

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



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# Why Do Business With NIH?

- Annual budget of \$ 45 billion (FY22)
- ~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: ~\$ 7B+

**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 FDA Approvals

- BioNTech Comirnaty® (COVID-19 vaccine)
- Bluebird Bio Abecma® (CAR-T myeloma)
- Ridgeback Ebanga® (ebola mab)
- PRF/Eiger Zokinvy® (progeria treatment)
- Janssen Spravato® (antidepressant spray)
- AstraZeneca Lumoxiti® (anti CD22 leukemia)
- Kite Yescarta® (CAR-T lymphoma)
- HRA Pharma Ella® (emergency contraceptive)

# 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*

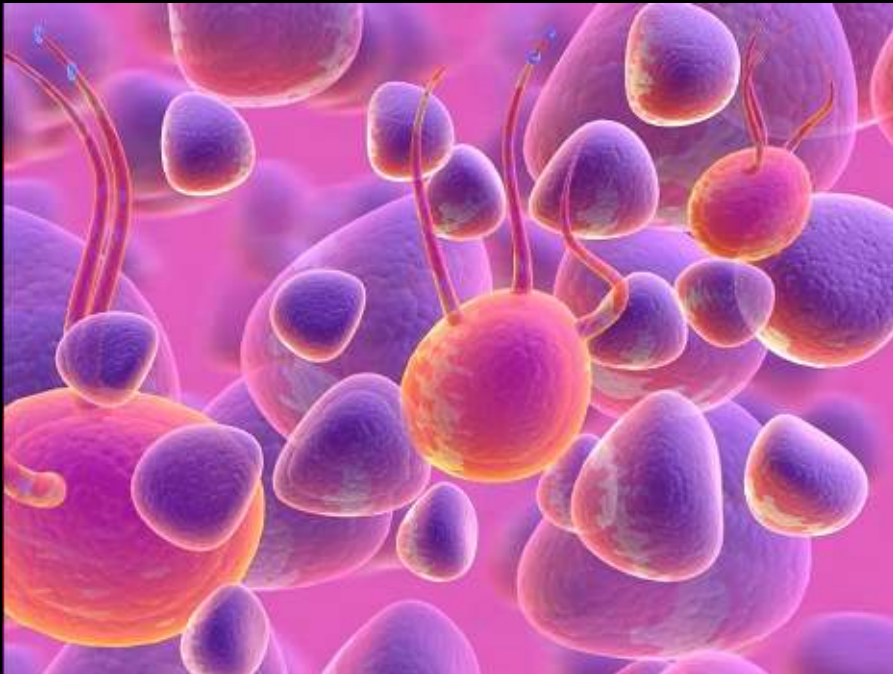
# Tip #2: NIH Basic Research Collaborations



# 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



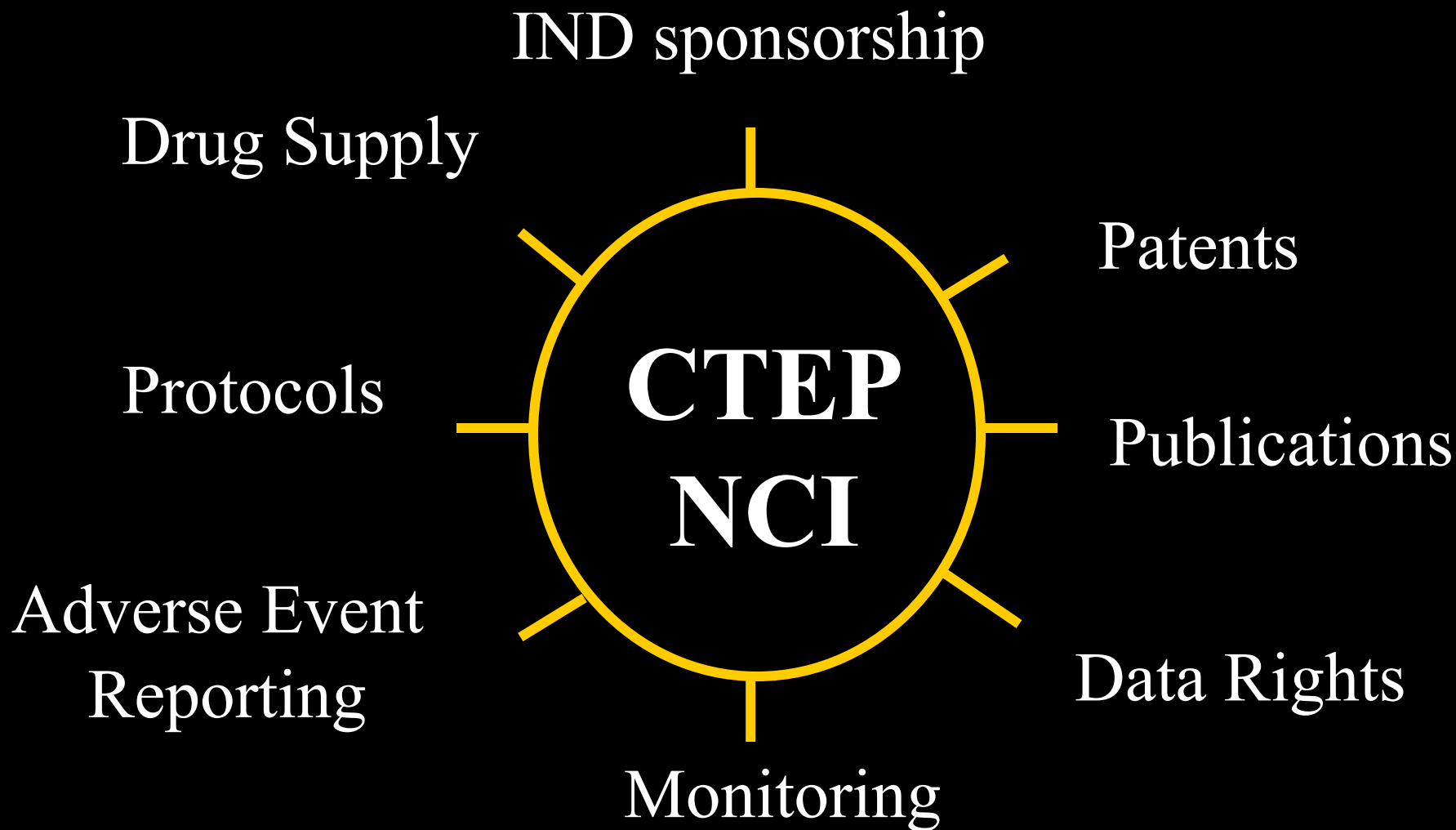
# Pre-Clinical Research: NCI Developmental Therapeutics Program

- 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

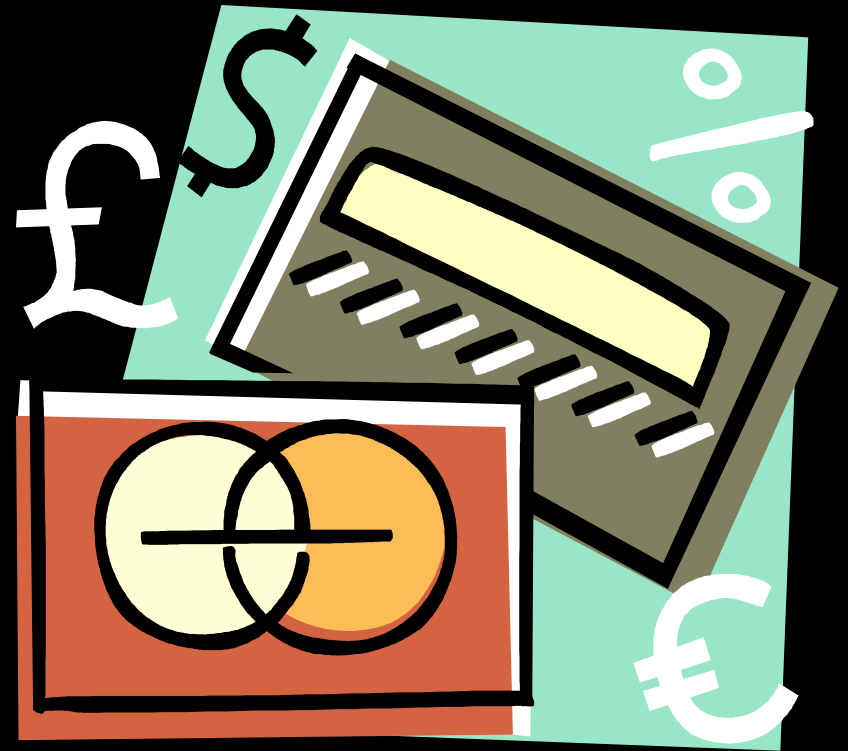
- ◆ Therapeutics for Rare and Neglected Diseases
- ◆ Office of Rare Diseases Research
- ◆ Bridging Interventional Development Gaps

## 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

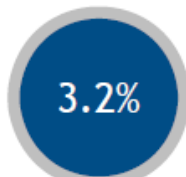
See: [grants.nih.gov/funding/contracts](https://grants.nih.gov/funding/contracts)

# Small Business R&D Funding

## SET ASIDE



(FY16)



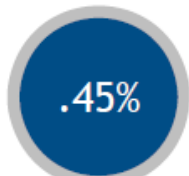
(FY17)

## SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

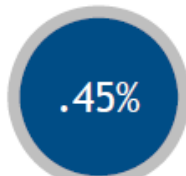
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

## 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



(FY16)



(FY17)

# 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*

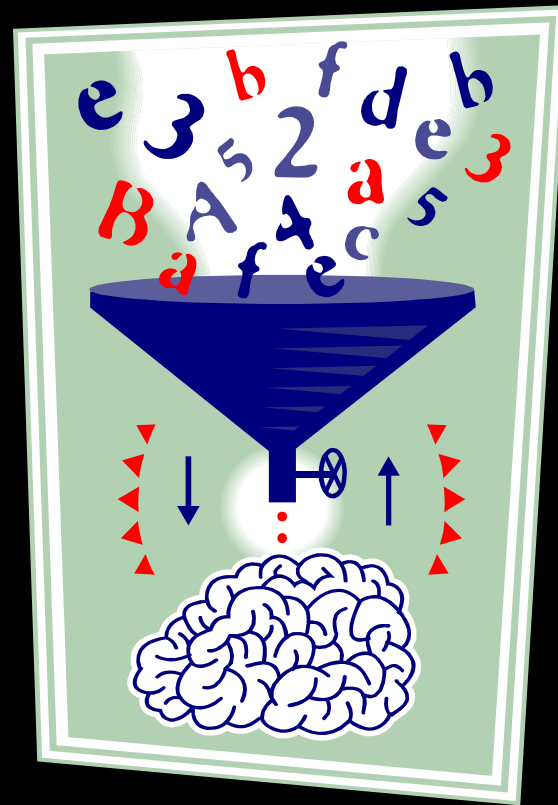
Phase III

## 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
  - [techtransfer.nih.gov/rss](https://techtransfer.nih.gov/rss)
- NIH Guide To Grants & Contracts Listserv
  - [grants.nih.gov/grants/guide/listserv](https://grants.nih.gov/grants/guide/listserv)
- RePORTER Database of Awarded Grants
  - [reporter.nih.gov](https://reporter.nih.gov)
- Exhibiting Your Products at NIH Research Festivals
  - cancelled in 2020 & 2021 due to pandemic



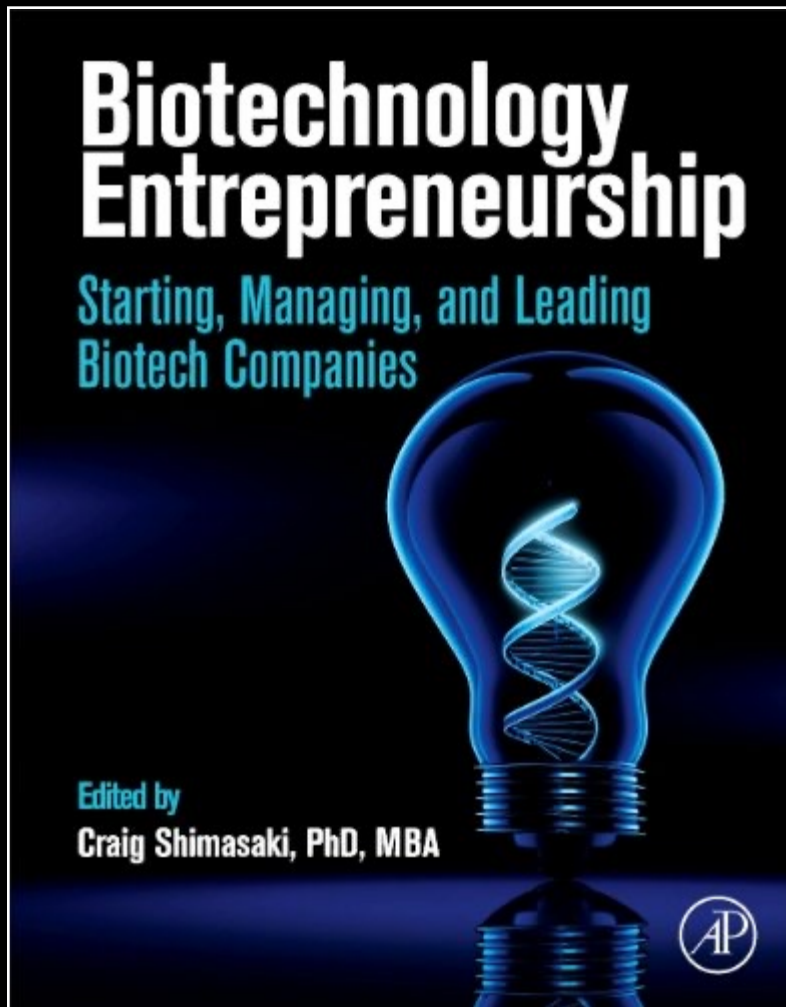
# For Further Reading ....



“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)



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

Thank you!