



Biotechnology
Innovation Organization

June 4–5, 2023

#BIO2023
#StandUpForScience

Biotechnology Entrepreneurship Boot Camp

Presented by:

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BIO Recognizes Course Sponsor:



**McDonnell Boehnen
Hulbert & Berghoff LLP**
Intellectual Property Law

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



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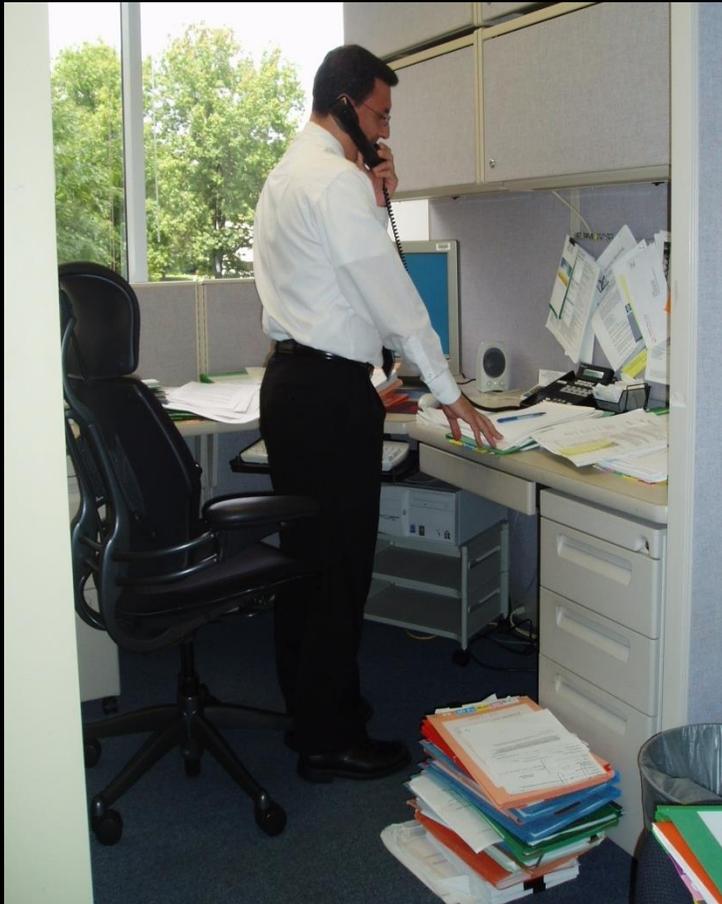
Why Do Business With NIH?

- Annual budget of \$ 47.7 billion (FY23)
- ~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 Non-Dilutive NIH 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*

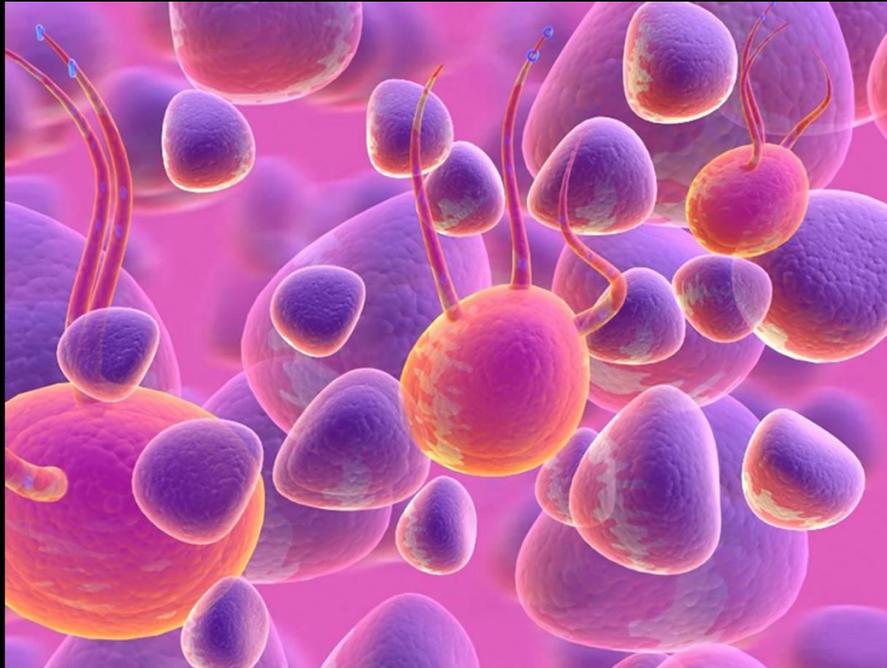
Tip #2: NIH Basic Research Collaborations



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



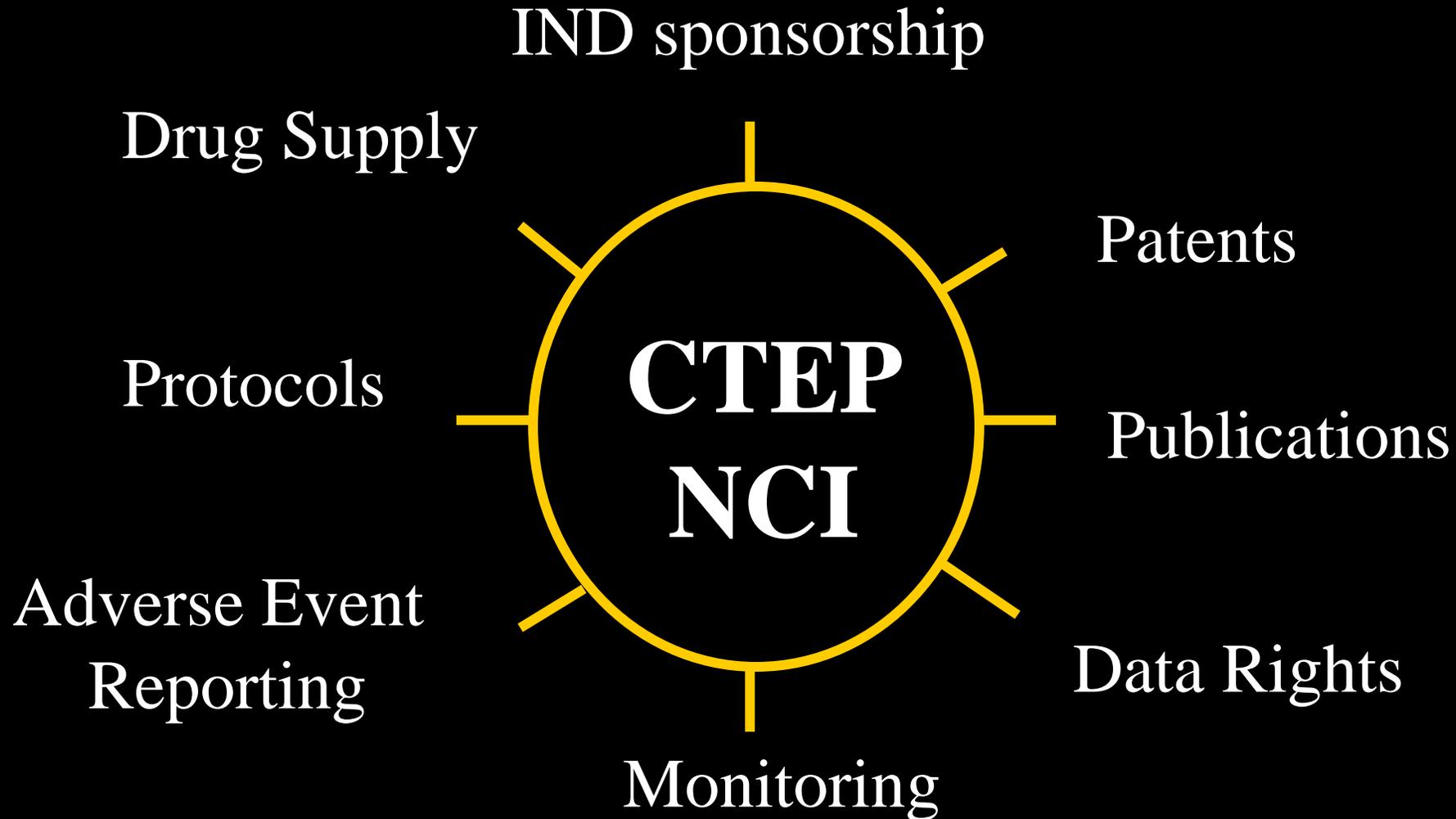
Pre-Clinical Research: NCI Developmental Therapeutics Program

- 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

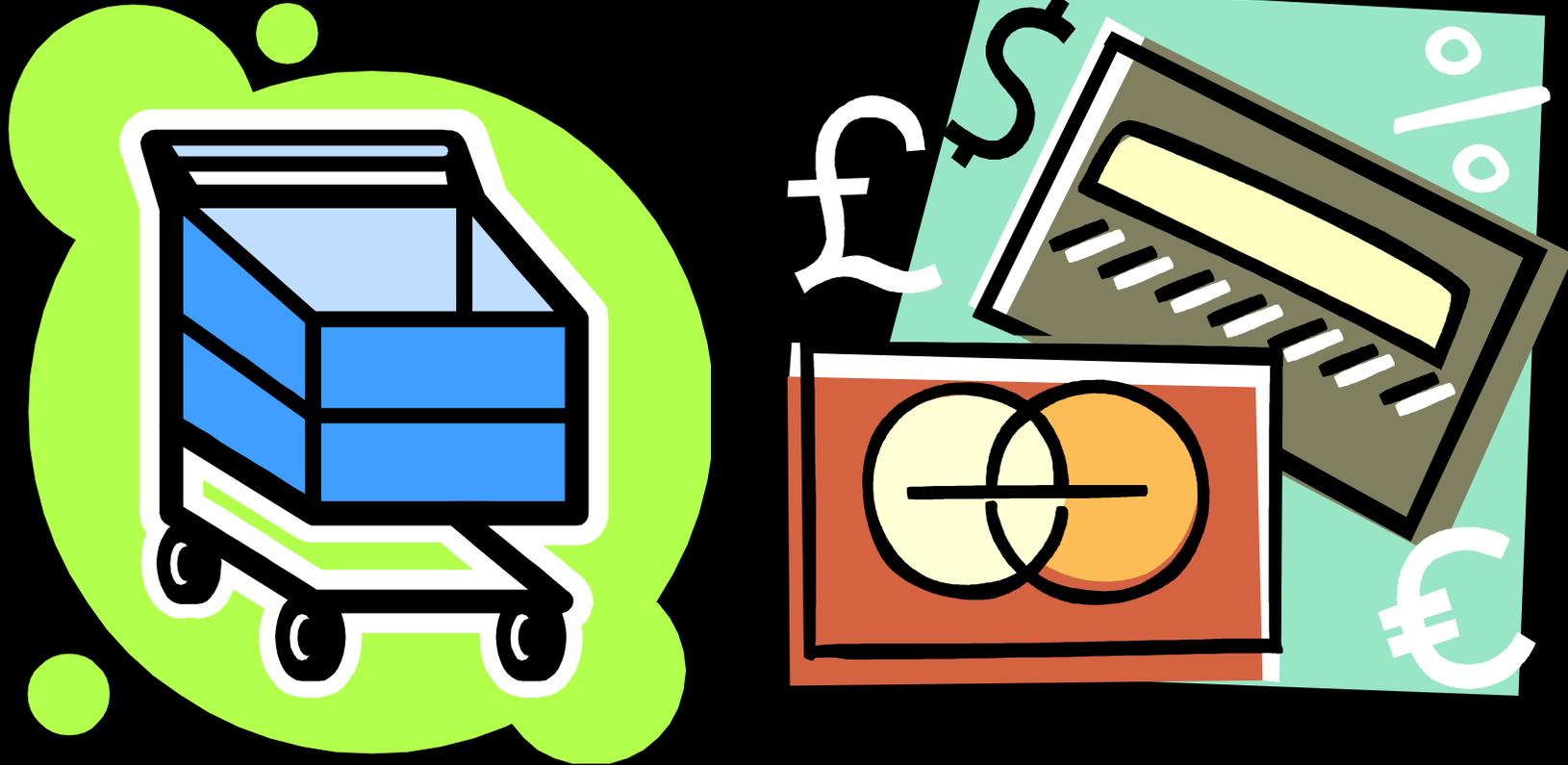
Rare Diseases Research and Therapeutics

- ◆ 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

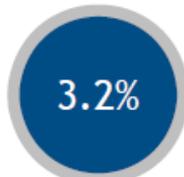
See: grants.nih.gov/funding/contracts

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



(FY16)



(FY17)

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*

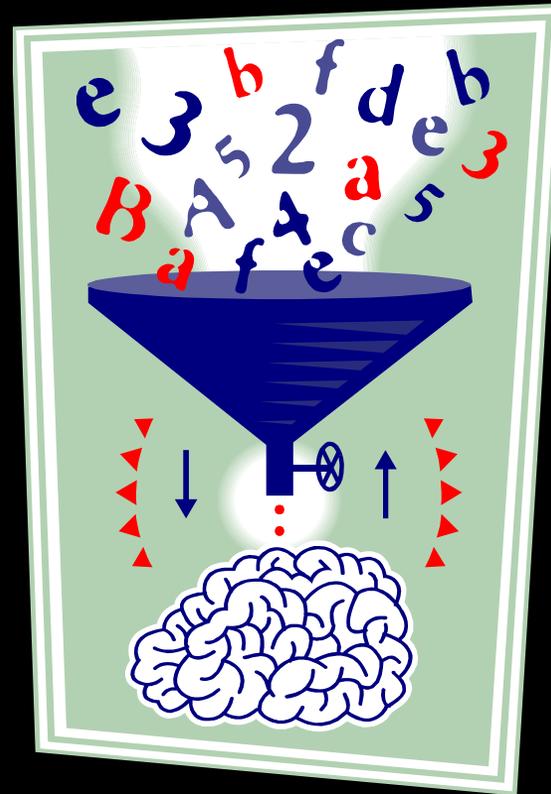
Phase III

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
 - techtransfer.nih.gov/rss
- NIH Guide To Grants & Contracts Listserv
 - grants.nih.gov/grants/guide/listserv
- RePORTER Database of Awarded Grants
 - reporter.nih.gov
- Exhibiting Your Products at NIH Research Festivals
 - cancelled in 2020-2022 due to pandemic

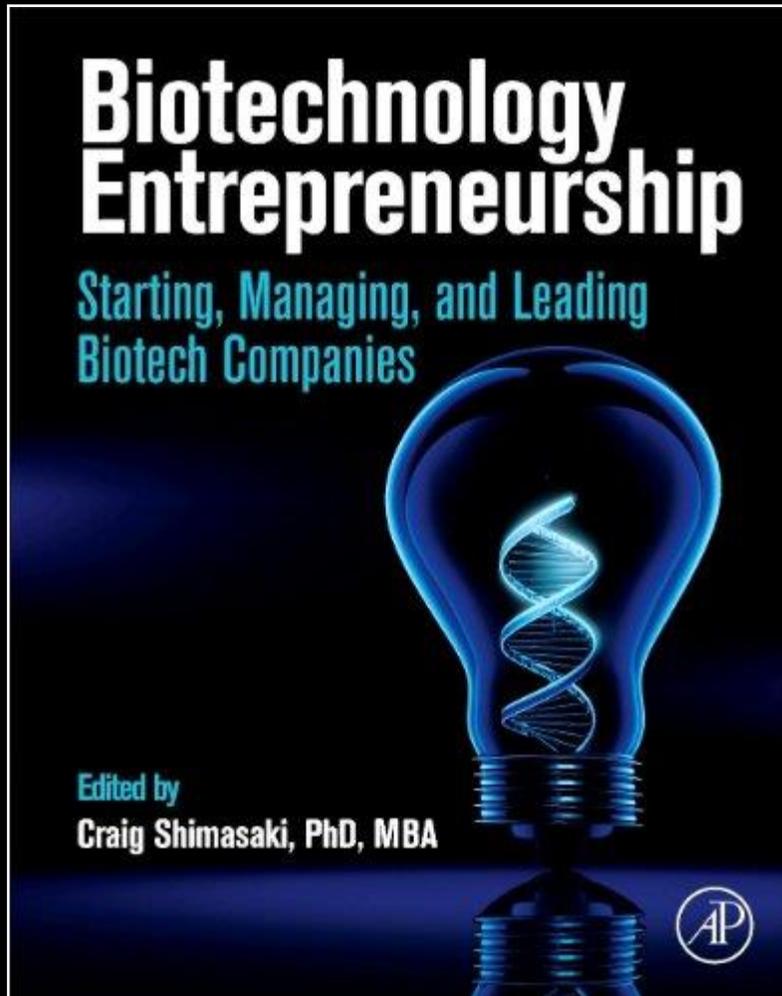
For Further Reading



“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
- Technology Transfer: techtransfer.nih.gov

Thank you!