

# Bio Start-ups: “Doing Business” With the NIH



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# Why Do Business With NIH?

- Annual budget of \$ 39.2 billion (FY19)
- ~10% of funding for intramural research
- 6,000 intramural scientists / 18,000 staff / 2,000 projects
- Basic & clinical research discoveries
- Collaborations with industry & academia
- Partners commercialize into products

# Your Six Top NIH Business Tips & Opportunities For Start-Ups

- In-licensing of NIH technology
- Research collaborations with intramural NIH
- Using pre-clinical / clinical NIH services
- Selling products / services to NIH
- Getting grants & contracts from NIH
- Utilizing NIH information sources

# Tip #1: NIH Technology Licensing



# Characteristics of the NIH Intramural Research Program “Pipeline”

- Novel, fundamental research discoveries
- “Supermarket” for research tools
- Collaborations (CRADAs) for basic or clinical studies
- Selected projects in early clinical trials
- Product sales by licensees: ~\$ 6B

**AcuTect™ AIDS Test Kit Beaucage**  
**Reagent BRCA1 Diagnostic Certiva™**  
**CHAPS Fludara Fecolator Havrix**  
**ImmunoWELL® Matrigel® Prezista®**  
**Invasion Chamber Mirakelle™**  
**NeuTrexin® ParaSight™ PixCell**  
**Soluble Interleukin-2 Receptor**  
**Squirrel Free™ Seed Saver Synagis™**  
**Taxol® Thyrogen™ TransProbe-1®**  
**Videx® Vitravene™**

# Sample Licensee Product Approvals

- Angiotech      Taxus & Zilver (drug stents)
- Genzyme      Thyrogen (rTSH)
- Medimmune      Synagis (RSV mab)
- Millennium      Velcade (myeloma drug)
- Biogen Idec      Zevalin (NHL I<sub>131</sub> mab)
- Amgen      Kepivance (KGF)
- Merck      Gardasil (HPV vaccine)
- Tibotec/J&J      Prezista (HIV protease drug)

# Special Developments For Small Companies

- Start-up Express License Agreements
  - Option & Exclusive licenses with low or deferred financial terms
- SBIR-TT Program
  - Bundle of SBIR award & exclusive license to intramural technology



# Start-Up Challenge Contests: Licensing to University Start-Ups



*Partnerships with  
Center for Advancing  
Innovation & private  
foundations*

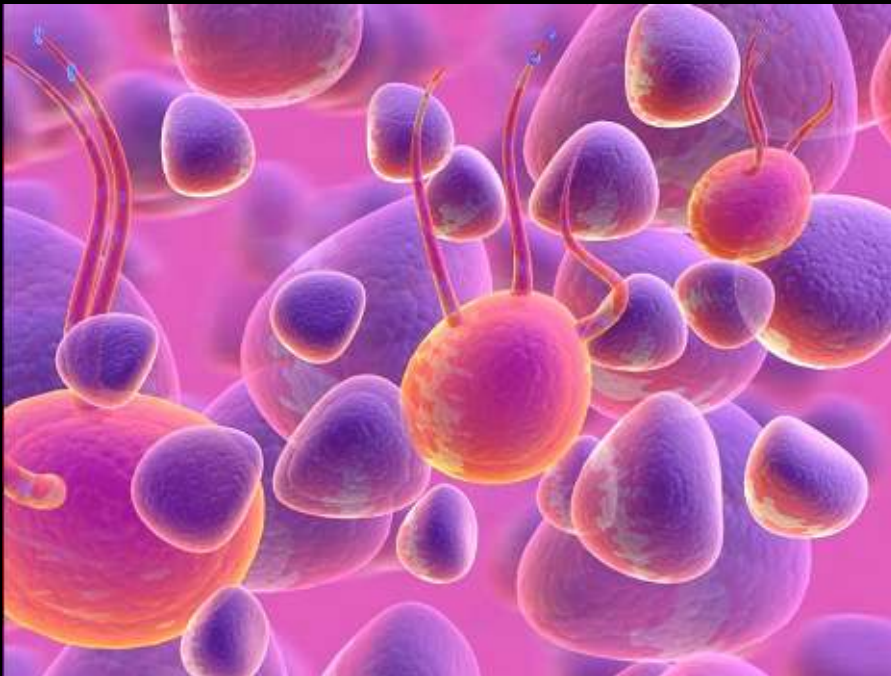
# Tip #2: NIH Basic Research Collaborations



# NIH Research Collaborations

- “Internal Use” Research Tool Licenses
- Cooperative Research And Development Agreement (CRADA)
- Clinical Trial Agreement
- Specialized Development Services
- Training Programs
- Informal “official duty” collaborations

# Tip #3: NIH Pre-Clinical & Clinical Research Services



# Pre-Clinical Research: NCI Developmental Therapeutics Program

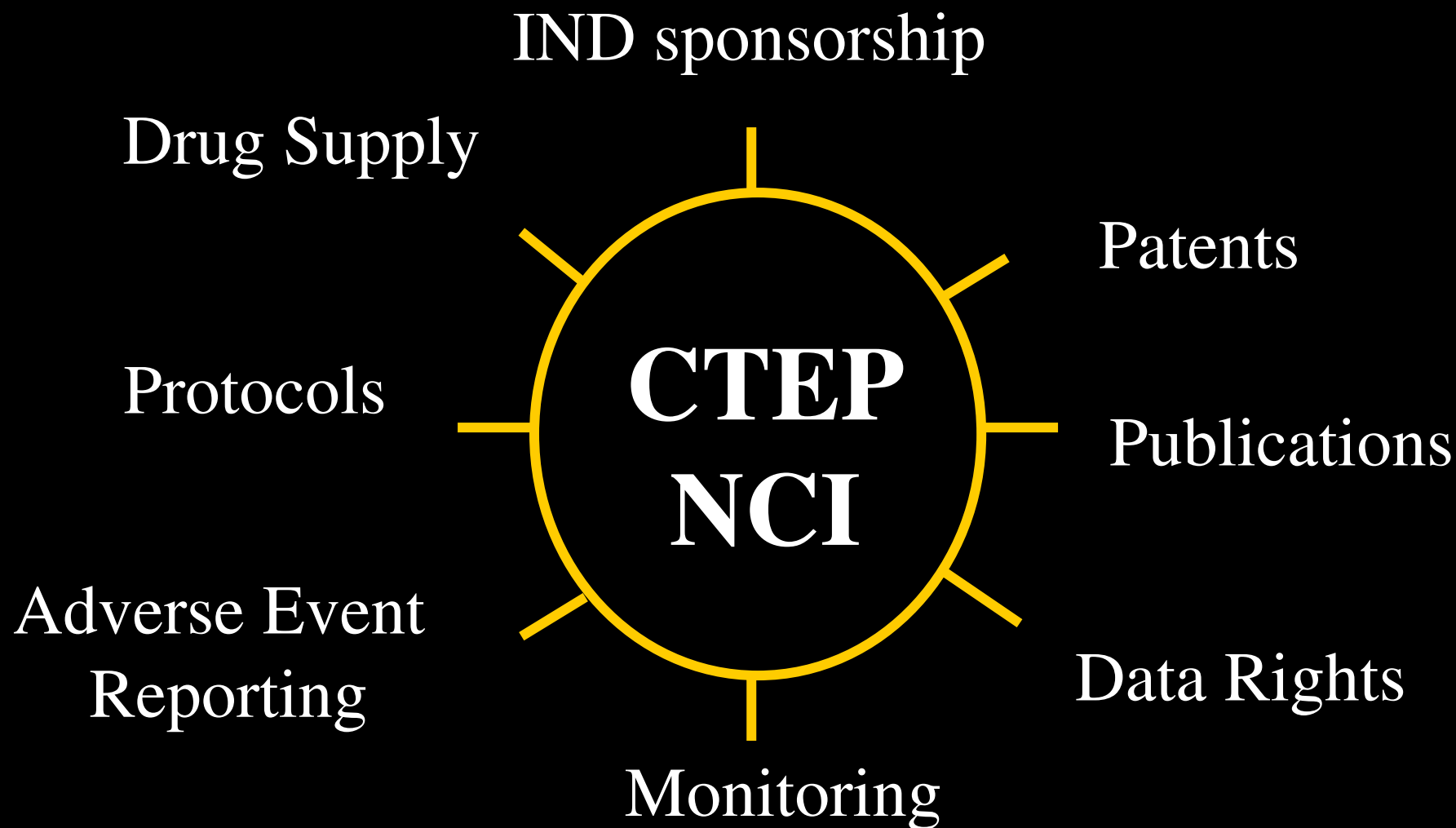
- Assay development for screening
- Synthesize small quantities of compounds
- Provide compound libraries & reagents
- Pharmacology and toxicology testing
- Formulation
- Clinical batch production
- Services open to NIH & non-NIH organizations



# Clinical Trials At NIH Clinical Center



# Clinical Trials Programs At Cancer Therapy Evaluation Program (CTEP)





National Center  
for Advancing  
Translational Sciences

## Clinical and Translational Science Activities

- ◆ Clinical and Translational Science Awards

## Rare Diseases Research and Therapeutics

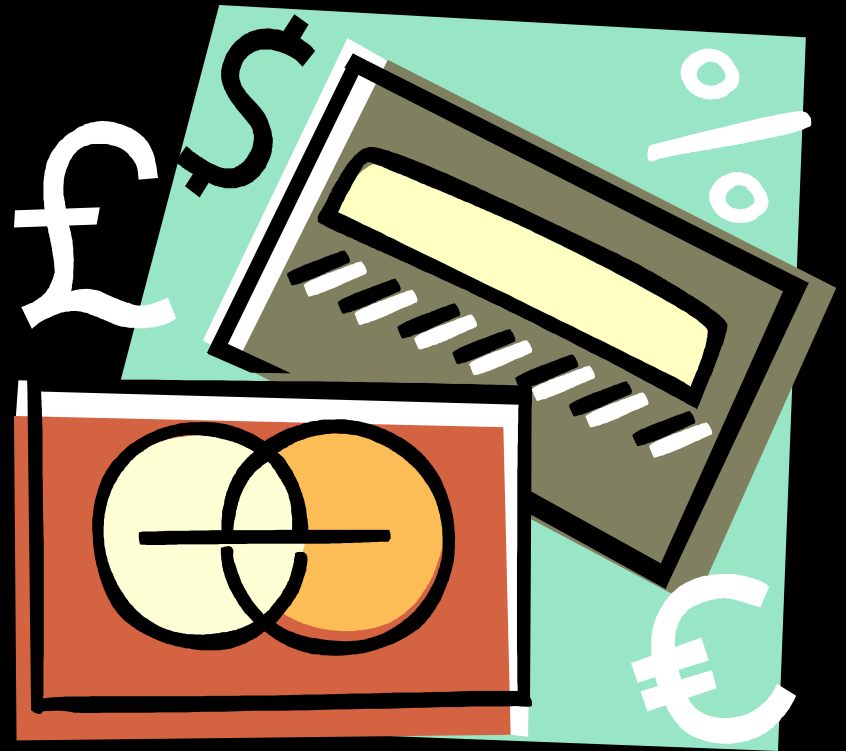
- ◆ Therapeutics for Rare and Neglected Diseases
- ◆ Office of Rare Diseases Research
- ◆ Bridging Interventional Development Gaps

## Re-engineering Translational Sciences

- ◆ NIH Chemical Genomics Center
- ◆ Toxicology in the 21st Century



# Tip #4: Selling Products To NIH



# Selling Products To NIH

- Largest US consumer of bioscience reagents & instruments
- Blanket purchase agreements (BPA)
- NIH Central Storeroom
- NIH Research Festival (Bethesda & Ft. Detrick Maryland campuses)
- Biodefense & translational research initiatives

# Tip #5: Getting NIH Grants & Contracts



# NIH Grant & Contract Opportunities

- Over 80% of NIH budget as grants & contracts
- Applicants for most programs can be for-profit or non-profit
- SBIR / STTR must be at least 51% US owned
- Venture-backed firms now eligible for SBIR
- Non-dilutive funding
- Many R&D contracting opportunities

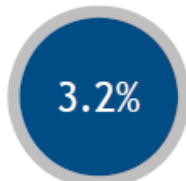
See: <https://grants.nih.gov/funding/contracts.htm>

# Small Business R&D Funding

## SET ASIDE



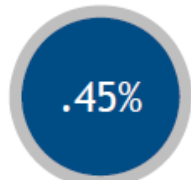
(FY16)



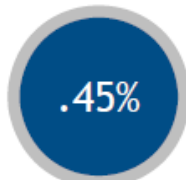
(FY17)

## SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization



(FY16)



(FY17)

## SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

# SBIR / STTR: 3 Phase Program



*Discovery*

Phase  
I

## Phase I Feasibility Study

**Budget Guide:** \$150K for SBIR and STTR

**Project Period:** 6 months (SBIR); 1 year (STTR)



*Development*

Phase  
II

## Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase  
IIB

## Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA

Many, but not all, IC's participate

Varies~\$1M per year; up to 3 years



*Commercial-  
ization*

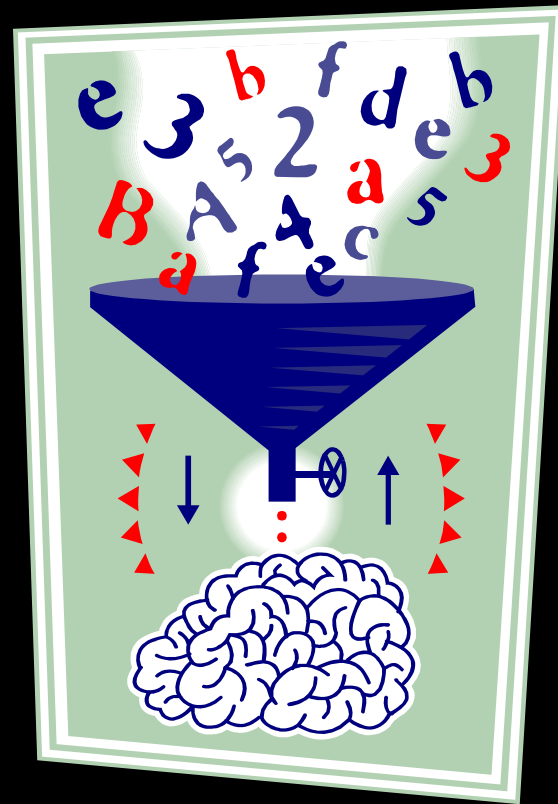
Phase  
III

## Phase III Commercialization Stage

NIH, generally, not the “customer”

Consider partnering and exit strategy early

# Tip #6: Utilizing NIH Information Sources For Your Business

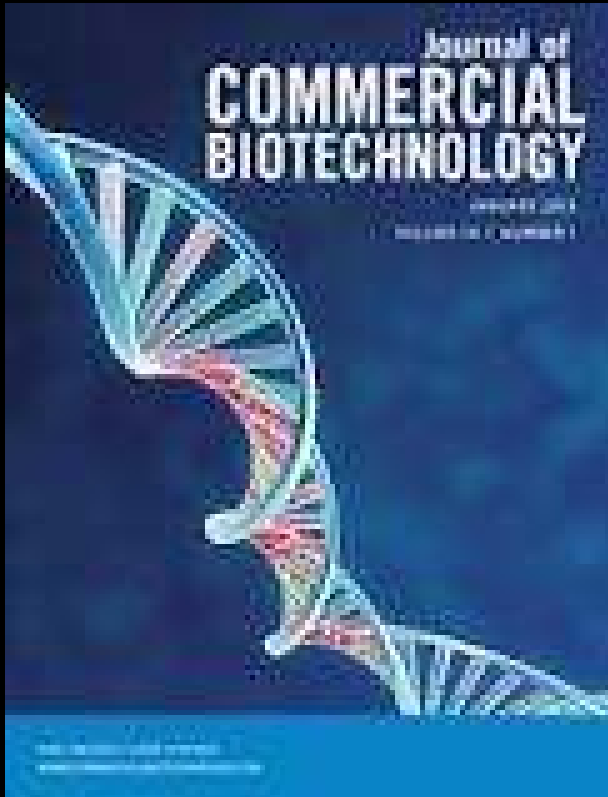


# Useful Business Information

- New Licensing Opportunities RSS Feed:
  - <http://www.ott.nih.gov/rss/>
- NIH Guide To Grants & Contracts Listserv:
  - <http://grants1.nih.gov/grants/guide/listserv.htm>
- RePORTER Database of Awarded Grants
  - <http://projectreporter.nih.gov/reporter.cfm>
- Exhibiting Your Products at NIH Research Festivals
  - [www.technicalsalesassociation.org](http://www.technicalsalesassociation.org)



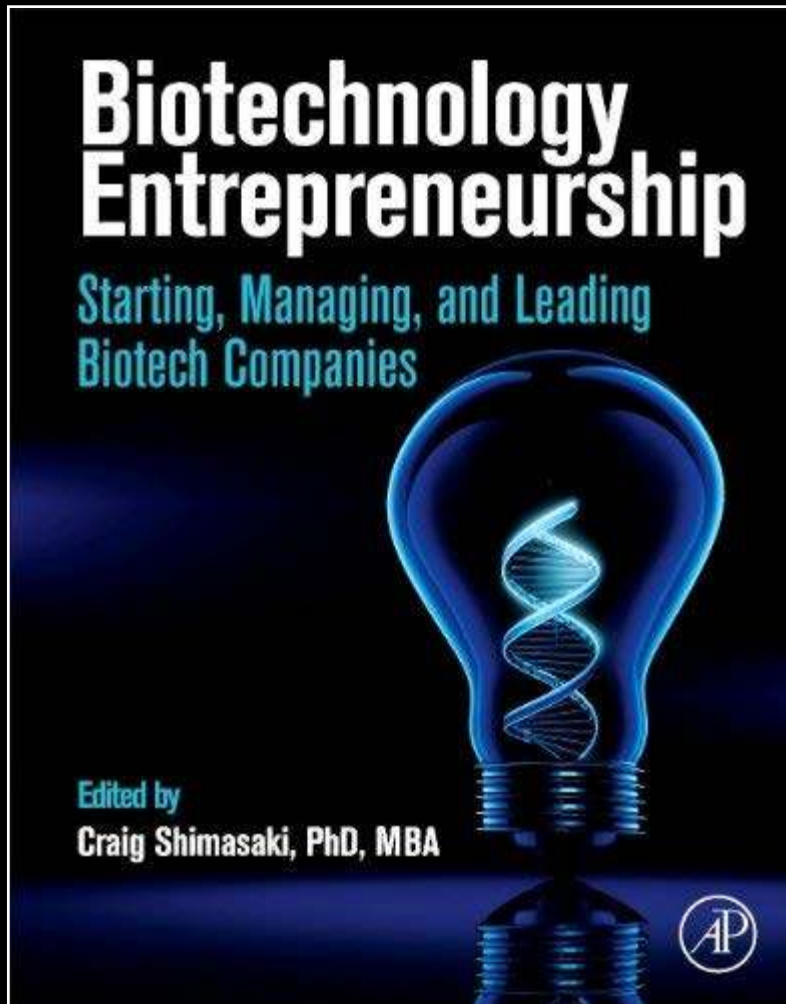
# For Further Reading ....



“Partnering with the NIH: Now part of the ‘Value Proposition’ for start-ups”

*Journal of Commercial  
Biotechnology* (2012)  
18, 60–67.

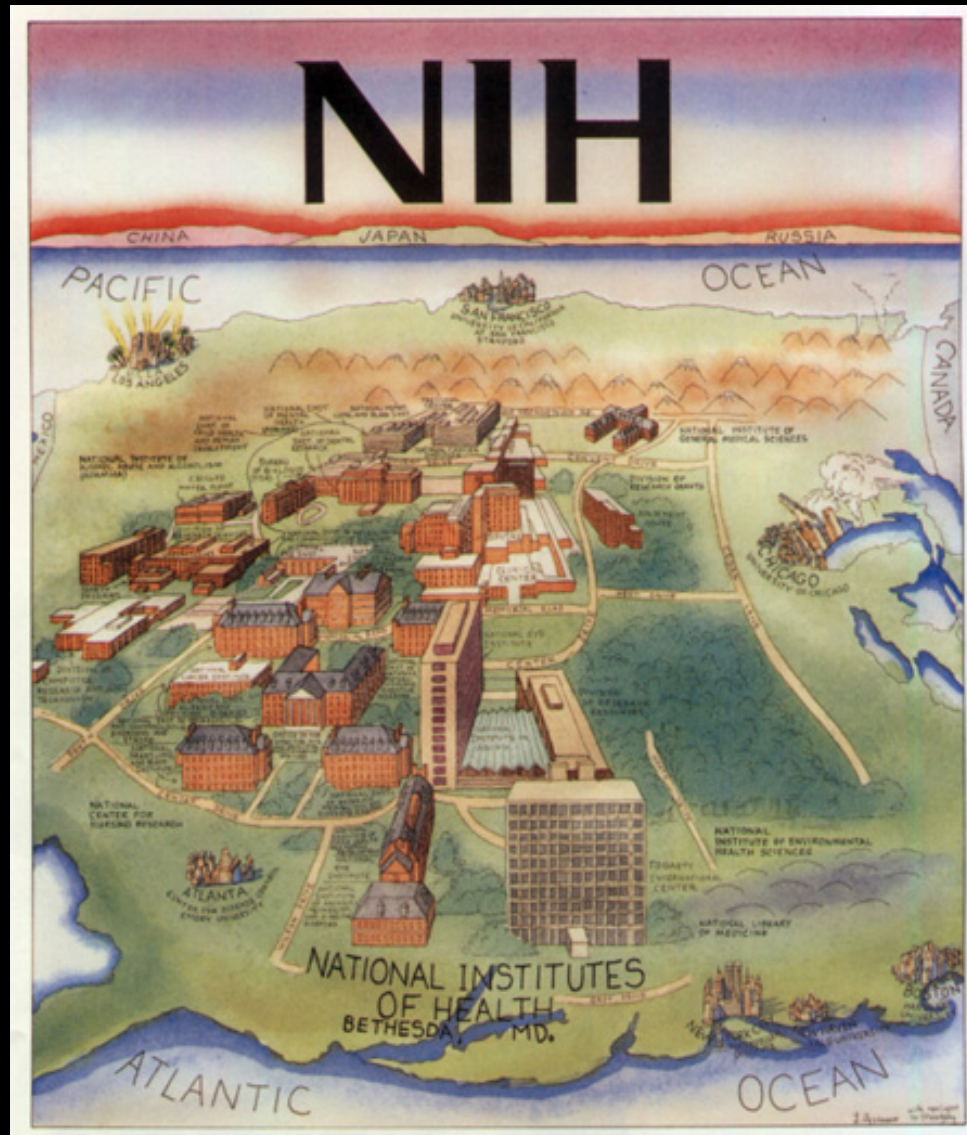
# And From the Bio Bootcamp ....



“Licensing the  
Technology:  
Biotechnology  
Commercialization  
Strategies Using  
University and Federal  
Labs”

(Chapter 14)

# For Start-ups -- Not Hard To Find!





- NIH Information: [www.nih.gov](http://www.nih.gov)
- Technology Transfer: [www.ott.nih.gov](http://www.ott.nih.gov)

Thank you!