**PFIZER CTI PRE-PROPOSAL**

***Required Contents of the Pre-Proposal***

*Please use the following form and follow italicized instructions below to* ***submit your non-confidential pre-proposal******to your TTO****.* ***DO NOT alter any section headers in blue****. Please limit the total length of your pre-proposal to 2-3 pages. This document or any attachments on the portal can not exceed more than 25MB size.*

[ ]  **Small Molecule Pre-Proposal** [ ]  **Large Molecule Pre-Proposal**

**PROJECT TITLE:**

*<Add Your Project title >*

**PRINCIPLE INVESTIGATOR:**

*Please follow the below format*

*<first-name>,<last-name>,<email>*

**CO-INVESTIGATOR (if Applicable):**

*Please follow the below format*

*<first-name>,<last-name>,<email>.*

**INVESTIGATOR HOSPITAL/ACADEMIC AFFILIATION:**

*<add name>*

**TECHNOLOGY TRANSFER OFFICER:**

*Please include contact information including email, phone and address*

**EXECUTIVE SUMMARY:**

*Add a brief summery of the proposal including the below. Please use simple text with no formatting. Do not add any objects like images, videos etc.*

* *Overall goal & impact of the mechanism*
* *Desired characteristics of the proposed drug candidate*
* *Potential clinical study to demonstrate proof of this mechanism*

**THERAPEUTIC AREA:**

*Add the relevant therapeutic areas. Please copy the `therapeutic area` name from the website as is and paste here.*

*<Inflammation & Immunology, Internal Medicine, Oncology, Rare Disease, Other (If you select Other, include the name of the other therapeutic area)>*

**PROPOSED TARGET:**

*<Insert target name, if undisclosed/blinded please list undisclosed>*

**SCIENTIFIC RATIONALE AND BACKGROUND:**

*This section should contain the below.*

* *A brief description of the target/pathway and link to human disease and disease mechanism(s).*
* *What is/are the unmet medical need(s) this target/pathway could address?*
* *Please indicate the novelty/differentiation of this target or approach relevant to disease mechanism (if there are other treatments available, please describe why this is different – greater efficacy/safety etc.)*
* *Key evidence available to support the hypothesis above (i.e. human genetic, human tissue, preclinical proof of mechanism/concept models)*

**PROPOSED DRUG CANDIDATE:**

*Please indicate the characteristics of the preferred agent including pharmaceutical category (example: small organic molecule, mAb, fusion protein, multi-specific Ig, etc.) and mechanism of action (example: inhibitor, antagonist, agonist, activator, etc.). If applicable, describe any available molecule(s) the Investigator has generated against the target and its mechanism of action. If available, please describe the characteristics of said molecule(s) (affinity, humanization, PK etc.) (Remember this is a non-confidential document; please be sure to communicate within limits of any Intellectual Property constraints).*

**RESEARCH PLAN AND REAGENTS:***Provide a brief description of the research plan to be carried out (objectives, specific aims) leading to demonstration of clinical PoM. Please list the available reagents and assays to support the research plan. Alternatively, please describe reagents and assays that may need to be developed, and any gaps in the plan (and how Pfizer scientists may contribute, i.e. complete mechanistic studies in vitro, develop cellular assays, discover biomarkers, etc.)*

**PROPOSED CONCEPT FOR FIRST READOUT IN CLINIC (PROOF OF MECHANISM):***Brief description of potential therapeutic indications expected to be impacted by this mechanism.*

*Describe* *the first potential clinical study to demonstrate proof of this mechanism in patients including:*

* *Patient stratification/selection for the study (i.e. molecular signature, SNPs, genetic deficiency etc.)*
* *Clinical study endpoints that would allow for testing the mechanism in patients.*
* *Will this allow for clinical differentiation from other therapies?*

**BIOGRAPHICAL SKETCH OF PRINCIPAL INVESTIGATOR:***Please attach a brief bio-sketch of the PI and listing of key publications. NIH biosketch is acceptable.*