We are USC’s technology transfer office
USC-Pfizer CTI Partnership

- Partnership Overview and Successes (Slides 3,4)
- **New Calls for Proposal for 2015!** (Slide 5)
- Guidelines for Proposals (Slides 6-8)
- Pre-Proposal Outline (Slide 10)
- Overall USC-CTI Proposal process and points of contact (Slide 11)
What is Pfizer CTI?

Pfizer CTI (Centers for Therapeutic Innovation) is an innovative Pfizer program that partners with leading academic medical centers and foundations nationwide to speed the translation of novel targets into potential therapeutics.

CTI’s goal is to identify new compounds and accelerate drug development from validated target to proof-of-mechanism in humans.

A partnership with CTI may include collaborative use of Pfizer’s proprietary antibody drug delivery technologies and/or compound library, broad publishing rights and significant financial awards in the form of milestone and royalty payments for successful programs.
USC Successes and Updates

- USC entered into partnership with Pfizer CTI on May 6, 2013

- In 2014, we had two USC faculty awardees:  
  Congratulations to Dr. Parkash Gill and Dr. Alan Epstein!

- In 2015, there will be 3 cycles for calls for proposals

  **Deadlines for Pre-proposals:**
  Cycle 1: February 13, 2014
  Cycle 2: June 12, 2015
  Cycle 3: October 16, 2015
CTI Calls for Proposals 2015

Therapeutic Areas of Interest:

Inflammation
Autoimmunity
Tissue remodeling
Neuroscience*

Oncology
Cancer Immunology
Rare or genetic diseases
Cardiovascular and metabolic diseases

*Of particular interest are submissions in: Multiple Sclerosis, including Remyelination; Alzheimer’s Disease; Huntington’s Disease; and Schizophrenia

Foundation Collaborations:

CTI partners with several foundations, including:

Alliance for Lupus Research (ALR)
Juvenile Diabetes Research Foundation (JDRF)
Crohn’s & Colitis Foundation of America (CCFA)
Foundation of Sarcoidosis Research (FSR)
What CTI Looks For

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

- **Therapeutic Area Opportunity**
  - Unmet medical needs, opportunity for novel therapeutic mechanism or modality

- **Therapeutic Drug Target**
  - Novel target, novel therapeutic strategy or new insight into target patient population
  - Defined target
  - Demonstrated cause/effect relationship to disease mechanism
  - Understanding of desired pharmacology
  - Tractability of target relative to drug modalities (monoclonal antibodies, peptides, proteins or small molecules), available reagents, assays and technologies

- **Project Feasibility**
  - Clear path to candidate development (biochemical/cell-free/cellular assays, disease models, preclinical testing, etc.)
  - Clear path to FIH clinical trial (approach for proof-of-mechanism in humans, accessible patient population, timeframe, safety issues, etc.)

- **Ability to Translate Basic Biological Research into the Clinic**
  - From molecular mechanism to therapeutic opportunity
  - Personalized medicine, patient stratification, molecular signatures, genetic associations, biomarkers
What CTI Does Not Look For

- **Target Discovery**
  - Technologies or projects looking for new target

- **Exploratory Research**
  - Development of animal models, cell line models, indication expansion or mechanism of action for existing drugs

- **Platform Technology**
  - Vaccine platform, RNAi platform, screening platform

- **Pre-clinical or Clinical Drug Candidates**
  - IND-ready candidates or clinical trials candidates
  - Note: *CTI may consider proposals for pre-existing drug candidates based upon discussions with PI and Technology Transfer Office*

- **In-licensing Opportunities Outside the CTI Agreement**
  - Note: *Pfizer may consider opportunities based upon discussions with PI and Technology Transfer Office*
USC Pre-Proposal Guidelines

Pre-Proposal: To begin the process, use the Pfizer CTI Pre-Proposal template to prepare a short, non-confidential proposal of the research you wish to have Pfizer consider funding. The proposal needs to be approved by USC Stevens and USC Stevens will then submit to Pfizer CTI on your behalf.

NOTE: At this stage, the Pre-proposal AND any discussions you have with Pfizer CTI about that proposal are NON-Confidential. Please do not include or otherwise disclose to Pfizer any non-public information during the initial proposal phase, as this could result in the loss of intellectual property rights, including in some cases the right to file for patents.

Prior to submission, USC Stevens will review the Pfizer CTI Obligations and Rights in the Research Results and obtain your acknowledgment.

To obtain the Pre-proposal template please contact Vasiliki Anest at anest@usc.edu
CTI Pre-Proposal
Non-Confidential Content

A. Investigator Name
B. Project Title
C. Executive Summary
D. Scientific Rational and Background
E. Proposed Biotherapeutic drug candidate
F. Proposed (or concept) for first biological readout in clinic (Proof of Mechanism)
G. Research Plan and Reagents
H. Biographical sketch of principal investigator (independent of 3 page limit)

To obtain the Pre-proposal template please contact Vasiliki Anest at anest@usc.edu

Total: 2-3 pages Max
Pfizer CTI-USC Proposal Process

**First Cycle**
- Pfizer CTI sends Call for Proposal (CFP) to USC Stevens
  - May 12
- USC Stevens distributes CFP to USC Faculty
  - May 12
- Faculty send Pre-proposals to USC Stevens
  - June 12
- USC Stevens submits Pre-proposal via Pfizer On-line portal
  - Week of June 12
- Joint Steering Committee Meeting (Go/No-Go decision)
  - Mid - July
- Full Proposals Due
  - Mid August
- Joint Steering Committee Meeting (Go/No-Go decision)
  - Late August
- SoW Executed and Project Kick-off
  - October

**USC Stevens Checkpoints**
Before Pre-Proposal AND Before Full Proposal Submissions to Pfizer:
- PI
- Project Overview
- Project Rationale
- Objective
- Deliverable

USC Stevens Checkpoints:
- Milestones/ Deliverables
- Team
- Budget/ Resources
- USC Decision Checkpoints: Stevens, DCG, COI

USC voting members:
- Steve Gruber
- Tom Buchanan
- Sarah Hamm-Alvarez

**USC Stevens Checkpoints**
Before Pre-Proposal AND Before Full Proposal Submissions to Pfizer:
- IP
- Obligation to 3rd parties
- Obligations to CTI agreement

2-3 pages max
- PI name
- Project Overview
- Project Rationale
- Objective
- Deliverable

4-6 pages
- PI name
- Project plan
- Clinical approach
- IP Review
- Resources

USC Stevens Checkpoints:
- Milestones/ Deliverables
- Team
- Budget/ Resources
- USC Decision Checkpoints: Stevens, DCG, COI

USC voting members:
- Steve Gruber
- Tom Buchanan
- Sarah Hamm-Alvarez

Confidential
Non-Confidential
Call for Proposal Deadlines and Points of Contact

For 2015, there will be 3 cycles for calls for proposals

Deadlines for Pre-proposals:
Cycle 1: February 13, 2014
Cycle 2: June 12, 2015
Cycle 3: October 16, 2015

All researchers, clinicians and post-docs whose work meets these criteria are invited to apply.

For more information about submitting a proposal, please contact Vasiliki Anest at anest@usc.edu or Mary Faris, Mary.Faris-Vespa@pfizer.com.