

# Resources & Collaborative R & D with the National Institutes of Health



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**NEPA: Partnering for Progress:  
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# National Institutes of Health

The National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services, is the primary U.S. Federal agency for conducting and supporting medical research.



# 27 Institutes & Centers at NIH



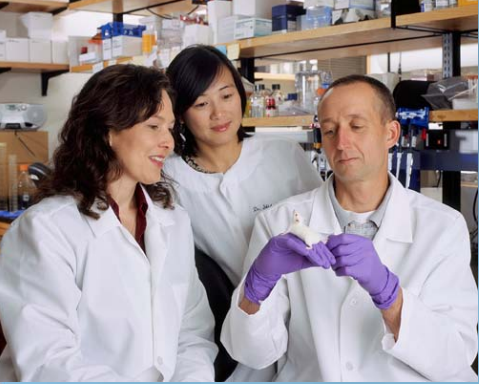
# Technology Transfer At NIH:

## The Institute Technology Transfer/Development Offices:

- Transactional Agreements
- Collaborative Research Agreements
- Specialized Agreements

## The NIH Office of Technology Transfer:

- Patent Prosecution via 14 contract patent law firms
- Licenses



# NCI Mission



“To eliminate suffering and death due to cancer.”

## Resources available for Collaboration:

- ▣ Unique research and clinical grade materials
- ▣ Unique expertise for mutual projects
- ▣ Unique testing capabilities
- ▣ Extensive clinical trials network for cancer
- ▣ Specific projects to develop NCI's
- ▣ Patented technologies



# NCI Programs

- ▣ Cancer Therapy Evaluation Program (CTEP)
- ▣ Developmental Therapeutic Program (DTP)
- ▣ Center for Cancer Research (CCR)

# The Advantages of Collaborating with CTEP

- ▣ Regulatory expertise.
- ▣ Ability to evaluate agent in wide variety of tumor types and disease settings.
- ▣ Expedite trials through extensive clinical trials network of cooperative groups, cancer centers, and phase 1 & 2 contracts.
- ▣ Exclusive access to primary data concerning a particular agent
- ▣ <http://ctep.cancer.gov>



# Developmental Therapeutic Program (DTP)

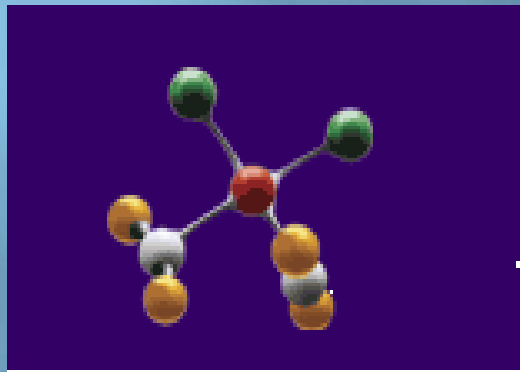
**DTP provides resources for:**

- **discovery**

- **Rapid Access to NCI Discovery Resources  
(RAND)**

- **development**

- **Rapid Access to Intervention Development  
(RAID)**



# Rapid Access to Intervention Development (RAID)

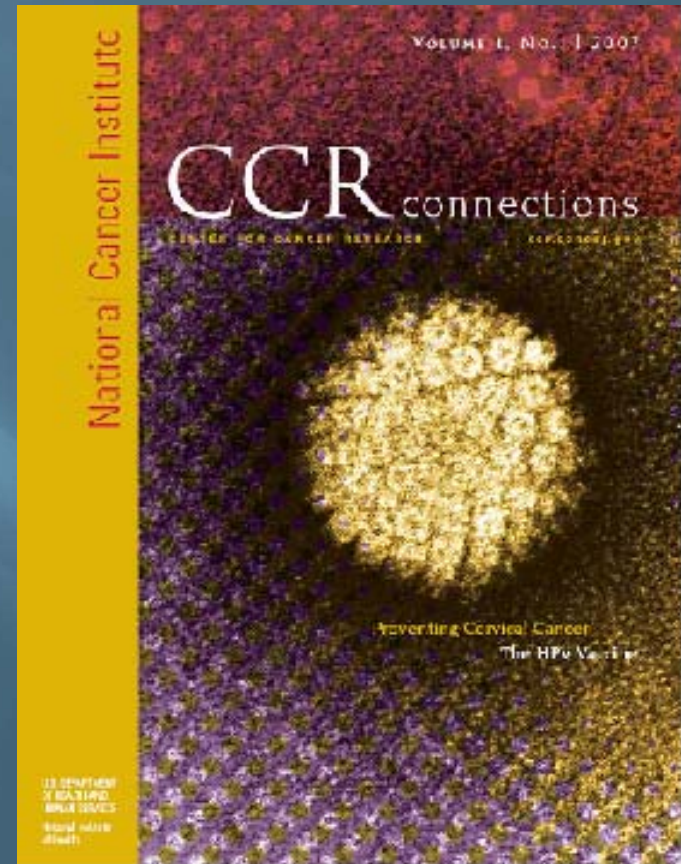
- ▣ clinical "proof of principle" that a new molecule or approach is a viable candidate for expanded clinical evaluation.
- ▣ RAID does not sponsor clinical trials.
- ▣ No funding
- ▣ Tied to a Academic applicant
- ▣ Provides NCI resources including our contract resources:
  - ▣ Small- medium scale production
  - ▣ Bulk supply
  - ▣ GMP manufacturing
  - ▣ formulation
  - ▣ Toxicology
- ▣ Most IP developed flows to Government to allow it to be unencumbered by such third party contracts for use by the RAID Recipient.
- ▣ <http://dtp.nci.nih.gov/docs/raid>



# Center for Cancer Research (CCR)

- ▣ To discover synergies with some of the exciting research efforts that are being conducted within NCI, check out the Website for our Center for Cancer Research.

<http://ccr.ncifcrf.gov/research>



## Services and Support: NCI-Frederick

- ▣ biopharmaceutical development program
- ▣ a high-performance IT center dedicated to biomedical research and informatics
- ▣ advanced technology programs:
  - genomics
  - proteomics
  - imaging
  - nanotechnology
  - histopathology
  - molecular biology
- ▣ clinical trial laboratory services

# Mechanisms for Collaboration

## Unique research materials and Information

- ▣ Material Transfer Agreements
- ▣ Confidential Disclosure Agreement



# Material Transfer Agreements (MTA)

- ▣ Identifies research material
- ▣ Generally prohibits human use
- ▣ Makes no promises regarding inventions made using the materials
- ▣ Addresses publication(s)
- ▣ Addresses liability
- ▣ Access to research materials developed at NCI
  
- ▣ NCI repositories
  - ▣ Tumor cell lines
  - ▣ Natural Products
  - ▣ Cytokines

# Confidential Disclosure Agreement (CDA)

**PURPOSE:** to specify terms for sharing of proprietary information.

- Controls information (vs. materials)
- One-way or two-way exchange
- Often first step in collaboration

# Mechanisms for Collaboration

- ▣ Collaboration Agreement
- ▣ Cooperative Research And Development Agreement (CRADA)
  - Basic Research & Development CRADA
  - Clinical Trial CRADA
- ▣ Clinical Trial Agreement



# Collaboration Agreement

- ▣ Defined mutual research project
- ▣ Permits exchange of proprietary resources (materials, information, and expertise)
- ▣ No exchange of \$
- ▣ Addresses publication(s)
- ▣ Addresses liability
- ▣ Does not provide an option to the anticipated IP, however;
- ▣ Does provides an option to negotiate a license under 35 U.S.C. §§ 207-209 and 37 C.F.R. Part 404.

# CRADA

- ▣ A focused collaboration, typically with for-profit
- ▣ A CRADA provides the Collaborator with an option to an exclusive license to CRADA subject inventions
- ▣ A CRADA is the only mechanism the NIH currently has to promise NIH intellectual property rights in advance



# CRADA



- ▣ The Collaborator may provide
  - Funds
  - Personnel
  - Services
  - Facilities, equipment, or other resources
  
- ▣ The Federal laboratory may provide
  - Personnel
  - Services
  - Facilities, equipment, or other resources

# Mechanisms for Collaboration

Extensive clinical trials network for cancer

- ▣ Clinical Trials Agreement
- ▣ Clinical Trials CRADA



# Clinical Trial Agreements (CTA)

Transfer and use of specific materials into NCI for research using human subjects

- ❑ Specifies a clinical protocol
- ❑ Assigns responsibility for drug supply, data monitoring, and addressing regulatory requirements
- ❑ Addresses data rights
- ❑ Addresses publication
- ❑ No funds are exchanged
- ❑ Makes no promises regarding inventions made through the use of the materials

# Clinical Trial CRADA



- ❑ Early or late phase clinical trials
- ❑ First option to future inventions by NCI scientist
- ❑ Exclusive access to drug, technology, data, expertise from NCI
  - Addresses IND
  - Takes advantage of NCI extensive network of clinical centers
- ❑ Significant funding may be received by NCI

# How much does it cost?

- ▣ In most collaborations, each party is responsible for their own costs.
- ▣ CRADAs permit NCI to receive funds from its CRADA partner
- ▣ NCI cannot provide funding to Companies under any of these agreements

# NIH/FDA Intramural Portfolios (2006)

- 383 invention disclosures (168 from NCI)
- 101 U.S. patents issued (50 from NCI)
- 3,400+ total pending/issued patents
- 254 licenses executed (122 from NCI)
- 364 technologies (inventions) were licensed (167 from NCI)
- 1300+ active licenses
- \$82.7 million in royalties collected
- 51 CRADAs executed (NIH only)
- 222 active CRADAs (NIH only)

# Licenses

NOTE: NIH Office of Technology Transfer

- ▣ Commercial Evaluation Licenses
- ▣ Internal Commercial Use Licenses
- ▣ Nonexclusive Patent Licenses
- ▣ Exclusive Patent Licenses
- ▣ Biological Materials Licenses

NIH Technologies available for licensing:

<http://ott.od.nih.gov/db/tech.asp>

# Finding Out More: NCI/NIH Technologies

Visit CCR's Research Directory:  
<http://ccr.ncifcrf.gov/research>

Technology-specific Notices:

- Collaborative opportunities
  - <http://ttc.nci.nih.gov/opportunities>
- Licensing opportunities with and without collaboration
  - <http://ott.od.nih.gov>

**\*\*Through discussions with NCI scientists\*\***