

# Technology Transfer: What You Need to Know About Inventions, Patents, and CRADAs

September 2016



# NCI Technology Transfer

TTC helps connect you with external partners to turn discovery into health

- Facilitates research by helping provide you with:
  - access to research and clinical materials
  - Industry and academic collaborations
- Navigates the process of invention reporting, patenting, invention development and licensing



# Tech Transfer Agreements

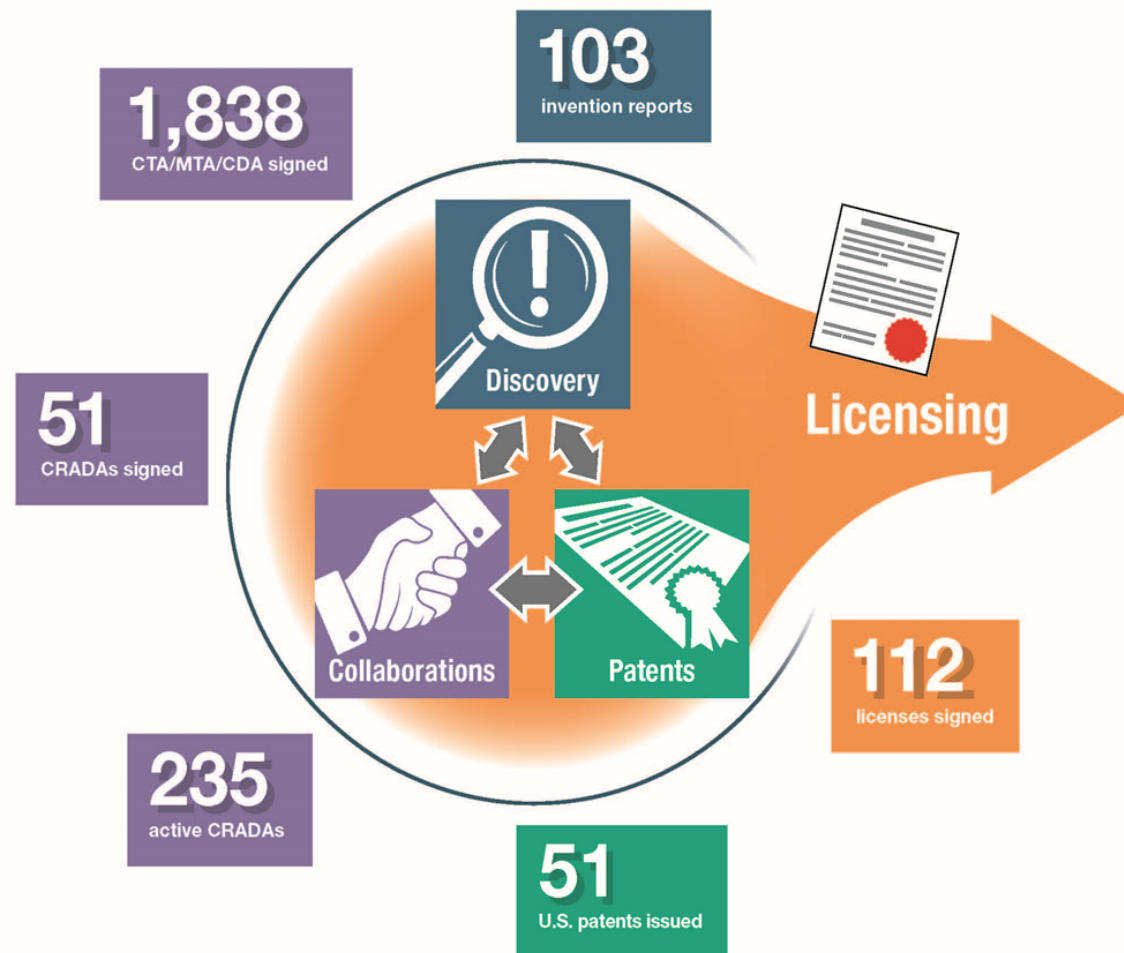
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# Types of Tech Transfer Agreements

- ✓ **Confidential Disclosure and Data Transfer Agreements (CDAs and DTAs)**
  - Protect confidential information or data
- ✓ **Material Transfer Agreements (MTAs)**
  - Send or receive materials for research
- ✓ **Clinical Trial Agreements (CTAs)**
  - Receive investigational drug for clinical trials
- ✓ **Collaboration Agreements**
  - Joint research project with university or industry
- ✓ **Cooperative Research Agreements and Development Agreements (CRADAs)**
  - Collaborative research project with industry
  - NCI can receive funds
  - Provides a license option to the collaborator
  - NCI CRADA research led by Principal Investigator

# Tech Transfer Agreements for NCI

## National Cancer Institute FY15 Technology Transfer Metrics



# Working Together to Shorten Negotiation Times

## Good Start

- TTC Specialists collect information from NCI and Collaborator scientists to select agreement type and terms.

## Setting expectations – metrics-based approach

- TTC Specialists manage negotiations resulting in efficient information flow and execution.

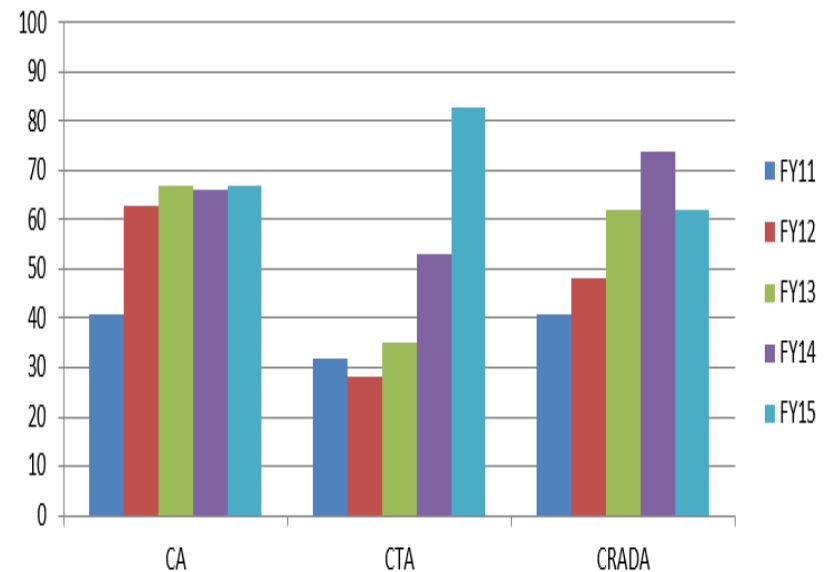
## What the scientist can do to help

- Respond quickly and comprehensively to TTC Specialists.
- Work with TTC so NCI can speak to outside party with one voice during negotiations.

## Overall impact

- ✓ Substantially increased the number of negotiations concluded within time expectations
- ✓ All agreement types
- ✓ NCI and Service Center Clients

% of Agreements Executed Under Target Days





# Inventions, Patents, Licenses & Royalties

# Examples of NCI Commercialized Inventions: *Success Together*



US\$2.4B\*



US\$1.9B\*



US\$1.8B\*



US\$18M\*



US\$12M\*

\*2015 world-wide sales



# Reporting Inventions



- **Complete an Employee Invention Report (EIR) at least three months before any public disclosure.**
  - <https://techtransfer.cancer.gov/intellectualproperty/inventions/reporting-an-invention>
  - Patent applications should be filed before the first public disclosure.
- **TTC Specialists can assist NCI inventors in completing the form, and answer related questions.**

# To Patent or Not Patent? It's a Business Decision

Discoveries	Research Tools	Inventions
Identify a biochemical pathway	Transgenic mouse Cell line Plasmid	Novel compounds for inhibiting pathway
Mathematical relationships	Software	New diagnostic test
<b>Publish</b>	<b>Publish</b> <b>License for commercial use</b> <b>MTA for academic research</b>	<b>Patent</b> <b>Publish</b> <b>License for product development and sales</b>



# Licenses Generate Royalties



- **Inventors receive:**
  - The **first \$2K** of royalties received under a license, and
  - **15% of receipts between \$2K - \$50K**, and
  - **25% of receipts over \$50K**
  - **Cap at \$150K per inventor per year** (total across all inventions)
  - **If inventor leaves the NCI, still entitled to royalty share**
  - **Inventors must keep up-to-date banking information with NIH to ensure royalties are received**
- **NCI's Institute-share of royalties used to pay patenting costs and a variety of mission-related activities**

<http://www.ott.nih.gov/information-nih-cdc-and-fda-inventors>

<https://techtransfer.cancer.gov>

# FY2015 NCI Inventions, Patents, Licenses and Royalties

**4,033 active patents/patent applications in “pipeline”**

**103** new inventions reported

**59** U.S. provisional patent applications filed

**51** new U.S. patents issued

**727 active licenses**

**112** new licenses for NCI

**\$122 M Total royalties received from licenses**

**\$ 8 M** to NCI inventors

**\$ 89 M** to NCI

**\$ 26 M** to outside org/co-owners

# Commercialization Challenges



## Challenges:

- Recent court decisions raised the bar on requirements to obtain biomedical patents
- Biomedical technologies are **high risk** to commercialize
- NCI's inventions typically **early stage** and often require additional development to be attractive for licensing.

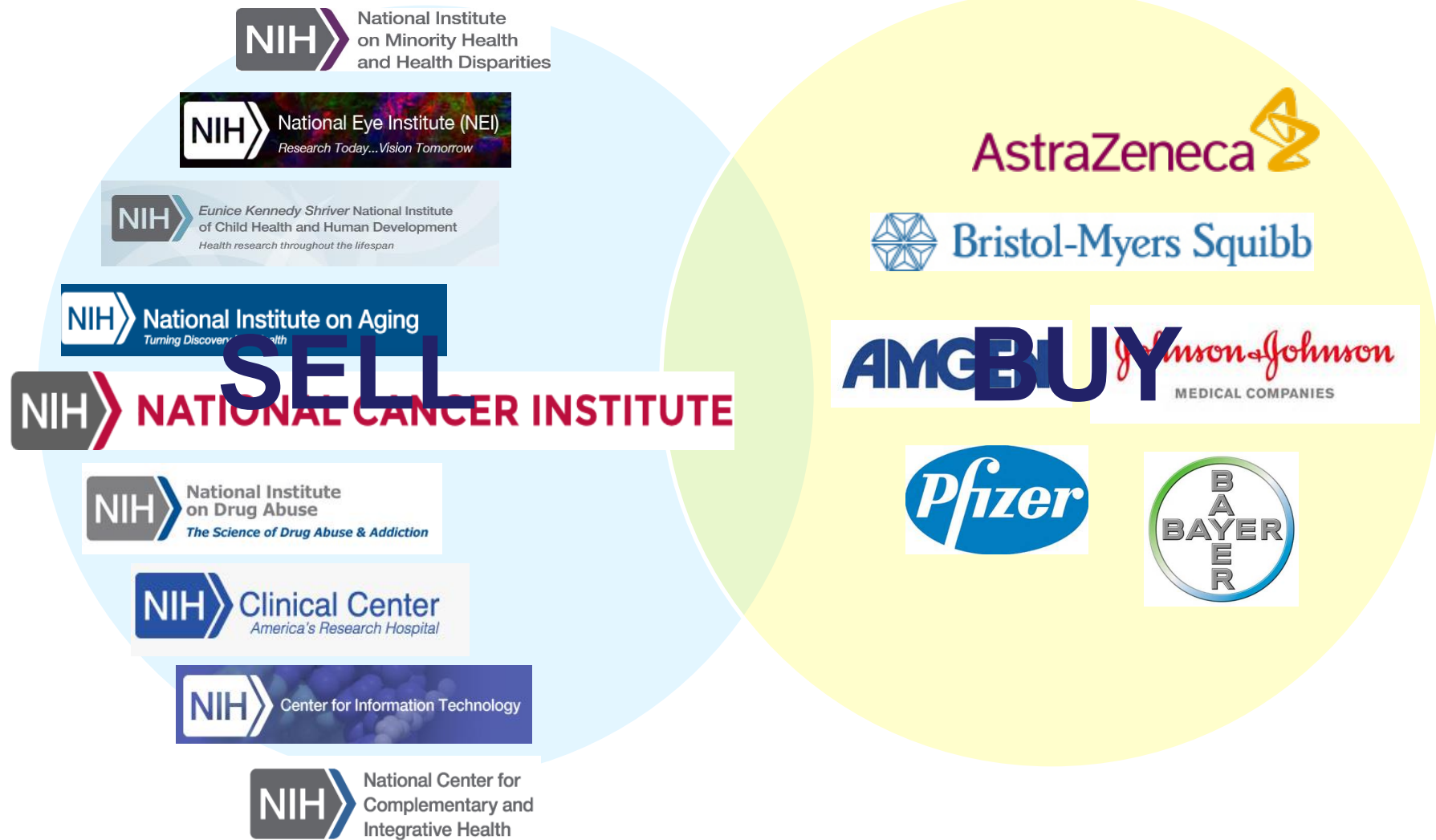
## Opportunity:

- 57% of NCI's portfolio remains unlicensed

## Response:

- TTC initiated multiple new approaches to advance development of NCI inventions

# Two Overlapping Interests: Sell-side and Buy-side



# Two Conflicting Interests: Sell-side and Buy-side



- Public dollars/Revenue Source
- Patent Cliff
- Scope
- Geographies/Markets
- Solutions to Patients/Customers



# New Marketing & Partnering Initiatives

- **NCI created the Invention Development and Marketing Unit (IDMU)**
  - Strategic approach to advance commercialization
  - Novel commercialization programs (e.g., Invention Development Program)
  - Reverse-engineering and pro-active marketing
- **Create awareness of NCI patent portfolio:**
  - Webinars
  - TT Delivers
  - Digital media (LinkedIn, Twitter, etc.)
  - Intramural staff as technology scouts





# New Commercialization Model – Startup Challenge Program

- Competition based on commercially viable technologies
- Advance development and commercialization
- Stimulate the creation of startup businesses



**The Neuro Start *UP* Challenge**  
Driving Innovation in Brain Health



**NANO STARTUP CHALLENGE**  
DRIVING INNOVATION IN CANCER NANOMEDICINE

**43**

Startups Created

**25**

Cancer-related technologies advanced

**146**

Teams competed

**2000+**

Entrepreneurs trained

# Invention Development Program



- New program piloted by TTC in 2014 to facilitate commercial development of NCI inventions.
  - Inventions in need of specific data to attract commercial interest.
  - IDP Review Committee provides commercial development feedback to inventors.
  - Funding available through IDP Review Committee, approval for proof-of-concept testing.

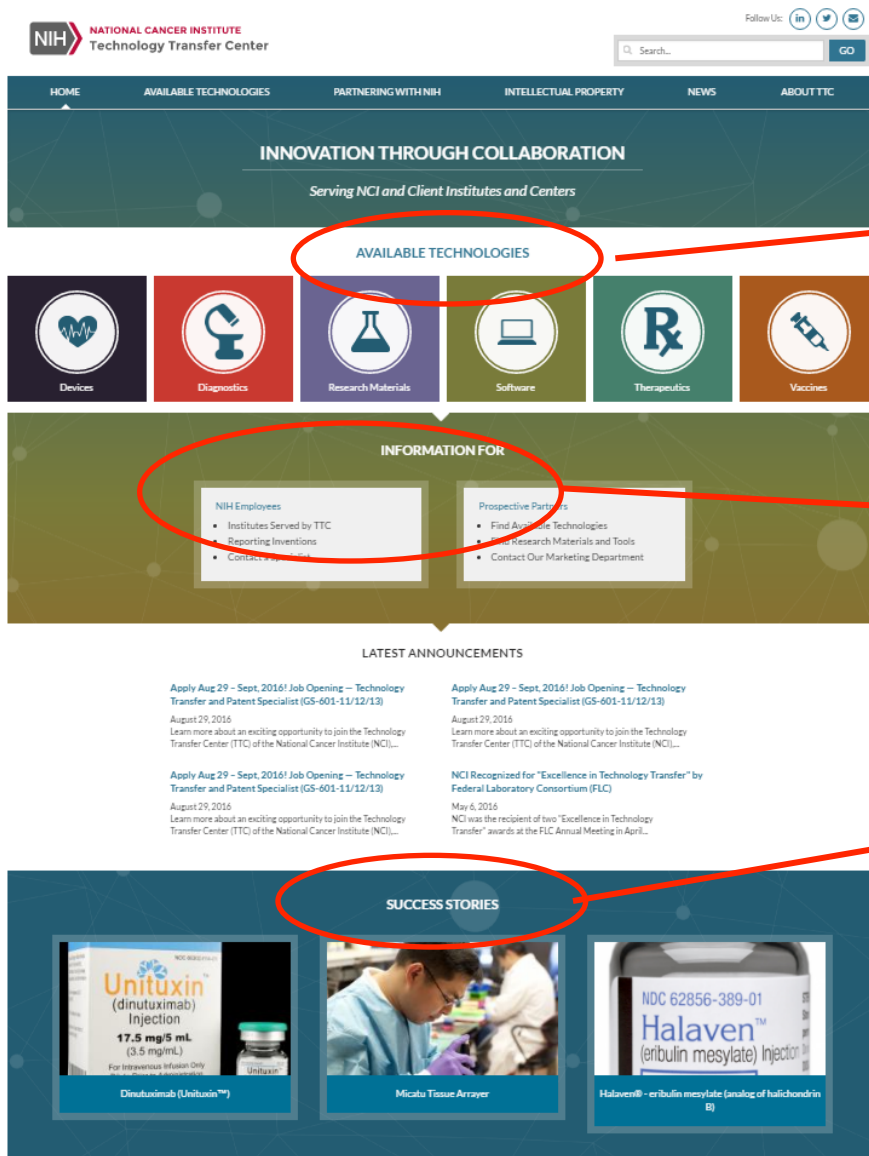
# How Inventors and TTC Can Work Together



- **Report inventions at least three months prior to disclosure**
- **Consider development of proof-of-principle data for commercial applications**
- **Update TTC about scientific projects related to patent-pending technologies**
- **Forward licensing leads or inquiries from commercial entities**
- **Talk with us about ways to promote development of your inventions**

# TTC Website

## <https://techtransfer.cancer.gov>



Website provides excellent platform to market Available Technologies

Information for NIH Employees easily accessible from homepage

Success Stories highlight the benefits and outcomes of technology transfer.

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