



Johns Hopkins University's Collaboration with Pfizer's Centers for Therapeutic Innovation (CTI)

Overview

Johns Hopkins University has been invited to join the group of over 25 institutions who are collaborating with Pfizer's Centers for Therapeutic Innovation (CTI) network, which is designed to help bridge the gap between early scientific discovery and its translation into new medicines through public-private resource sharing. Pfizer's CTI program pairs leading researchers with Pfizer resources to pursue scientific and medical advances through joint therapeutic development. Partners in the CTI network include 25 academic institutions, four patient foundations, the NIH, and now Johns Hopkins University.

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The goal of this new collaboration is to identify large and small molecule compounds with activity in a pathway or target of interest to a JHU researcher and to Pfizer. Together, the collaborators will work to move these compounds into the clinic. Funding amounts range between \$100,000 and \$250,000 per year, with an approximate 4x invested internally at Pfizer. There will be two informational seminars about this new program, one on June 27th and the 2nd on July 25th in the John G. Rangos, Sr. Building, room 490 starting at 2 pm. The seminar will involve an overview presentation by Pfizer (2-3 pm) followed by informal discussions with light refreshments provided by Forest City (3-5 pm).

How CTI Works

JHU researchers selected for CTI projects will have identified disease-related pathways or mechanisms as potential therapeutic targets that culminate in Phase I clinical trials to demonstrate proof-of-mechanism. The CTI collaboration enables these investigators to advance research projects from the lab into the clinic by providing access to Pfizer's drug development resources. A cooperative research and development agreement collaboration with CTI includes access to Pfizer's drug development expertise, publishing rights and resources. A joint JHU-Pfizer steering committee will govern the collaborative effort and be responsible for selecting and making decisions about the progress of each research program. The committee will consider funding research in various stages, from early research project concepts to those with a therapeutic candidate developed.

This new collaboration will enable JHU scientists to move novel disease targets into therapeutic development using industry-standard translational tools and expertise. For Pfizer, the





collaboration will provide access to JHU's expertise. Most importantly, patients will benefit from two of the world's premier research organizations working together to develop treatments faster.

CTI Proposal Process

Pfizer's CTI program has two calls for proposals each year. The next scheduled call will close in the fall of 2016.

All JHU researchers and clinicians whose work meets these criteria are invited to apply to CTI. The first step is submitting a pre-proposal brief, which is a non-confidential two- to three-page overview of the target, mechanism (including evidence for disease linkage), and the proposed therapeutic drug. At a high level, the pre-proposal should explain how the therapeutic hypothesis could be tested in the clinic. Investigators then must submit this pre-proposal for initial review and for submission to the Pfizer CTI Portal. For more information, contact Tyler Chavez (JHTV).

The JHU-Pfizer Joint Steering Committee will review all submitted proposals. For selected projects, a team of scientists from CTI and JHU will work together to submit a full proposal and project plan to advance the research. Investigators for projects selected in the fall of 2016 proposal cycle will be notified early 2017.



Therapeutic Areas of Interest

- Oncology: Immuno-oncology; epigenetics targets; novel, tumor-specific, cell-surface antigens; and targets identified by unique insights in tumor biology
- **Inflammation and immune disorders:** Crohn's disease and colitis, gastrointestinal disorders, and rheumatoid arthritis
- Cardiovascular and metabolic diseases: Non-alcoholic fatty liver disease, non-alcoholic steatohepatitis and heart failure
- Neuroscience: Neurodegenerative disorders with a primary focus on Alzheimer's disease and Parkinson's disease (non-A beta therapies) and psychiatric symptom domains such as cognition, anxiety and motivation/apathy
- Rare monogenic genetic diseases: Hematologic, neuromuscular, pulmonary and inherited metabolic/endocrine diseases





Project Scope

- As a general rule, CTI **does not** accept therapeutics of the following kinds: radiotherapy, nanoparticle delivery systems, and vaccines.
- Pre-proposals for collaboration will be evaluated initially on the basis of fit with Pfizer internal program portfolios, other CTI collaborations, and business and technical feasibility specific to each project.

Success Factors: What We Look For

• Strong project rationale

- o Demonstrated association between target biology, pathway and disease mechanism
- o Target validation as demonstrated by genetic or pharmacologic evidence

• Ability to address unmet medical needs

Validated therapeutic drug target

- o Tractable target relative to proposed drug modalities (antibodies, proteins and peptides)
- o Novel target, novel therapeutic strategy or new insight into target patient population
- Defined target
- Understanding of desired pharmacology
- o Demonstrated cause-effect relationship to disease mechanism

Project feasibility

- o Clear path to candidate development (biochemical/cell-free/cellular assays, disease models, pre-clinical testing, etc.)
- o Clear path for translation into clinical trials (approach for proof-of-mechanism in humans, accessible patient population, time frame, safety issues, etc.)

• Clinical differentiation

o Therapeutic strategies including personalized medicine, patient stratification, molecular signatures, genetic associations and biomarkers

Modalities

- Small molecules
- Large molecules (antibodies, proteins, peptides, antibody drug conjugates and fusion proteins)