Alfred E. Mann Foundation for Biomedical Engineering

Venture Philanthropy and Directed Philanthropy as a New Mode of Capitalization to Move University Scientific and Technological Research to the Marketplace and Commercial Success

-Rethinking Translational Research to Facilitate the Movement of University IP to the Commercial Cycle-

-Technology Transfer on Steroids and an Emerging Applied Research Model Leading to Enhanced Delivery of Healthcare-

Flying Over the Valley of Death: Accelerating from Discovery to Products
February 13, 2008

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Universities: Intellectual Capital and Intellectual Property

- **The Traditional Role of Universities**
  - **UCLA's Charles Young Definition**
- **Is It Changing?**
- **Do Universities Have a Responsibility to Bring their Intellectual Capital and Intellectual Property to Benefit Mankind?**
- **Existing Realities and Impediments**
  - **Trends**
  - **Solutions**
    - **New Programs Initiated by Foundations**
    - **Alfred E. Mann's Approach**
      - **Translational Research <-> Translational Development**
      - **Alfred Mann Institutes for Biomedical Product Development**
      - **12-15 at $150m to $200m each**

Return on Investment on Sponsored Research at US Universities

- $45 billion of sponsored research conducted by top 200 U.S. universities, research institutes, and hospitals in 2006

- $1.4 billion of licensing and royalty income

ROI of ~3%

- The best minds are being funded (largely with public dollars) on research which is focused on achieving “breakthroughs” for the benefit of mankind…yet sufficient delivery of innovation and commercializable outcomes have not been attained

AUTM (Association of University Technology Managers)

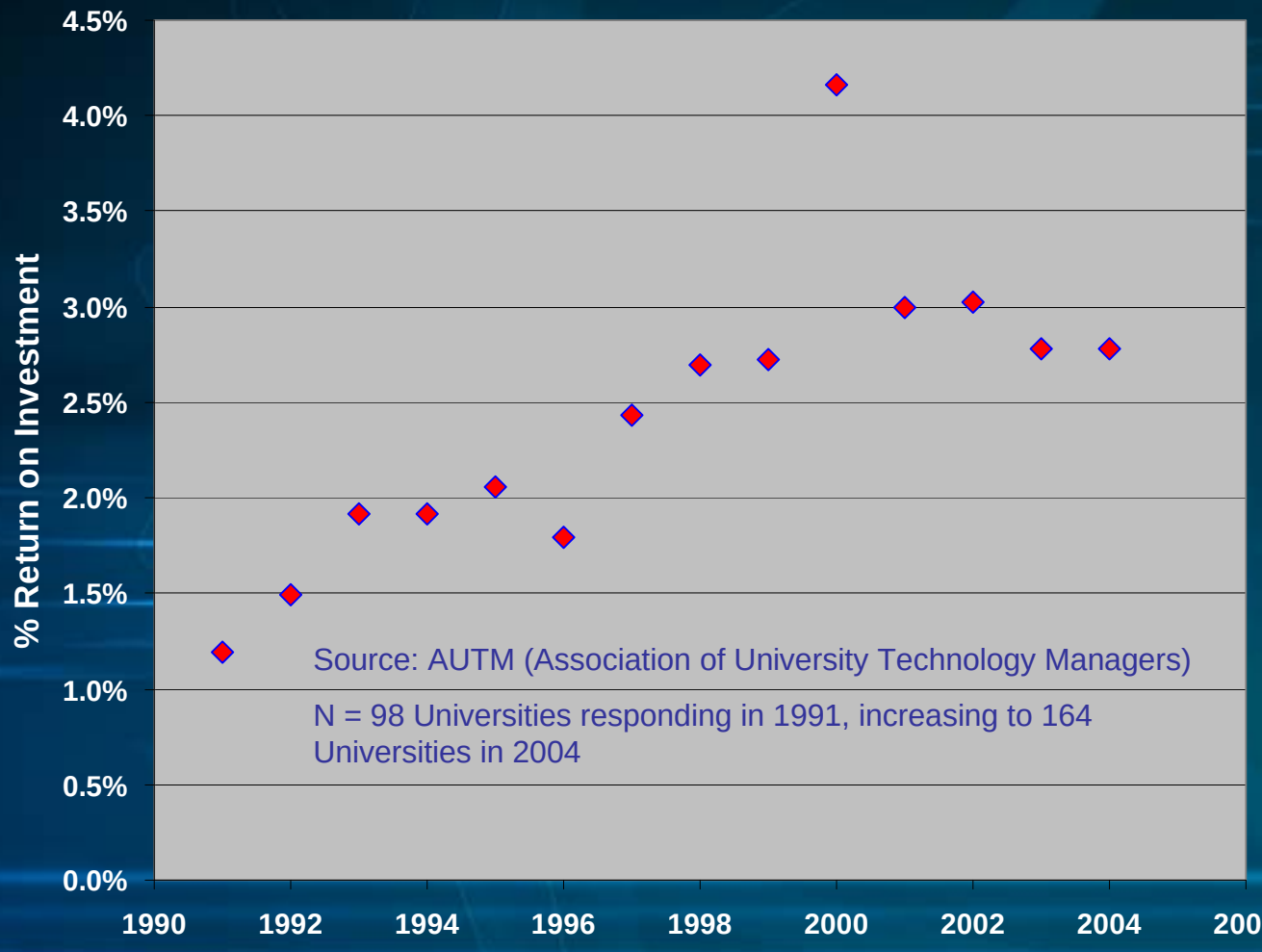
Impediments to Successful Delivery of Innovation to the Commercial Cycle

- **Commercialization "output" from universities has failed to keep pace with research-dollar input**
- **Interest by faculty to develop research with commercial potential lags behind their desire to perform the search for new knowledge**
- **Commercial potential of basic research and consequent IP is under-developed…with the university, the inventor, and the public provider of research dollars not receiving the potential benefit of their investments**
- **Handoff of IP to industry can get bogged down in negotiations, bureaucratic overload, and unrealistic university expectations of returns (UIDP)**

Differences Between Academia and Industry

	Academia	Industry
Main focus	Generating and disseminating new knowledge	Commercialization of ideas for profit
Resources	Limited resources	Often substantial resources available
Financial motivation	Money not the critical incentive for performance	Money important incentive to boost performance
Pace of research	Outcomes driven by desire for high quality research	Time to market is critical and permeates most every decision
Career achievement	Tenure based on publications not entrepreneurship	Value of research outcome often based mostly on revenue generated
Information exchange	Free exchange of ideas	Intellectual property becomes corporate asset

Universities' Net Licensing and Royalty Income as a % of Total Sponsored Research Expenditures



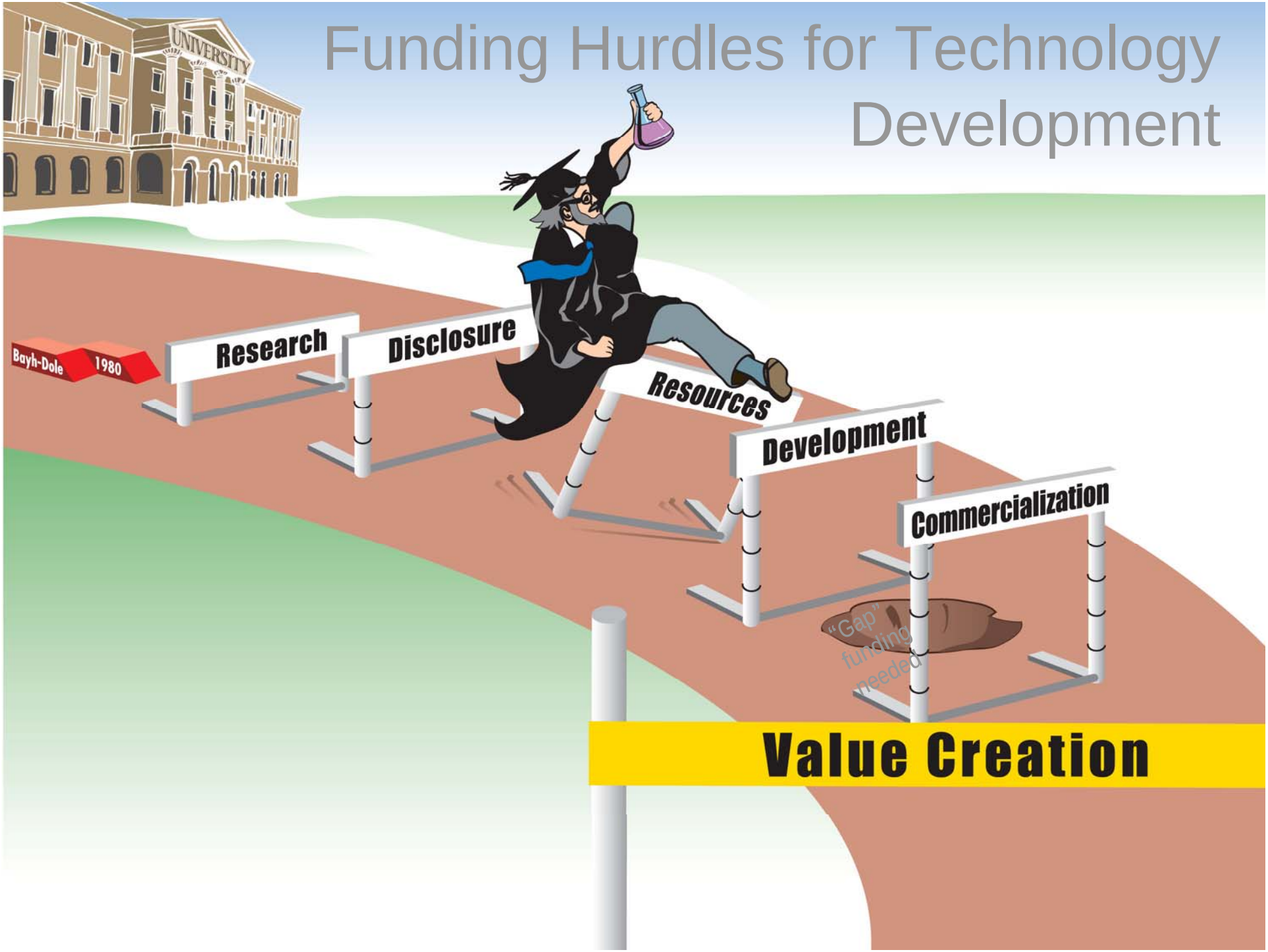
ROI: The Top Tier

- **Only 25% of the top 100 US universities have 'theoretical ROI' over 1%**
- **Diversity of university objectives is appropriate; 'theoretical ROI' isn't everything; while university goals should remain weighted toward basic research, 'balancing the portfolio' on the commercializable science side also makes sense – to see that science advancements benefit mankind.**

The Commercialization of Compelling Ideas is Critical!

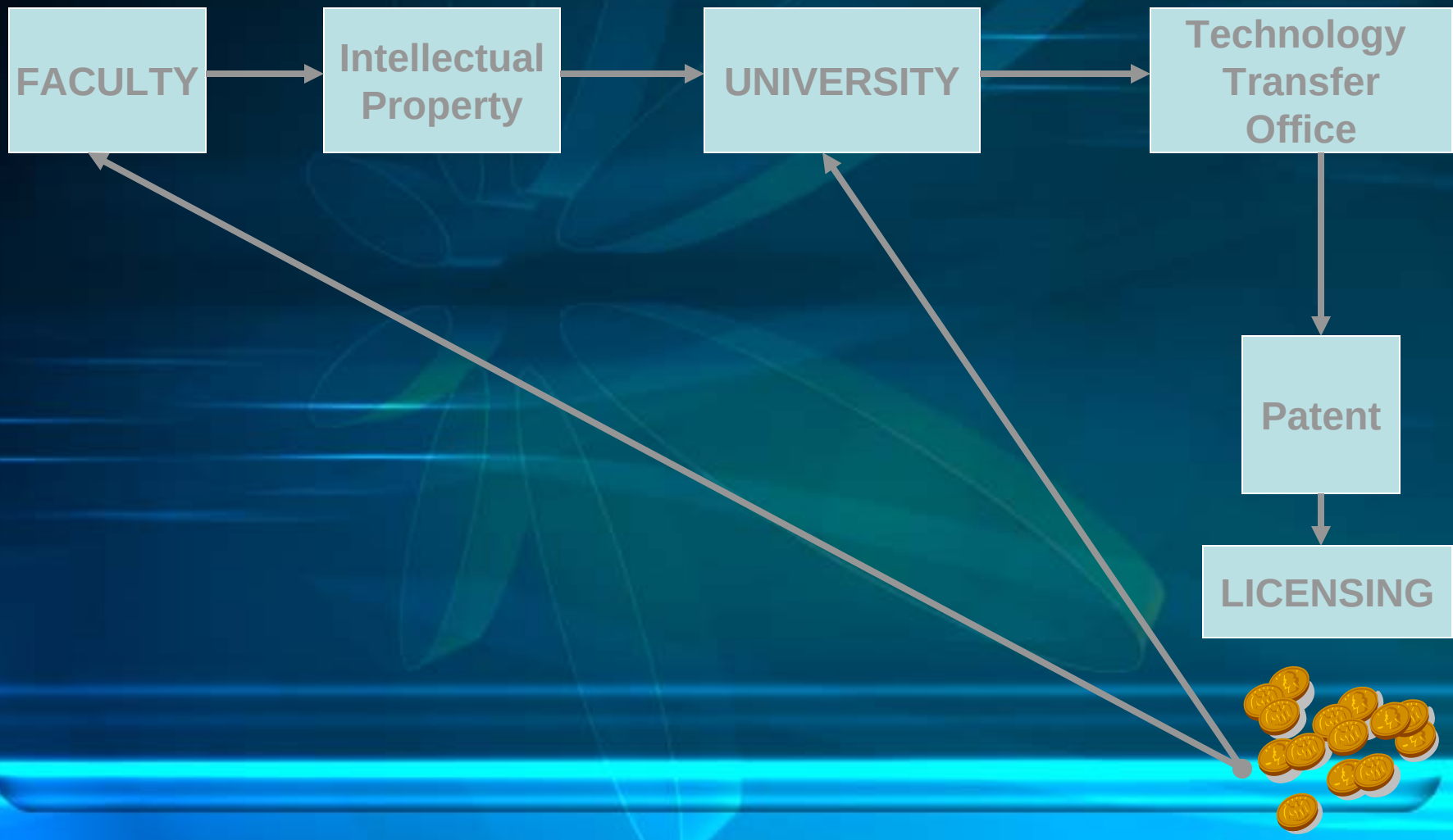
- **Innovation fuels the entrepreneurial enterprise and both are keys to a thriving economy**
- **As a world, we are failing to develop and commercialize the majority of promising research**
- **Discoveries that could lead to new medical devices, therapeutic drugs, and other life-saving or life-enhancing technologies are languishing within the walls of our universities…or the university IP resides in the hands of small companies with inadequate capital to develop it**

Funding Hurdles for Technology Development

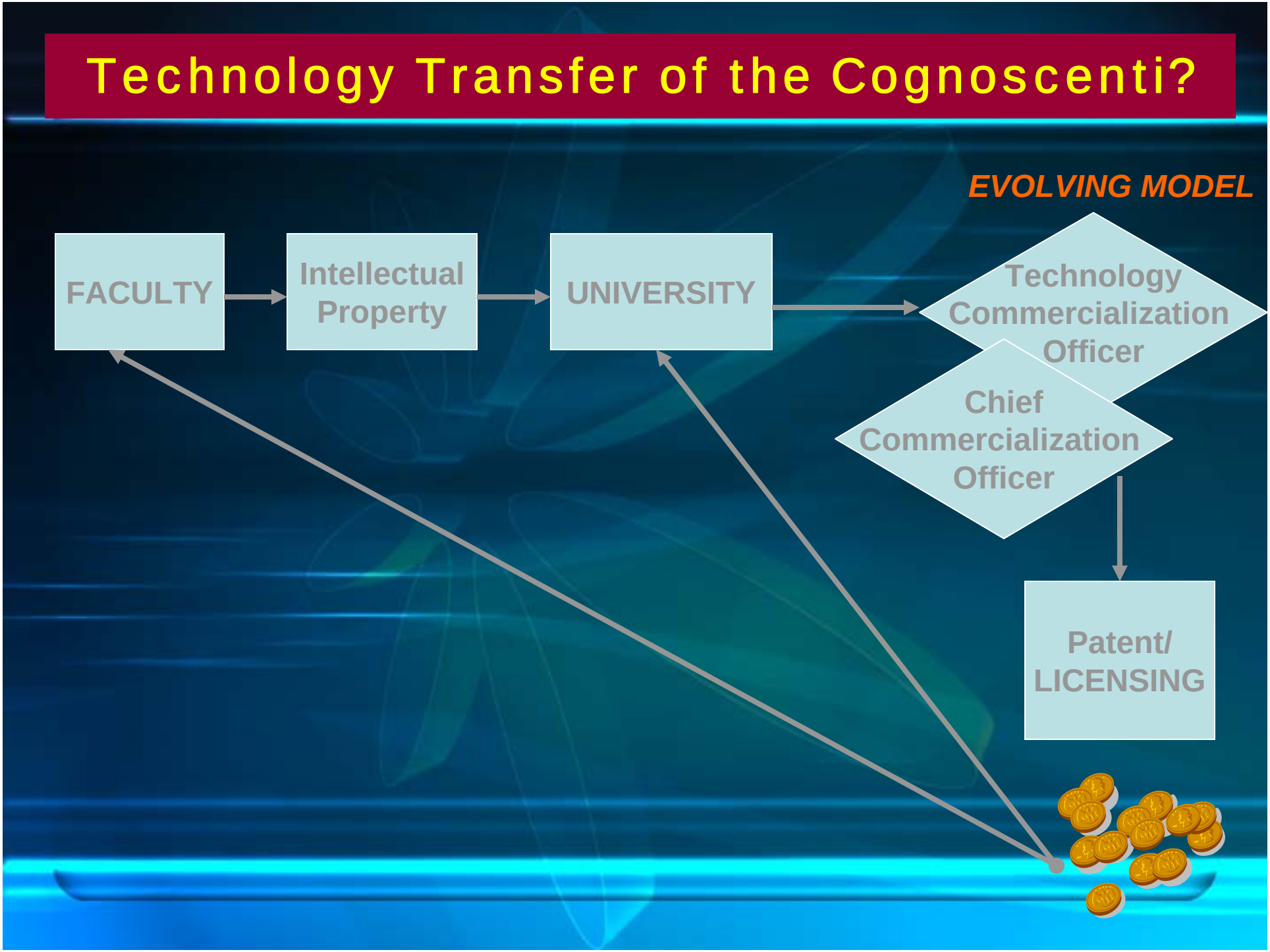


Technology Transfer of Yesterday

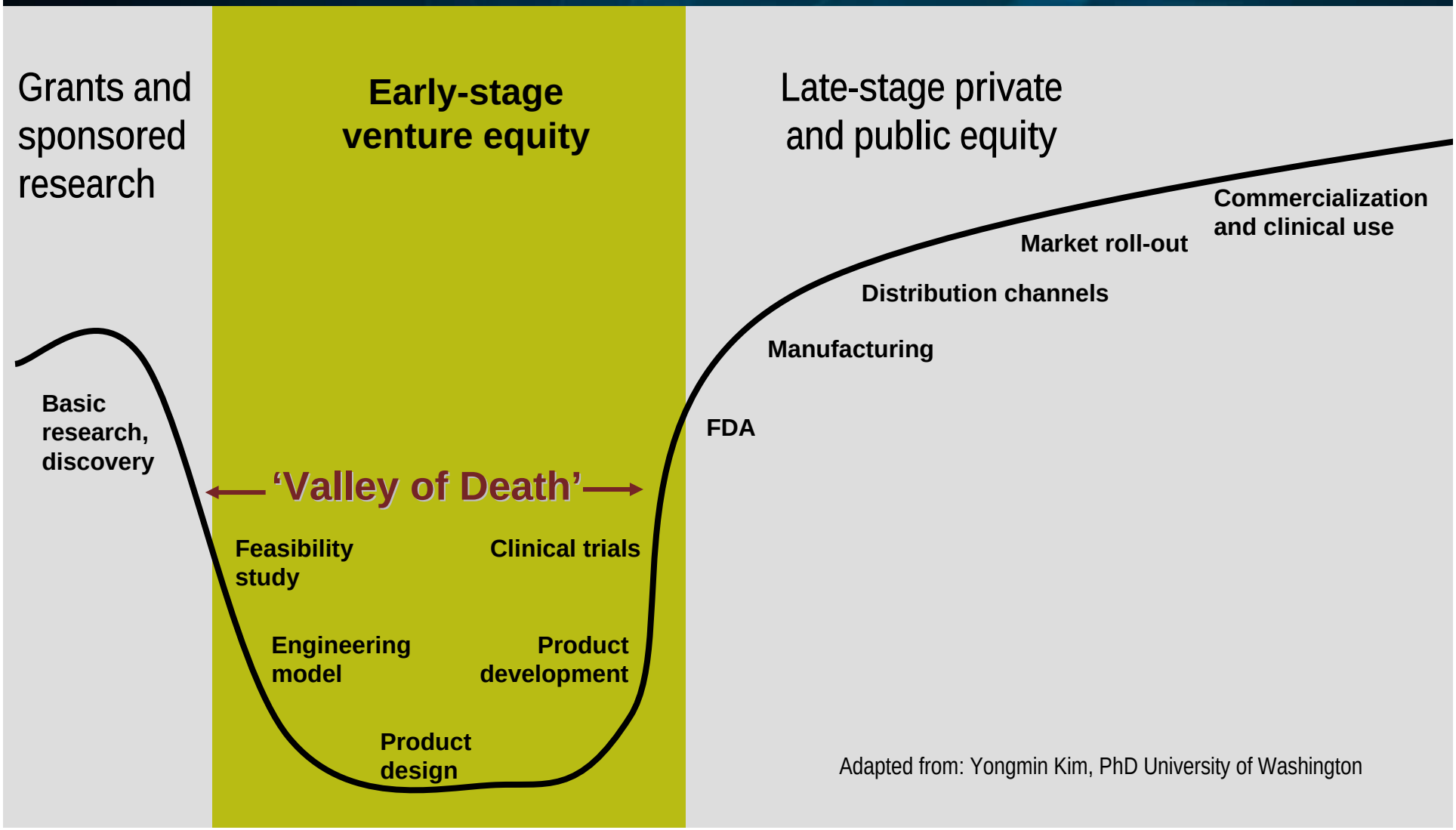
OLD MODEL



Technology Transfer of the Cognoscenti?



The Execution Gap



Adapted from: Yongmin Kim, PhD University of Washington

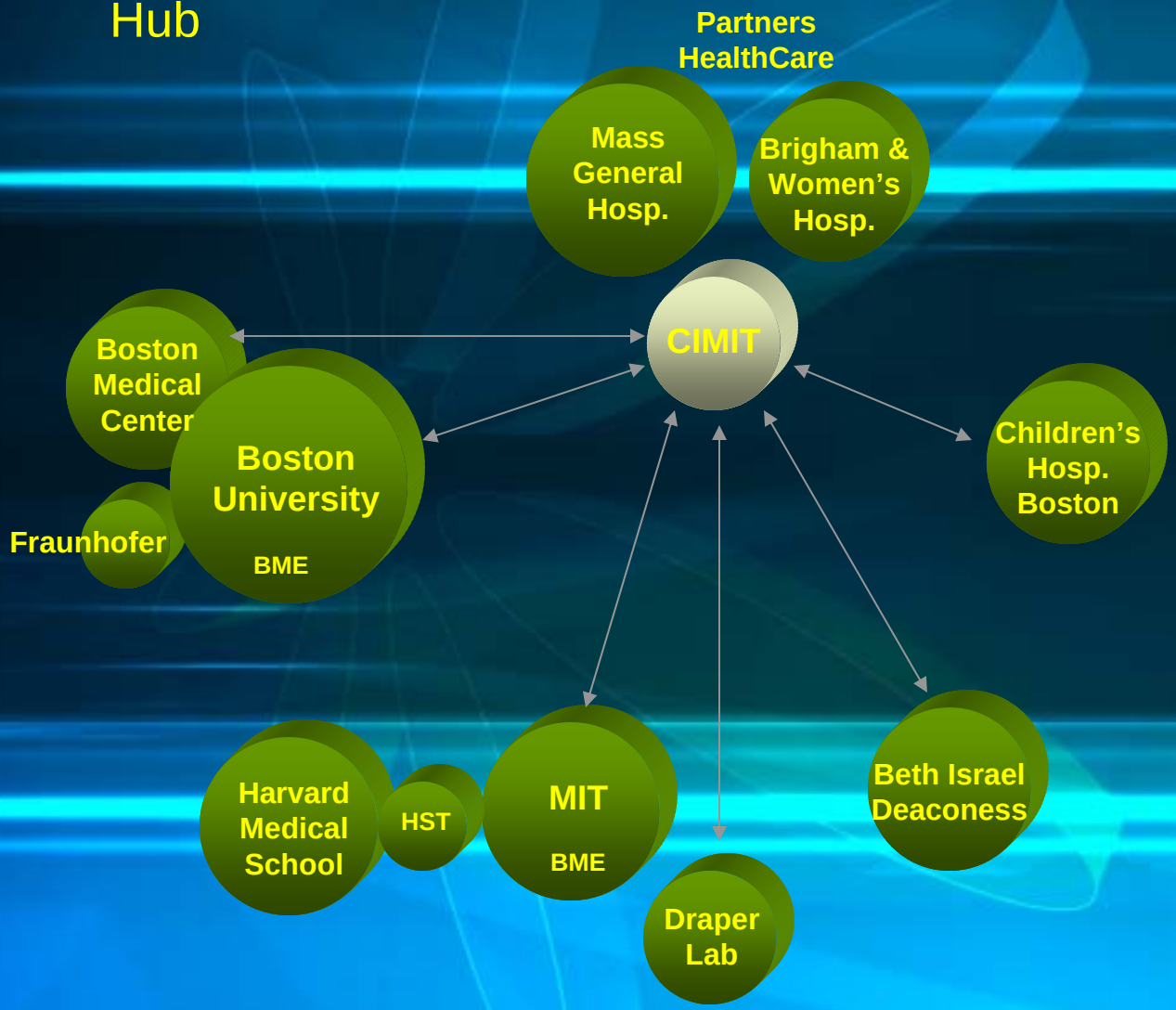
New Models in the US

- **Boston-based Center for Integration of Medicine and Innovative Technologies (CIMIT)**
- **Coulter Foundation**
- **Disease-focused Foundations**
- **Alfred Mann Foundation for Biomedical Engineering**

CIMIT

- **Regional technology assessment and commercialization-enhancement organization…biomedical arena**
- **Boston U, Harvard hospitals, MIT, etc.**
- **$50k-$150k awards**
- **$2.5 million per year**

Boston Medical, Biomedical, and Engineering Research Hub



Coulter Foundation

- **IP -> commercial cycle**
- **Seed capital awards to link faculty to new university commercialization processes**
- **Biomedical engineering focus**
- **9 universities**
- **$580k/yr, 5 yrs**
- **2-3 universities, $10m endowment**

Disease Foundations

- **Myelin Repair Foundation, Multiple Myeloma Foundation, Leukemia Society, etc.**
- **University IP -> companies**
- **$1-$5m awards to the companies**
- **Equity position**

Alfred E. Mann Institutes for Biomedical Development

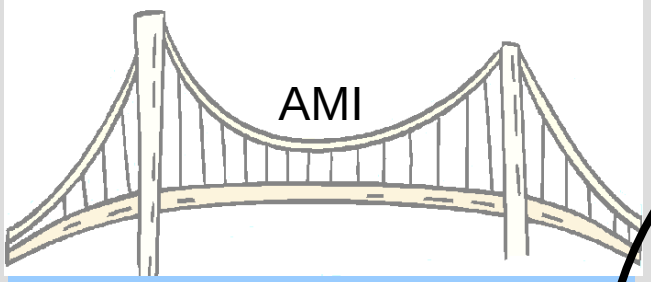
A Vision to Commercialization

A Bridge Across the Funding Gap

Grants and sponsored research

Private equity

Late-stage private and public equity



Basic research, discovery

‘Valley of Death’

Feasibility study

Engineering model

Product development

Product design

FDA

Manufacturing

Distribution channels

Market roll-out

Commercialization and clinical use

Source: Yongmin Kim, PhD University of Washington

The Alfred Mann Institutes

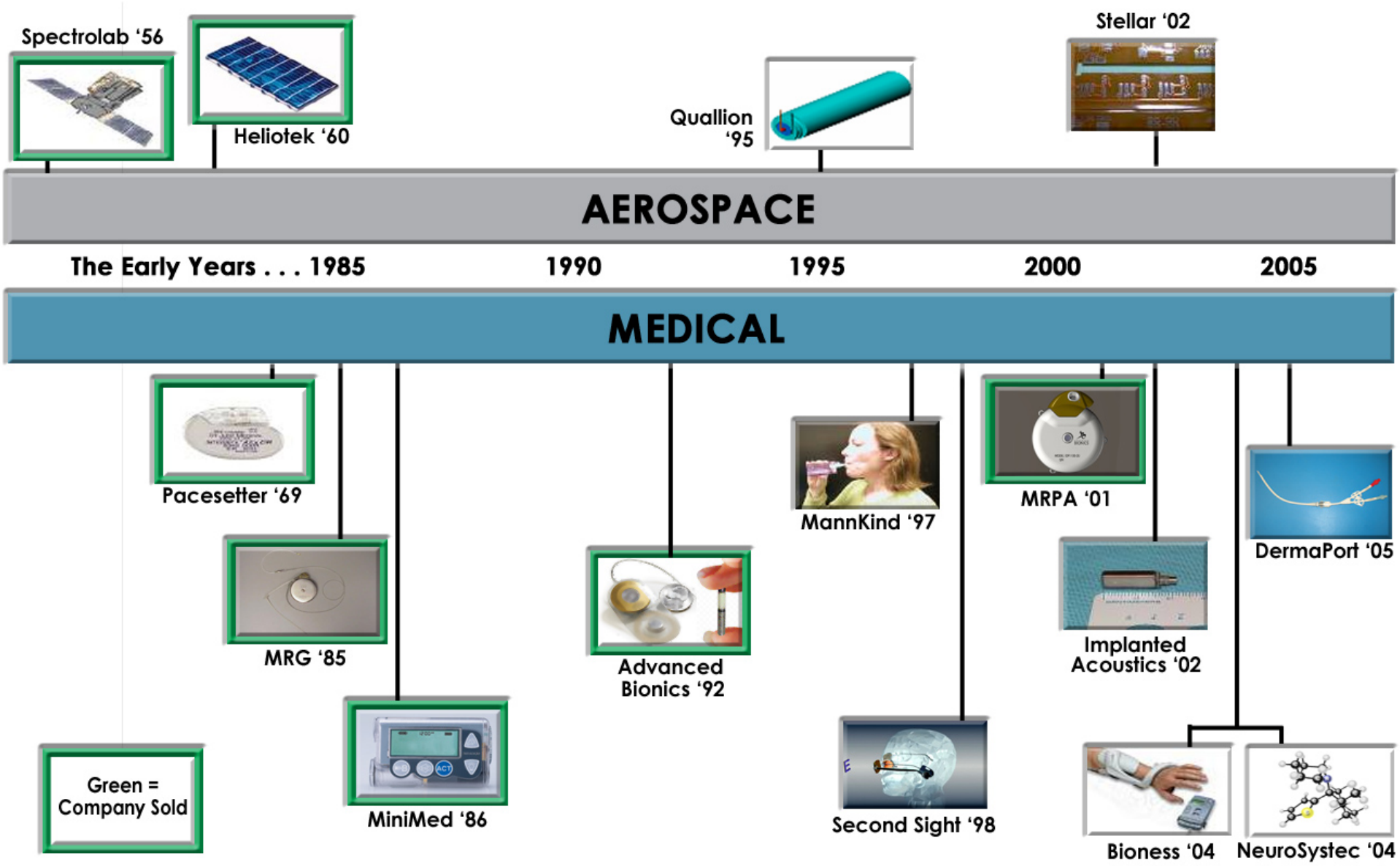
Alfred Mann's vision:

To enhance the flow of university biomedical research of into the stream of commercialization by speeding the transfer of technology.

Alfred Mann's plan:

To create 12 to 15 Institutes for Biomedical Development at selected elite universities and to provide the financial and business resources to guide the commercialization of promising research…with funding of $150 m to $200 m each. The Alfred Mann Institute at USC is the first of these, followed by the Technion University, followed by Purdu

Timeline of Alfred E. Mann Companies



How to Engineer the "Model for Success"

1. Select a Target Market
2. Identify Underserved Needs
3. Evaluate Barriers to Entry
4. Establish Product Specifications
5. Create Business Model
6. Allocate Development Resources
7. Organize Market, Sales, Reimbursement and Support Infrastructure
8. Validate, Qualify & Transfer to Manufacturing
9. Pursue Clinical Trials & Regulatory Approval
10. Unleash Sales/Marketing and Service

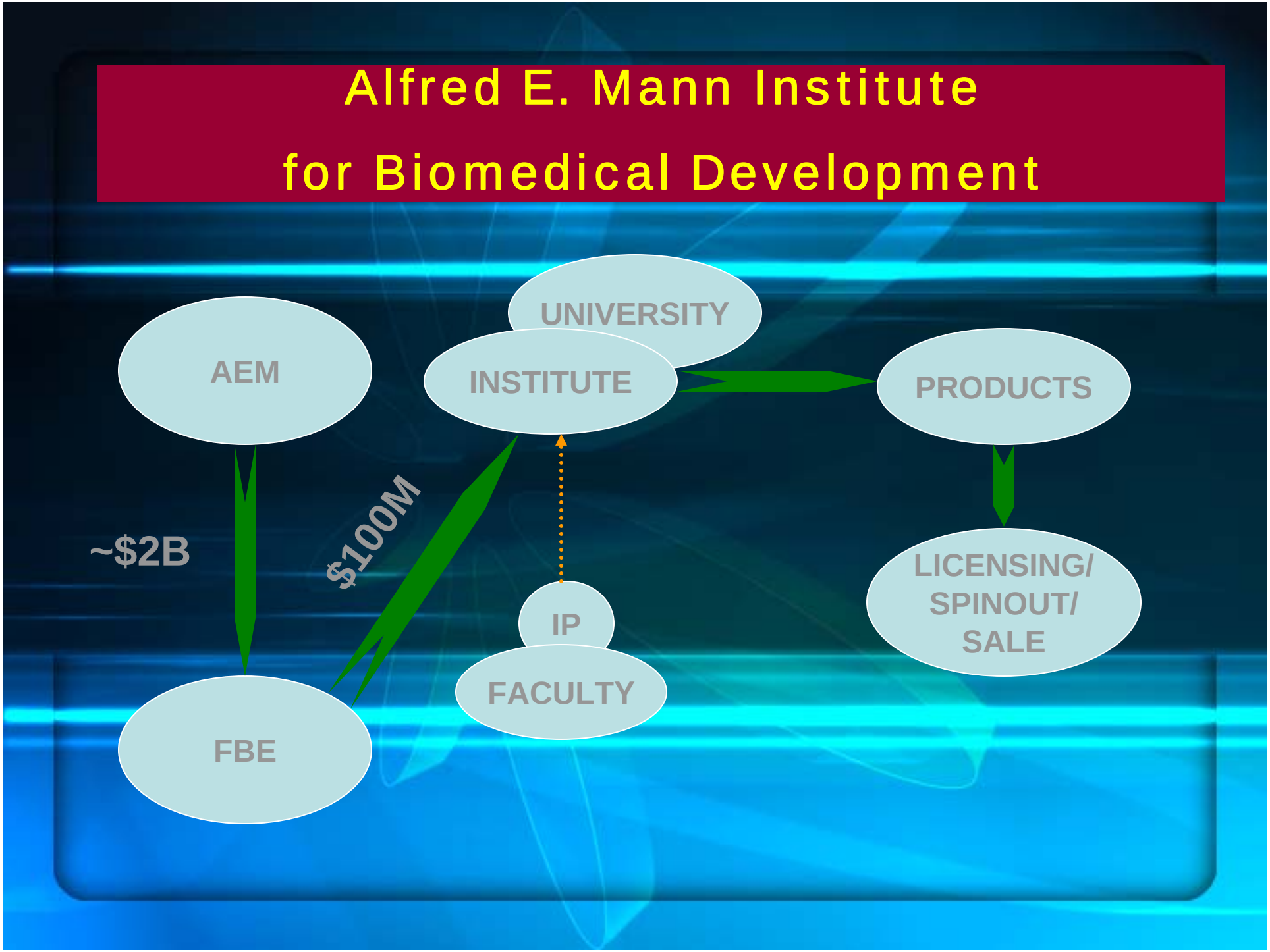
Alfred E Mann Foundation for Biomedical Engineering

- **A non-profit foundation has been endowed with an initial investment of $2.1b**
- **Its mission is to expedite development of promising new technologies at selected universities to create biomedical products that benefit mankind, while generating substantial value for universities and inventors, and the public taxpayer…and importantly, the patient**
- **In the first round of his investment in expediting IP perfection, 12-15 universities will be selected from a pool of ~50, and each will receive a minimum of $150 million dollars to establish an Alfred E. Mann Institute on their campus**
- **The Foundation is seeking universities with strong biomedical engineering programs and commitments to interdisciplinary and translational research**
- **Funded projects at the selected universities will include medical devices, pharmaceuticals and biotechnology**

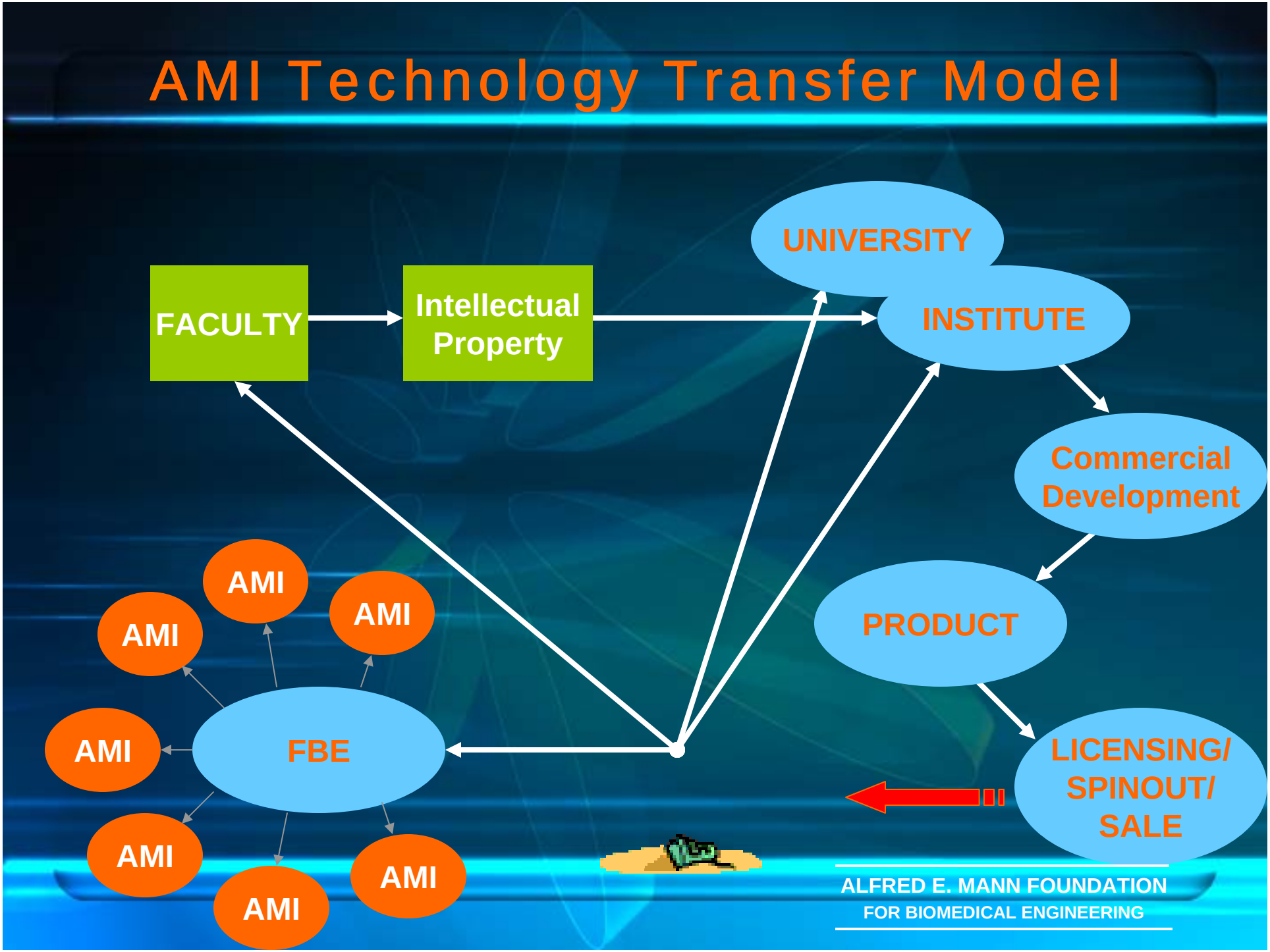
Alfred E. Mann Institute Model

- **Following the model of the first Alfred E. Mann Institute at University of Southern California**
  - **Institutes will operate under affiliation agreements between their universities and the Mann Foundation**
  - **Institutes will operate as a 501c3 under the umbrella of the university, with university co-governance**
  - **Institutes will function as ~nonprofit angel investors, shepherding new technologies through the development process, using undiluted capital**
  - **Products, developed with undiluted capital, will be commercialized via sub-license agreements or the establishment of new start-up ventures**

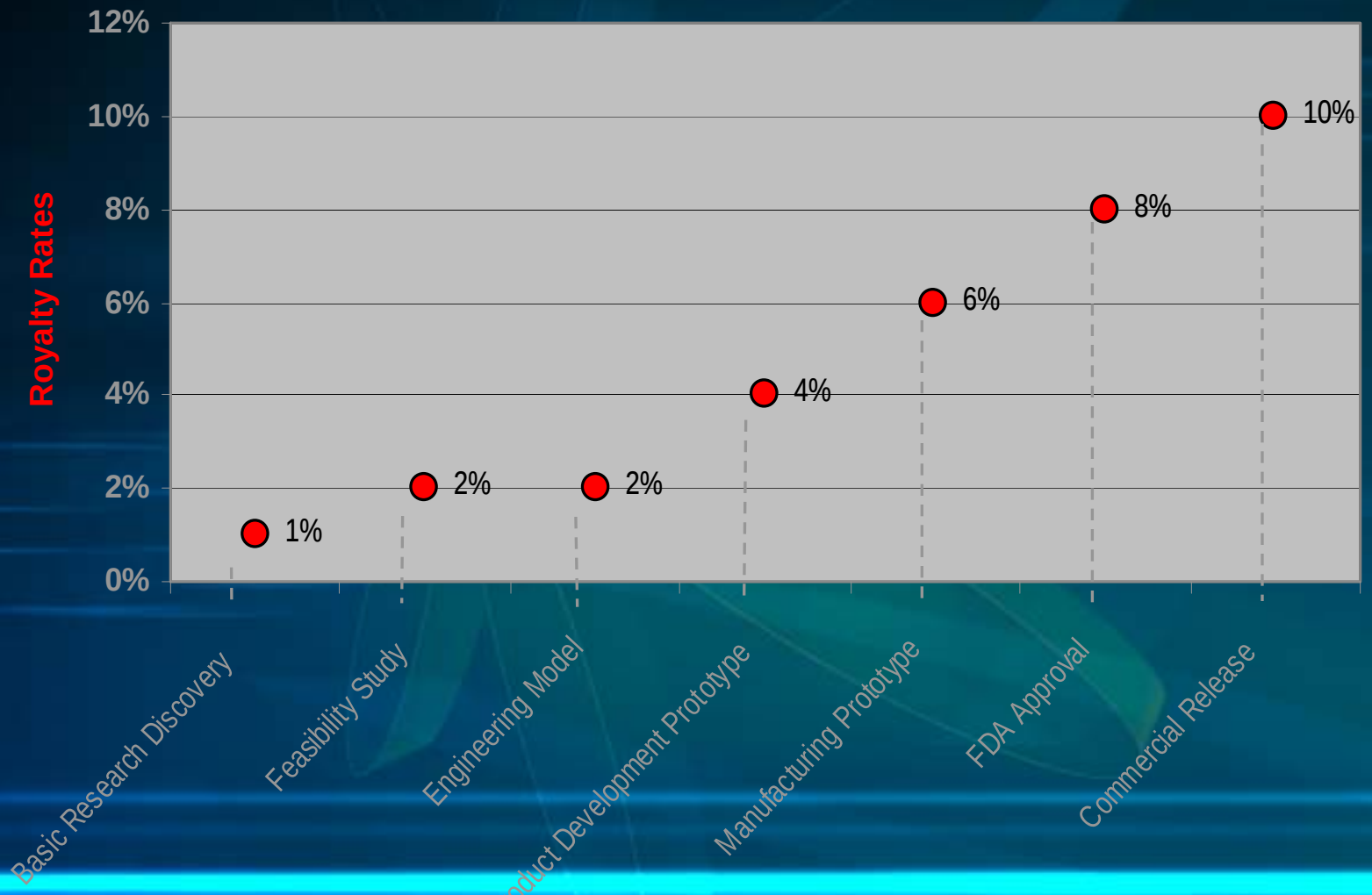
Alfred E. Mann Institute for Biomedical Development



AMI Technology Transfer Model



Enhancement of Royalty Rates as a Function of Commercialization Stage



Character of the Alfred Mann Institutes

- Each Institute is a non-profit corporation….affiliated and located within the university
- Governed by a Board: half university, half Foundation
- Funded through earnings from endowment held in trust
- The Director works closely with academic staff to select and manage projects
- All projects have defined commercial goals, via 40-70 staff
- Institute licenses a very select and small portion of university IP
- Institute provides resources and staff for commercialization
- Income is shared among inventors, university, the Institute, and the Mann Foundation for Biomedical Engineering, which in turn acts as a coordinator and facilitator among Institutes

Robust Due Diligence Process

- **A 12-member AMI Site Selection Committee has been established with significant experience in a range of scientific, financial and business development areas**
- **On-going evaluation to select potential partnering universities is in process, with a total of ~50 universities to be identified and evaluated in the first round**
- **Metrics include analysis of the current university "brain trust", areas of research, collaborative research focus, amount of sponsored research, patent portfolio, technology transfer metrics and a range other matters**
- **Campus site visits requested as a component of the analysis**
- **16 Universities have been invited, 12 have been site-visited, 5 have been selected, 3 have been made public**
- **1-2 AMI's per year**

Examples of just a few of the metrics analyzed follows

What Makes a Good University/AMI Alignment

- Quality and type of research work that is likely to generate specific products on a continuing basis
- University senior management team with entrepreneurial spirit and commitment to make the AMI work
- Willingness to accept critical AMI requirements on IP, governance, project selection, endowment management, and income sharing
- Faculty that supports conduct of application-focused commercialization, as opposed to research
- Track record of Engineering and Medical School collaboration
- Track record of conducting clinical trials
- Adequate, on-campus facilities for the AMI

AMI's Recipe for Success

- Working with the best people on projects with the best commercial potential
- Creation of an entrepreneurial environment and dedicated project teams
- Strong commitment to generate an economic return
- Adequate resources to projects with undiluted capital, including augmentation with federal and corporate funding
- Control of IP
- Institute staff capability to bridge from academic to commercial areas
- Consonance with the philanthropic objective and the vision to further link universities with societal impact – a sharing of Alfred Mann's vision and commitment

The Process

- IP access (post-disclosure) provided by the university to the AMI Director in areas defined by the AMI Board
- AMI Director selects potential projects for Board funding (note: only 2-3 projects will be in the AMI at any one time)
- University co-directed AMI Board approves projects and budgets
- University provides an exclusive, worldwide royalty-free license to the AMI
- The AMI staff brings the IP to a stage of perfection for out-licensing, thereby having greatly increased the value of the IP and the rewards for all parties
- Revenues flow
- 5-8 years required per project, with $5-20 million expended per project

What is Next for TT on Steroids?

- **12-15 more Institutes after 5-7 years?**
- **Mann peer activities?**
- **International activities**
- **Specialized smaller scale projects for colleges or departments**
- **Larger scale projects**
  - **Regional AMI's**
  - **NIH**
  - **Federal labs**
  - **AMI Consortia**
  - **Regional accelerator funds**
  - **Mann Foundation Development Corporation**

Summary

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