The following are some of the ways the NIH helps you:

- Provides direct access to NIH capabilities including top scientists with unique expertise and cutting edge infrastructure from bench to beside;
- Contributes NIH personnel, equipment and facilities which help reduce the cost of scientific development;
- Shares the risk associated with the development of a new technology;
- Allows use of NIH generated data for regulatory purposes;
- Offers flexible collaboration mechanisms and agreement types.

There are specific benefits to collaborating with the NIH via a CRADA (Cooperative Research and Development Agreement).

- Only under a CRADA can your company be granted the rights to future government intellectual property.
- If any government inventions are made under the CRADA, your company will have the option to elect an exclusive, partially exclusive or non-exclusive license to those inventions.
- This CRADA licensing option protects your investment in the research project and in the future commercialization of any invention made under the CRADA.

For More Information

Rockville, MD Office:

Telephone: 301-496-0477 http://ttc.nci.nih.gov

Frederick, MD Office:

Telephone: 301-624-8775 http://ttc.nci.nih.gov







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Public Health Service
National Institutes of Health



Product Development Through Collaborations Between Industry and NIH



TTC Offers a Wide Variety of Collaboration Opportunities

Some examples are:

Diagnostic Kit Development

NIH Contribution:

- Conceives idea for the kit
- Develops technology or materials needed
- May combine NIH technology with a collaborator's technology

Collaborator Contribution:

- May contribute technology
- Develops and refines technology into kit format

Successful Outcome and/or Product

Product on the market that improves current diagnostic capabilities

Collaborations to Develop New Devices/Equipment

NIH Contribution:

- Conceives the idea
- Invents special materials
- Develops methods of use
- Develops prototypes

Collaborator Contribution:

- Conceives the idea
- Invents special materials
- Develops methods of use
- Develops prototypes

Successful Outcome and/or Product:

- Product that may replace or improve current equipment and /or research capabilities
- Publications in a variety of scientific journals



Early Testing of Collaborator's Agent

NIH Contribution:

- Provides data in support of a new Investigational New Drug (IND) application
- Conducts pre-clinical research and Phase I studies in adult and/or pediatric patient populations at the NIH Clinical Center

Collaborator Contribution:

- Provides agent for testing
- Files IND with the Food and Drug Administration

Successful Outcome and/or Product:

- Evaluation of a new agent including safety, tolerability, pharmacokinetics, immunogenicity, etc.
- IND for agent



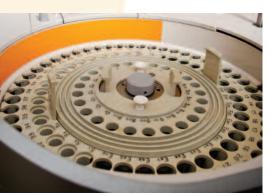
Research Collaborations for Evaluating Devices/Equipment

NIH Contribution:

- Conducts a variety of pilot studies to test the technology and compares results to other methods
- Assists in validating assays and methods
- Provides data and other feedback for equipment and methods improvements

Collaborator Contribution:

- Places equipment in an NIH facility for testing by NIH scientists for a limited time
- Offers on-site training sessions and technical support for NIH scientists interested in using the equipment



 May provide equipment upgrades, accessories, reagents/disposables, and maintenance related to technology

Successful Outcome and/or Product:

- NIH has use of the latest equipment to advance its projects during testing and evaluation phase
- Improved product

Research Collaborations for Antibody Development

NIH Contribution:

- Chooses target proteins for antibody development
- Validates using a wide variety of available cell systems
- Provides validation data to company

Collaborator Contribution:

- Designs and develops antibodies
- Provides agreed upon quantity of product to NIH

Successful Outcome and/or Product:

- Developed custom antibodies
- NIH first to publish using new antibodies
- Company owns antibodies and can make them available to others

Clinical Testing of Agents Leading to New Therapeutics

NIH Contribution:

- May provide agent
- Conducts preclinical studies for the agent
- Develops or contributes to better formulation or alternative administration methods
- Conducts clinical trials through its network of clinical centers including NIH
 Clinical Center

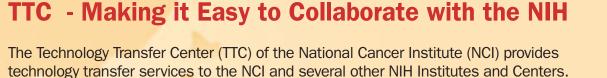
VELCADE Uniformitible for injection 3.5 mg Intermediate and Intermediate

Collaborator Contribution:

- Provides or synthesizes the agent
- Conducts preclinical and clinical studies in collaboration with NIH and other institutions
- Works with NIH to develop data needed for FDA approval

Successful Outcome and/or Product:

- FDA approval of agent for specified indications
- Product on the market
- Other clinical trials for additional indications



Finding Technologies for Collaboration:

- Sign up on our listserv, http://ttc.nci.nih.gov, to receive notices of new technologies available for collaboration.
- Contact TTC to discuss individual research collaboration needs (see brochure back cover or the Contact Us page at http://ttc.nci.nih.gov/contact.php).
 NIH has collaborative opportunities in many research areas including:
 - Cancer therapeutics and diagnostics
- Biomarkers of cancer early detection, development and metastasis
- Immunotherapy against cancer and AIDS

TTC's staff makes it easy for you to collaborate with the NIH by:

- AIDS therapeutics and diagnostics
- Non-invasive and sensitive imaging technologies for tumor detection
- Medical devices for cancer and AIDS detection and diagnostics
- Molecular targets in cancer and AIDS
- Nanotechnology and siRNA in cancer therapeutics
- Vaccine development
- Genomic Atlas
- Proteomics and metabolomics
- Natural products in cancer treatment and prevention
- And more...

Establishing Agreements:

- TTC works with your company to execute a collaborative agreement that meets the needs of all parties.
- TTC's staff are highly trained and experienced professionals with scientific and legal backgrounds who guide you through the process.

Monitoring Progress:

• TTC staff monitor the progress of each agreement and are your source for information and assistance during the life of the agreement.

Evaluating Results:

 TTC staff facilitate the transfer of final research results between your company and the NIH.

If you would like to learn more about NIH's successful collaborations, please visit our website at http://ttc.nci.nih.gov.