Introduction to Cell Biology 8401
Essentials of Translational Science

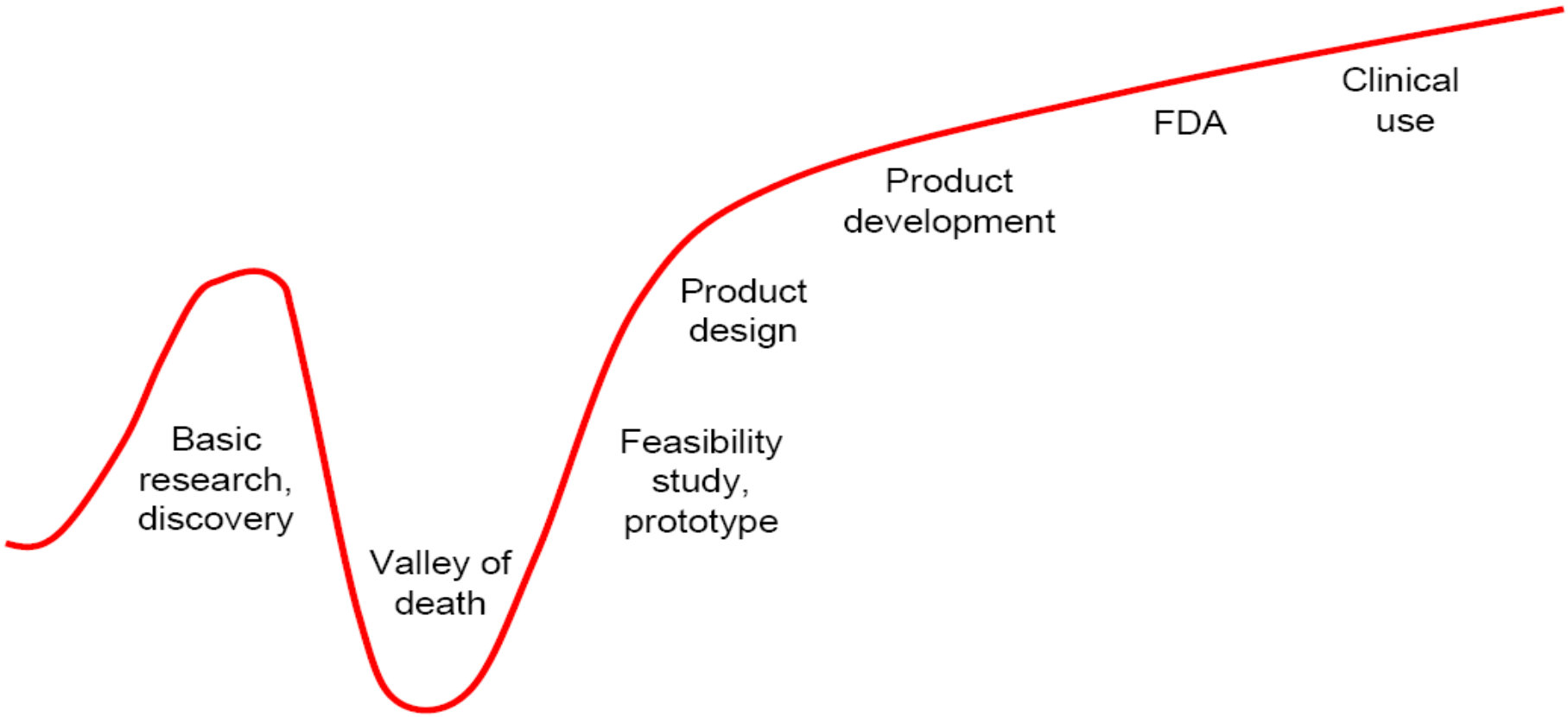
disciplines and interdependencies
interfacing research and patient care

John C. Herr, Ph.D.

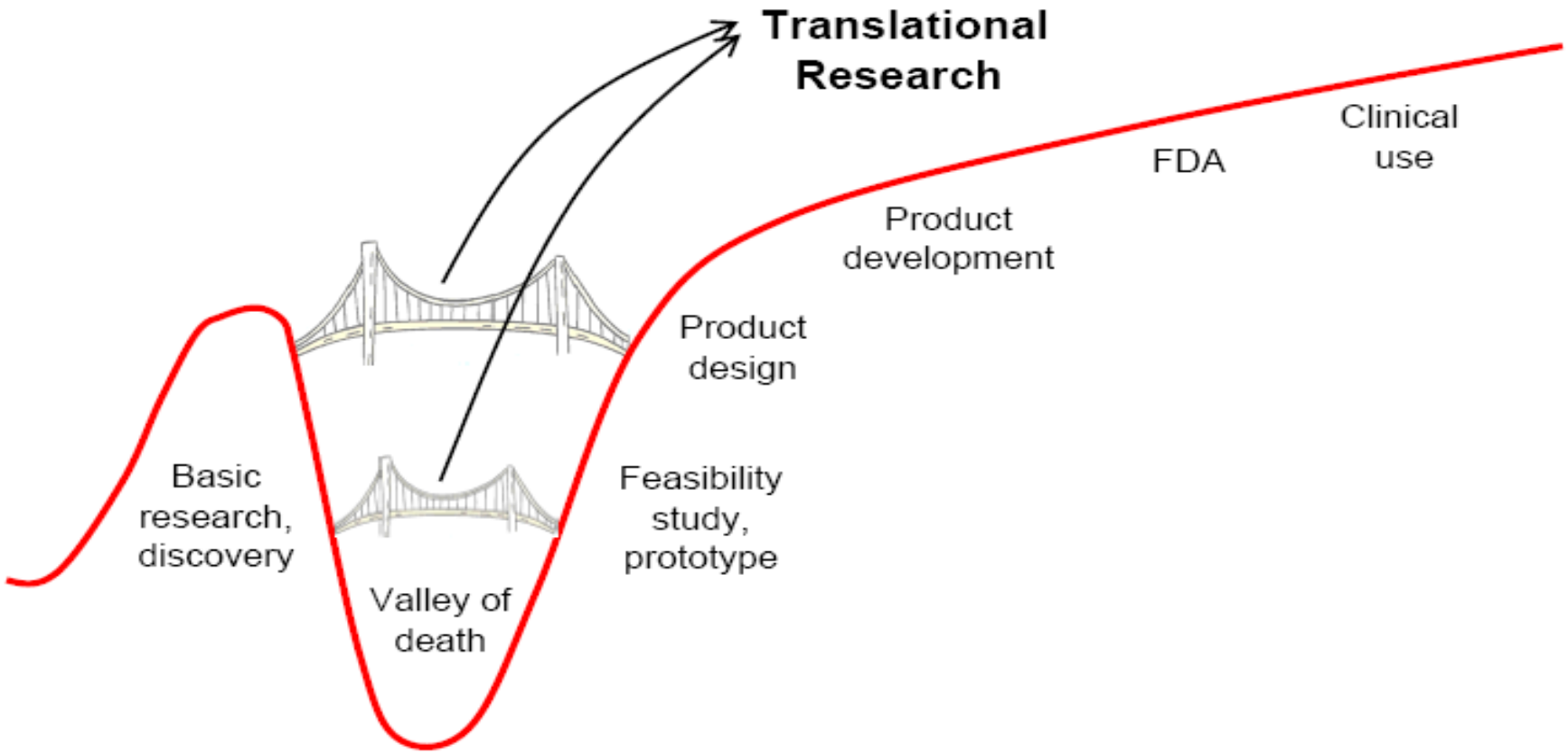
"Innovation is the central issue in economic prosperity."

- Michael Porter

INNOVATION & TECHNOLOGY STAGES



BRIDGING THE VALLEY OF DEATH



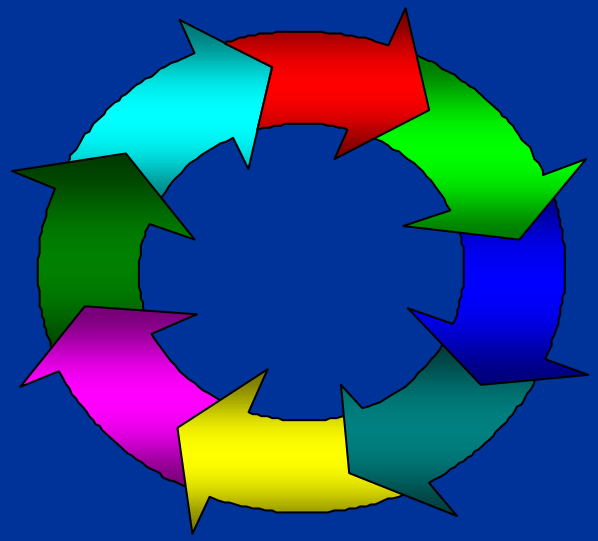
A Definition of Translational Research

- Those activities that follow from a basic discovery that enable the strongest possible patent claims, validate or add value to a model, and are essential to the implementation, practice, or commercialization of an invention.
  - includes proof of concept research for new drugs or devices.
  - market research and analysis.
  - prototype development and testing for software and devices.
  - pre-clinical testing for pharmaceuticals and medical devices.
  - human trials of experimental therapeutics [safety, efficacy].
  - outcomes assessment.

Think Human Model

FROM BIOMARKER DISCOVERY TO UTILIZATION:
The Communities of Science, Intellectual Property, Finance, Manufacturing and Marketing.
A CONTINUUM OF CO-OPERATING TEAMS AND CAPITAL

IP-composition of matter,
use, process patent claims



IP

IP

IP

IP

Examples of Translational Research in green.

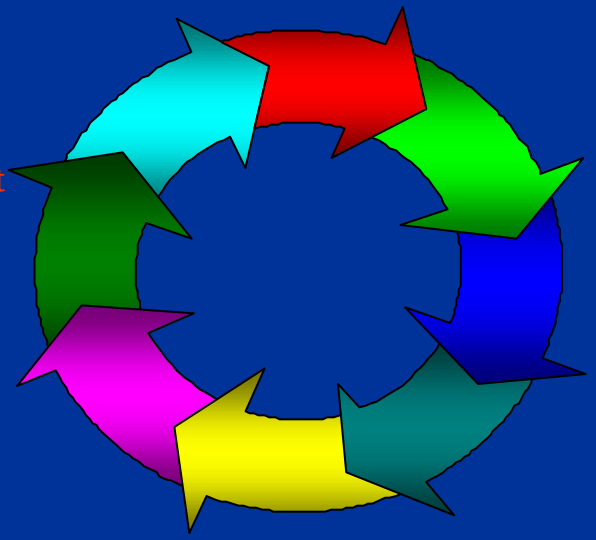
TALENTS AND DISCIPLINES NEEDED TO REACH THE DRUG STORE SHELF

University is assembling many of the key talents to emerge as an integrated translational research entity.

Molecular biology, bioinformatics, protein chemists, genomics and proteomics

Project officers, MDs, statisticians, health evaluation sciences

Cell biologists, X-ray crystalographers, structural genomics immunologists, chemical genetic engineers, transcriptomics



Manufacturing scale-up, integrity of supply-chain, Advertisement, fulfillment

Organic chemists, materials science, robotics, manufacturing standardization, regulatory affairs

Everybody, FDA regulatory affairs

IN SILICO

MD specialists, nurse practitioners
Project managers, statisticians

Sociologists, demographers, information technology,
Statisticians, market analysis, MBAs, acceptability

Veterinarians, animal technicians, pathologists, toxicologists, genotoxicology

Examples of Translational Research in green.

NIH Director Elias Zerhouni's NIH Roadmap
NIH Director Francis Collins' NCATS

The mission of the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) is to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

- Accountability to Congress and the Public
- Coordination of efforts of NIH Institutes
- Benefits for patients
- Research spanning bench to bedside
- More interdisciplinary, goal oriented research.

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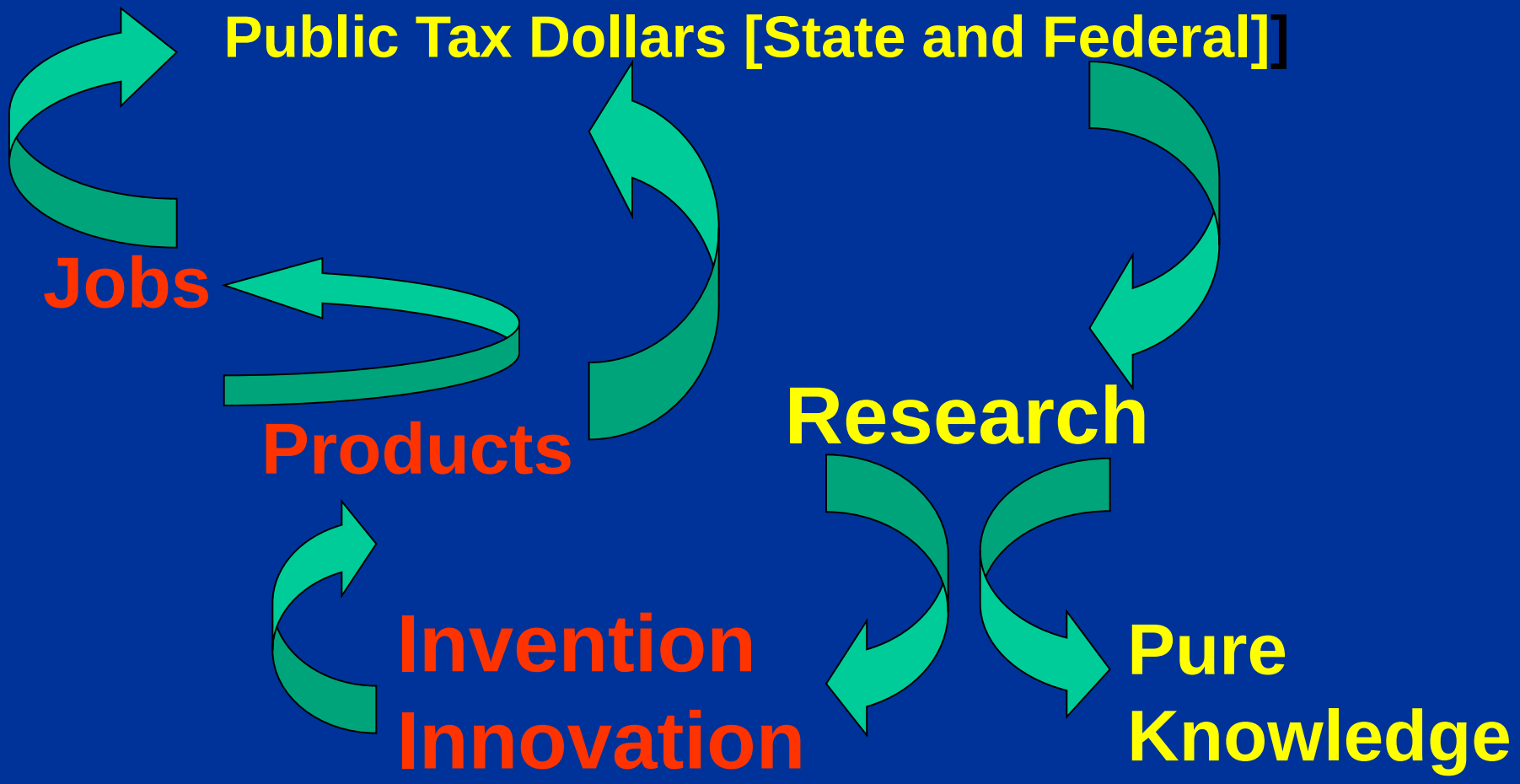
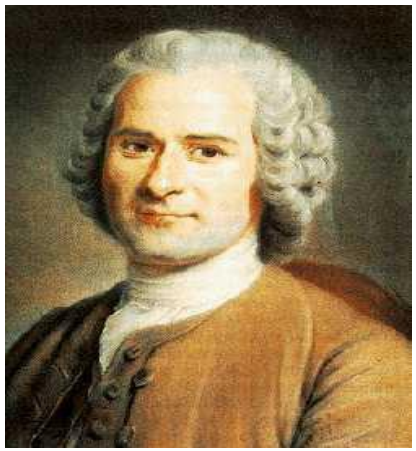
–NIH Bioethicist at a Recent Fogarty Center Directors Meeting

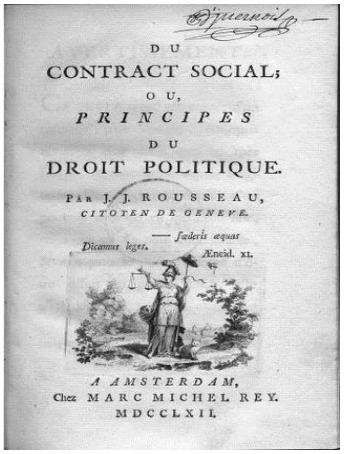
Translational Research Faces Cultural Challenges

- Faculty sentiments divided as to the place of commercialization in the university.
  - Purists: Some faculty believe the process of commercialization does not belong in academe and that it represents a "low road".
    - "We are not a technical University but one concerned with great ideas."-Anon UVA professor
      "We intend to hire only Einsteins, not Edisons"- Anon University Professor
  - Others embrace, encompass and see translational research as a vehicle for expanding research efforts and the impact of their science on society.


Public Tax Dollars [State and Federal]
Jobs
Products
Research
Invention
Innovation
Pure
Knowledge

Innovation's "Social Contract"





National citizenry

Risk Capital

Tangible and intangible payoffs

Research enterprise

New products

New solutions

New businesses

New jobs

New ideas

New practices

New talent

Traditional Academic Sources of Risk Capital

- Grants & Contracts: NIH, NSF
  - R01; UO1; U54, etc
  - SBIR, 67% SBE phase I, 50% SBE phase II
  - STTR
- Commonwealth
  - CIT
    - CTRF
  - VBHRC
- Philanthropy: Foundations, Grateful Patients, Alumni
- Internal Translational Grant Sources at UVA
  - Coulter Foundation, Ivy Foundation, Buchanan, LaunchPad

Venture Based Risk Capital

- Private Equity Markets- fund start-ups in exchange for stock in venture
  - Angels [friends, family, sophisticated investors], Angel Networks, Venture Capital, Investment Bankers
    - Private equity augmented by grants (non-dilutive capital)
  - CIT Gap Funds; convertible notes, stock
  - Strategic partnerships with other companies: equity stakes, access to proprietary technology

Nota Bene: Access to Private Equity Markets relies on due diligence of established professional investors/partners to make investment choices. The business plan is the main vehicle along with the pitch deck that establishes credibility and markets your start-up ideas.