

**Missouri Regional Life Sciences Summit  
March 9, 2010**

**The Institute for Advancing Medical  
Innovation**

**Stepping into the future of drug discovery, delivery and  
biomedical engineering**

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<http://www2.kumc.edu/iami/>

## “Meltdown” in Pharmaceutical industry

### Lessons from 60 years of pharmaceutical innovation.

Bernard Munos,  
*NATURE REVIEWS | Drug Discovery*,  
V.8 DECEMBER 2009 | 959

### A Call for Sharing: Adapting Pharmaceutical Research to New Realities

Bernard Munos\* and William Chin  
*Science Translational Medicine*.  
December 2009, Vol. 1 Issue 9

Crisis

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# Institute for Advancing Medical Innovation

**Novel Drugs &  
Drug Targets**

**Drug  
Discovery  
Research**

**Drug Products &  
Delivery  
Platforms**

**Drug  
Delivery  
Research**

**Biomaterials  
& Medical  
Devices**

**Bio-  
Engineering  
Research**

**Drug-Device  
Combination  
Products**

**Integrated  
Bio-Engineering  
& Drug Research**

**Training the Next Generation  
Of Medical Innovators**

**Advance Medical Innovations To Commercialization**

## Institute Objectives

- Advance novel, new medical innovations for the diagnosis, treatment, prevention and control of human and animal disease – To clinical proof of concept.
- Create a culture of multi-disciplinary, multi-organizational collaboration focused on advancing medical innovations from discovery to commercialization.
- Prepare graduate and postdoctoral students for careers in development and commercialization of medical innovations.

## Features of the Grant

- ~\$16.1 M over five years beginning January 1, 2009
  - » \$8.1M from Kauffman Foundation
  - » \$8.0M match from KUEA
- Advisory Board makes project funding decisions
- Industry experienced project managers
- Fellowships
  - » 10 graduate students
  - » 4 postdoctoral students
  - » 1 additional postdoctoral fellowship through Kauffman national fellows program
- ~\$1.6M per year proof of concept funds available to projects actively managed by Institute
- Nine industry adjunct instructors
- Seminars, showcases, and networking of innovations
- Market research performed in collaboration with KU Business School

# Proof of Concept Overview

- \$1.6 million annual budget for investment in faculty research
- RFP and ad hoc funding mechanisms
  - » Projects from both mechanisms meet same criteria and are reviewed and approved by Advisory Board
- Funding is milestone driven, focused on assisting project teams in advancing projects from one go/no go decision point to the next in an overall project plan.
- IAMI staff work with PI and project teams to identify commercialization and follow-on funding opportunities

# IAMI Advisory Board

**Christopher P. Austin**, Director, National Institutes of Health Chemical Genomics Center

**Steven D. Averbuch**, Vice President, Oncology Global Clinical Research, Bristol-Myers Squibb Company

**Anand C. Burman**, Chairman of the Board, Dabur India Limited, New Delhi, India

**David Jenkins**, Managing Partner, FatBoy Capital, L.P.

**Michael D. Webb**, Executive Chairman, Virtify, Inc.

**David Vranicar**, President, Heartland Bioventures, Kansas Bioscience Authority

**Thomas Wiggans**, former Chief Executive Officer and Chairman of the Board, Peplin, Inc.

# **IAMI Adjunct Instructors**

**Mike Baltezor (Enturia Inc, a Cardinal Health company)**

**Tony Barnes (Rules Based Medicine)**

**Mike Beckloff (Beckloff Associates, a Cardinal Health company)**

**Tom Engler (Eli Lilly & Co.)**

**Bo Fishback (Kauffman Foundation, Orbis Pharmaceuticals Inc.)**

**Ken Lynn (New Link Genetics)**

**Matt McClorey (Lawrence Regional Technology Center)**

**John Neet (J.M. Neet & Associates. Lawrence, KS)**

**Andrew Parkinson (Xenotech)**



# Supporting Translational Research Initiatives

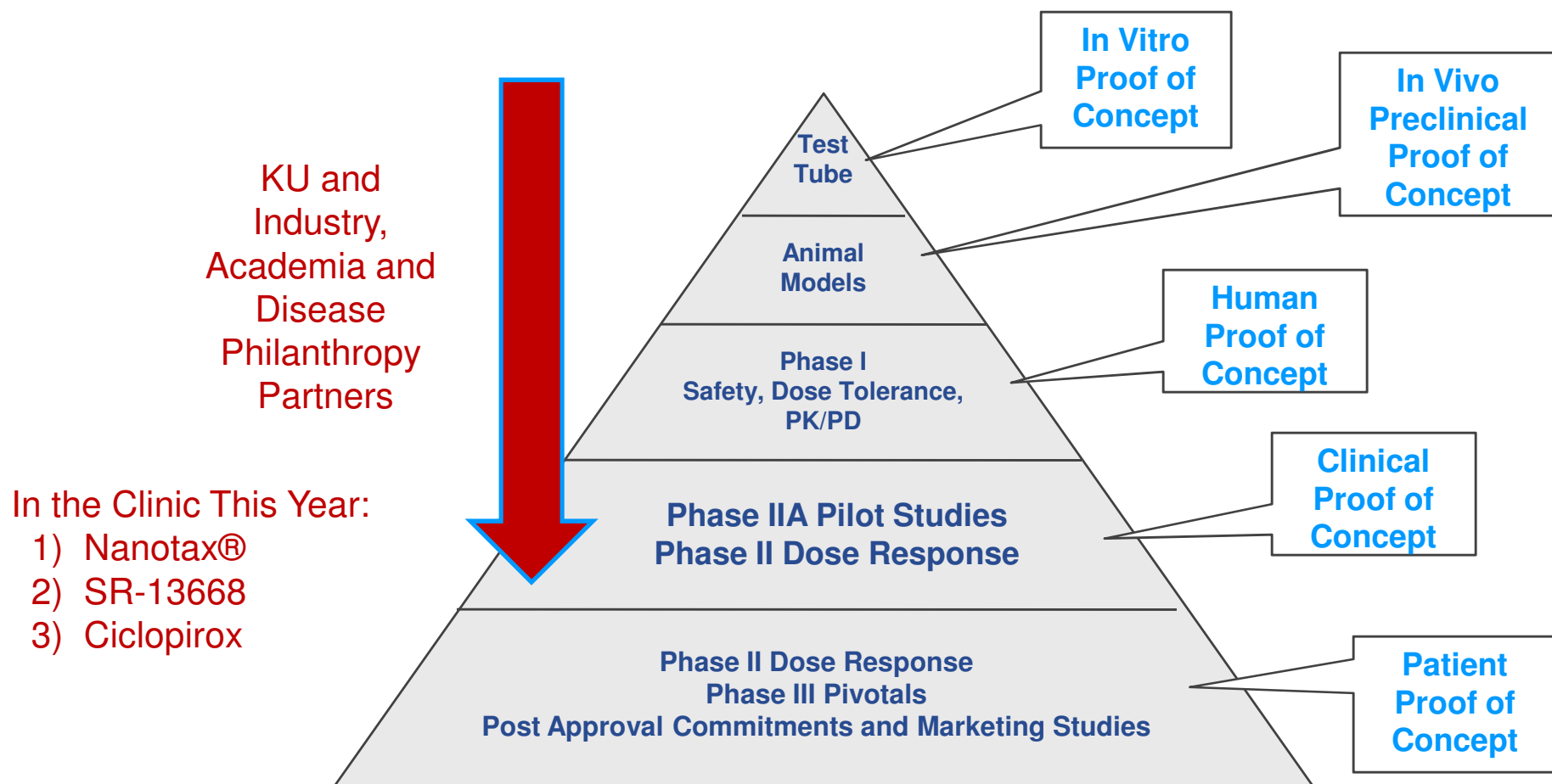
- Key differentiator for NCI designation
  - » Mission to become #1 academic generator of anti-cancer agents
  - » Drug Discovery, Delivery and Development Program (D4)
  - » NCI Experimental Therapeutics (NExT) Program
    - Long-standing formulation contract.
- Key differentiator for Clinical and Translational Science Award (CTSA) application
  - » Grant submitted in October, 2009
  - » Last chance submission date June 1, 2010

# Proof of Concept Criteria

Project objectives, go/no go decision points, and detailed project plans are required for funding consideration and project funding proposals are required to address:

- Medical innovation novelty (unmet need)
- Potential market size
- Market definition
- Medical innovation maturity
- Utility of proof of concept funding
- Intellectual property position
- Principal investigator credibility

# Proof of Concept Pyramid in Drug Discovery and Development



# The IAMI Innovation Fellows Training Program

- The IAMI program is available to KU master's and doctoral candidates from the Schools of Business, Pharmacy, Engineering, Medicine, and other applicable clinical health sciences disciplines.
- Post-doctoral fellowships are available to those who are no more than five years post-receipt of their PhD or MD in a field related to pharmacy, engineering, or clinical health sciences.
- A required deliverable for all IAMI Fellows is a comprehensive Research Commercialization Plan presented orally to the IAMI Leadership Team that also serves as the fellow selection committee. This plan includes a written evaluation from academic and relevant industry advisors.

# Ellis Family Seminar Series

- Location alternated between the KU-Lawrence campus and the KUMC campus
- Open to the public
- Individuals from regional industry, universities, and research institutes will be invited to attend the seminars
- Captured in video format and transmitted by an interactive webinar format to both campuses and other regional campuses
  - » live interactive questions between campuses or individual computers
  - » post lectures (slides or video of speakers) IAMI website to be viewed by anyone without additional cost

# Transforming Federally Funded Research into Medical Innovations

Partnerships with Industry, Academia, Government and Disease Philanthropy

Project and Pipeline Prioritization

Strong Medicinal and Pharmaceutical Chemistry  
Molecular Biology Research

Integration with Technology Transfer

Process Reengineering

Drug Discovery, and Development Guidelines Adapted from Industry

Outstanding Institutional Support

Underpinning Major University Translational Research Priorities

Industry Experienced Drug Discovery and Development Experts

Outsourcing Strategy to Leverage Strengths

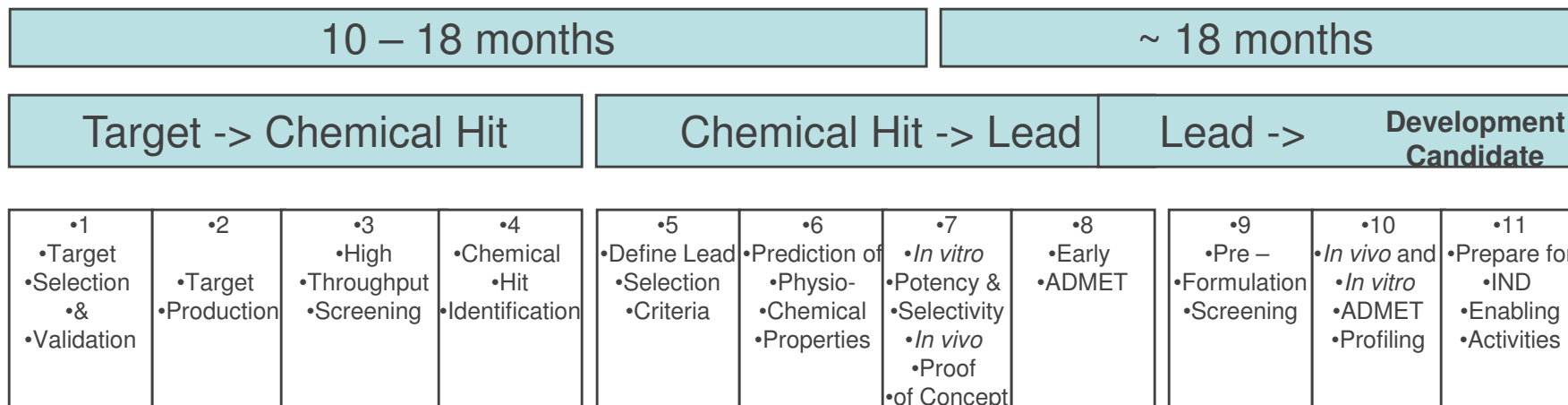


Regional and State Economic Development



**Thanks!**

# Entry Point into Drug Discovery



Novel Drug Target

Targets from KU, other academic institutions, disease philanthropy organizations

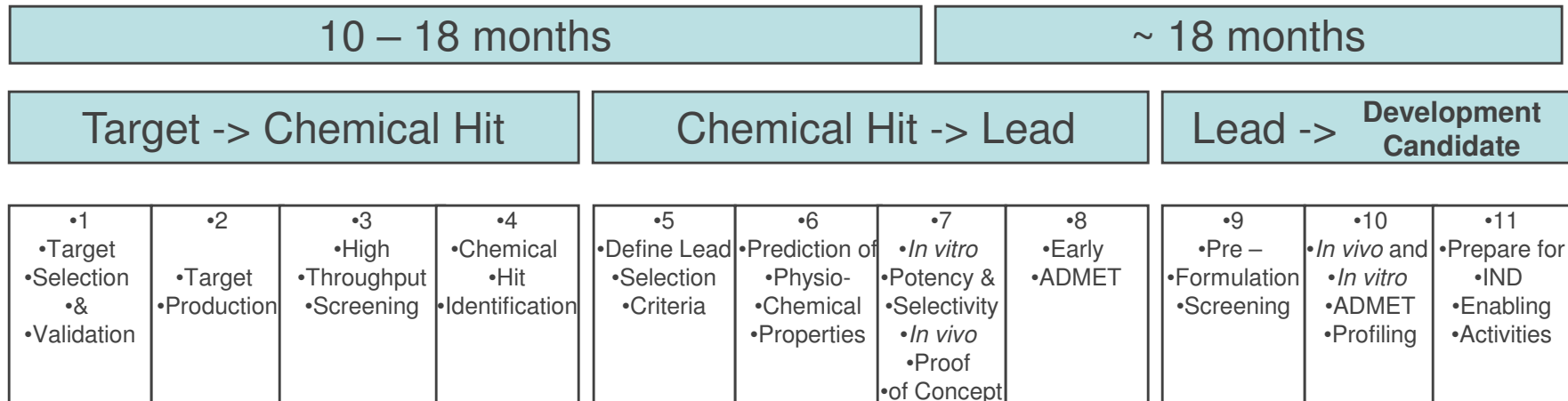
Targets validated using industry approach

Targets Prioritization Committee sets priorities, finds resources, defines early drug discovery strategy

Project teams implement



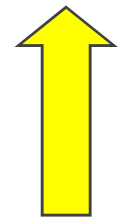
# Clinical Candidate Enters Drug Development



Lead generation and optimization to selection of development or clinical candidate

Continual assessment against predefined criteria

Seeking partners to support IND enabling activities



Selection of Clinical Candidate