edinburgh, United Kingdom

Evaluation of Excess Significance Bias in Animal Studies of Neurological Diseases

Konstantinos K. Tsilidis[1,9], Orestis A. Panagiotou[1,9], Emily S. Sena[2,3], Eleni Aretouli[4,5], Evangelos Evangelou[1], David W. Howells[3], Rustam Al-Shahi Salman[2], Malcolm R. Macleod[2], John P. A. Ioannidis[6]*

Is animal research sufficiently evidence based to be a cornerstone of biomedical research?

Public acceptance of the use of animals in biomedical research is conditional on it producing benefits for humans. **Pandora Pound** and **Michael Bracken** argue that the benefits remain unproved and may divert funds from research that is more relevant to doctors and their patients

Threats to Validity in the Design and Conduct of Preclinical Efficacy Studies: A Systematic Review of Guidelines for In Vivo Animal Experiments

Valerie C. Henderson[1], Jonathan Kimmelman[1]*, Dean Fergusson[2,3], Jeremy M. Grimshaw[2,3], Dan G. Hackam[4]

Areas Needed to Enhance Program

- Behavioral analysis, animal models in neuroscience and data capture and analysis
- Neurodevelopmental processes
- Clinical neuroscience
- Bioinformatics

nature
neuroscience

Focus on big data

Nature Neuroscience presents a special focus issue highlighting big data efforts under way in the field.

Big behavioral data: psychology, ethology and the foundations of neuroscience

Alex Gomez-Marin, Joseph J Paton, Adam R Kampff, Rui M Costa & Zachary F Mainen

Behavior is a unifying organismal process where genes, neural function, anatomy and environment converge and interrelate. Here we review the current state and discuss the future effect of accelerating advances in technology for behavioral studies, focusing on rodents as an example.

General Summary

- Establishing a Program in Drug Discovery and Development has created many new opportunities and avenues for innovative education and career opportunities in neuroscience

- The issues facing the discovery and development of new drugs for CNS disorders are intimately related to the identification of new disciplines and technologies

- The program has flexibility, accommodation and interactions with other disciplines and is capable of adapting and incorporating new trends to train neuroscience students and faculty