Technology Transfer:
A Source for Economic Growth

San Salvador

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Introduction and Outline

- What is Technology Transfer
  - What is needed for a successful program
- LA BioMed – A source of biomedical innovation
- The US Federal model for Technology Transfer
  - Bayh-Dole Act
- Best Practices for Technology Transfer
- Realities of Biomedical Discovery and Development
- Current Business Environment for Biomedical Tech Transfer
  - - The Translational Research Gap – what to do about it

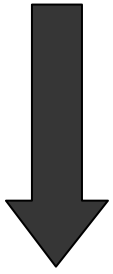
What is Technology Transfer ?

Technology transfer:

the exchange of intellectual property (i.e., patents, know-how, trade secrets, copyrights, etc.) usually through licensing, from a public to a private entity to commercialize a useful discovery

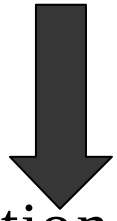
The Biomedical Discovery & Development Chain

Academic / Non-Profit Research (Public Funding)



Tech Transfer

Small Biotech / Start-Up



Big Multi-National Pharmaceutical

LABioMed (Formerly Harbor/UCLA REI)

- Independent Research Institute
- Created by Harbor Hospital Medical Staff - 1952
- Uses LA County land and buildings rent-free
- Financed primarily with soft money

LABioMed Facts

- LABioMed is an independent, not-for-profit entity, with its own Board of Directors
- $67 million budget, ~ $40 million of which involves biomedical research
- $25 million in NIH funding

LABioMed Facts *Continued*

- Nearly1000 research projects ongoing, conducted by 200 investigators; 1,100 full- and part-time employees overall

- Conducts an average of 125 clinical trials ongoing at any one time, sponsored by the federal government, industry and LABioMed itself

LABioMed Facts *Continued*

- Among the fifteen largest independent, biomedical/behavioral research organizations in U.S.
- Affiliated with, but independent of, the David Geffen School of Medicine at UCLA and the Harbor-UCLA Medical Center
- Owns and manages its own Intellectual Property

Major Research Accomplishments

- Invention of the modern cholesterol test
- Invention of the infant thyroid deficiency test
- Major role in development of artificial surfactants
- Pioneered exercise testing and pulmonary rehabilitation
- Developed enzyme replacement therapy for MPS 1 disorders (Hurler's Disease)

TECH TRANSFER: WHY WE DO IT

- Brings the fruits of research into the private sector for commercial development
- Fosters industry / academic collaboration
  - IP draws industry research funds
- Offers financial reward and entrepreneurial opportunities to faculty
- May generate income - but rarely more than 2% of institutional operating budget
- Promotes economic growth downstream

Multi-Disciplinary Process

- Scientific *evaluation*
- Commercial *valuation*
- Legal / IP protection

and…

Multi-Disciplinary Process

- Marketing
- Legal / Transactional
- Policy Overview
- Public Relations

Essential Conditions for Successful Technology Transfer

- Intellectual Property Ownership at the Institutional (Possibly State) Level
  - Ownership by Inventors is a barrier to successful tech transfer
- Resources to Invest in IP development
  - Patent budget
  - Trained Staff with business and technical knowledge (legal counsel can be outsourced)
- Policies and Procedures which facilitate and do not obstruct

The Federal Model for Tech Transfer: The Bayh-Dole Act

- **1978-1979 in the U.S**.: 28,000 U.S. Government owned invention
  But …Less than 4% licensed
  Exclusive licenses were rare

- Bayh / Dole Act passed in 1982 allows host institutions to take title to federally funded inventions
  - Local control; exclusive licenses permitted
  - Incentives for all including inventors

- Proven track record for technology commercialization

The Bayh-Dole Act (cont.)

- Provides flexibility in licensing for the best path to commercialization and/or use for the public benefit
- Local Institutions are close to the inventors and can act fast to license to industry
- The Bayh-Dole Act has been a major success and a driver of the development of the Biotech Industry

Economic Impact of Bayh-Dole Act

- More than 200 US universities, teaching hospitals and research institutes are now engaged in technology transfer, which added about $40 billion to the US economy in 1999
- More than 5000 US companies created since 1982
- Bayh-Dole has transformed the US role in the global economy
- Other countries are following suit

Data for the Year 2000

Table 1. Global patenting and licensing data for select countries

	Patents granted	Patent applications	Licenses issued	Licenses gross income (Euro thousands)	Startups and spin-offs created
Australia	498	834	417	99,525	47
Belgium	57	121	46	240	15
Germany	747[a]	1,058[a]	555[a]	46,468[a]	37[a]
Italy	64	190	36	NA[b]	36
Japan	163	567	89	1,397	6
Korea	1,018	1,692	247	3,822	56
Netherlands	167	212	368	11,400	37
Norway	28[a]	43[a]	22[a]	9,700	67
Spain	64	133	125	961	11
Switzerland	112	175	475	5,650	68
United States	5,103	8,294	7,056	1,366,452	390
Russia	349	171	206	1,375	15

THE ACADEMIC/INDUSTRY INTERFACE: INHERENTLY CHALLENGING

- Academic primary mission - teaching and research -public benefit
- Corporate primary mission - return on investment to shareholders, then public benefit
- Mutual understanding of need and limitations on both sides is essential
  - What are the respective boundary conditions for academia and industry

TECHNOLOGY TRANSFER: MAJOR SOURCES OF INDUSTRY/UNIVERSITY FRICTION

- Protection of confidential information and publication delays for patents or other business reasons - *Academic Freedom*
- Reserved Rights to practice and share for non-commercial research use
- Warranty and Indemnification-*Liability*
- Control of patent prosecution- especially jointly owned patents- *IP Ownership*
- For Start-Ups - research in founder's labs - *Conflicts of Interest*

Managing the Non-Profit / Industry Interface

- Protect the Public investment while fostering strong collaborations with the private sector essential to move from Bench to Bedside
- Promote informed and productive interaction with industry
- Seek fair and equitable return recognizing that industry will take most of the financial risk
- Establish an industry advisory board
- Establish clear conflict of interests guidelines including guidelines for conflict management

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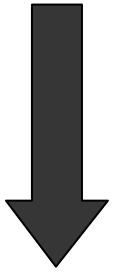

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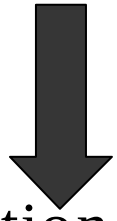
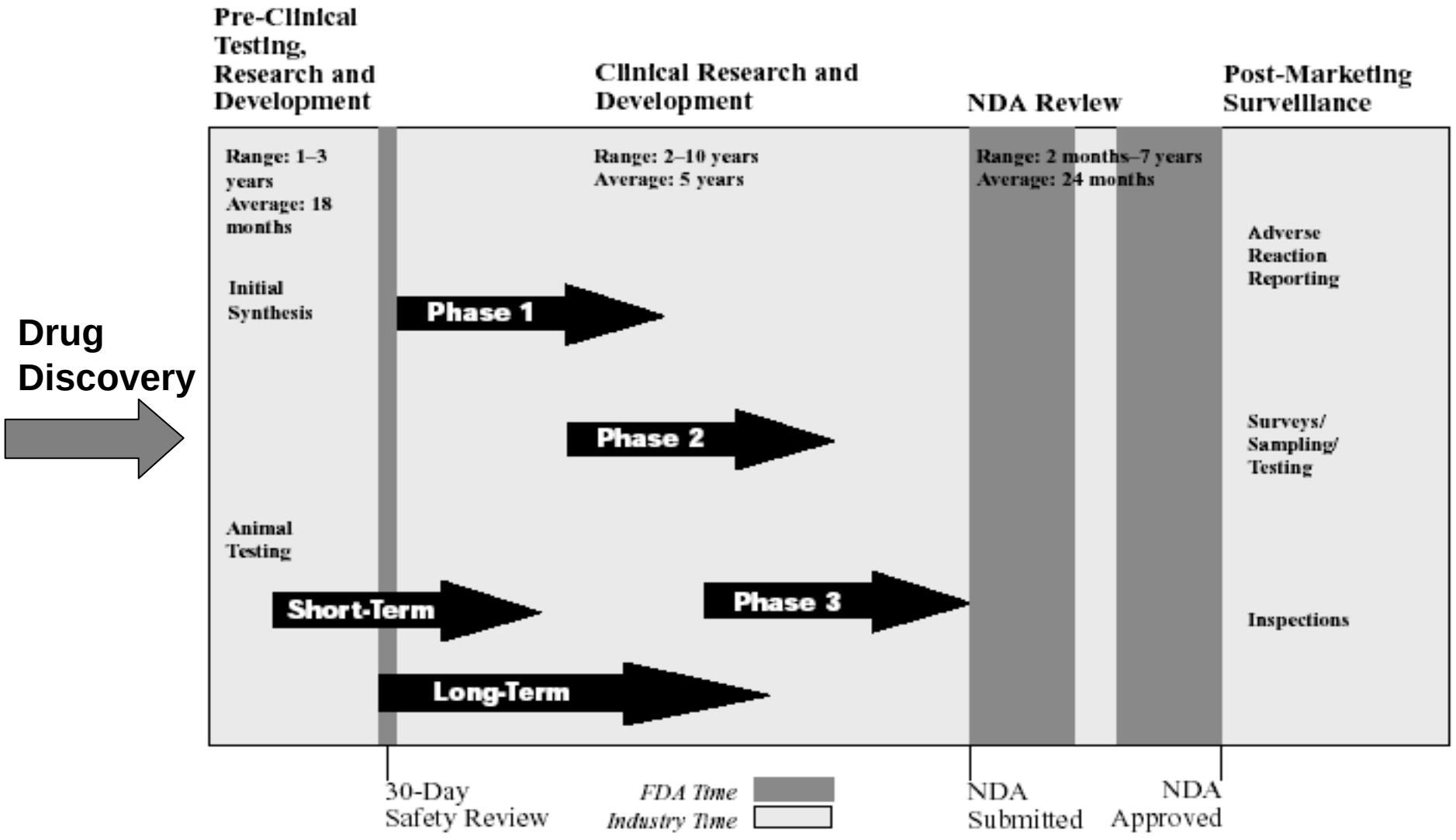


Big Multi-National Pharmaceutical

New Drug Development Timeline



Reality of Drug/Therapy Development

- Industry will be a key partner and major investor for bringing cures from Bench to Bedside
- It will take 5 to 10 years after discovery for a treatment to reach clinic
- It will take Hundreds of Millions of Dollars for each Product to reach clinic- mostly from Industry Partners

Current Market Conditions for Early Stage Technology

- Companies and Investors want later-stage, more market-ready technology
- Typically seeking products less than two years from human clinical trials
- Chasm between early stage technology and research and commercialization

  "The Translational Research Gap"

Crossing the Translational Research Funding Gap

- NIH: “ The Roadmap”
  - Federal funding of selected drug development projects
  - Federal funding of Industry / Academic collaboration (SBIR, STTR grants)
- Institutional Development Funds
  - Harvard
  - USC
  - UCSF
  -

A Successful Technology Development Program

- Foster Public / Private partnership
  - Know your partners and their business needs
- Incentivize **all** players:
  - Institution, Investigators, Investors
- Recruit a skilled staff
- Create policies and procedures which facilitate the exchange
- Establish realistic expectations for performance

***The Ultimate Prizes*:**

Therapies and Cures

Economic growth