National Cancer Institute (NCI)
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

Project Team Member Applications (PTMA) and Team Participation

Contents

Introduction

When a drug is accepted into the NCI's Experimental Therapeutics program (NExT), a Project Team is formed to develop and prioritize the clinical trials for the drug. The Project Team consists of extramural clinical, translational, and basic scientists, members of the NCI's Cancer Therapy Evaluation Program (CTEP), and representatives from other NCI-supported programs.

Several times a year, CTEP releases a Project Team Announcement (PTA) which includes publicly available information about a drug, CTEP's preliminary plan for clinical trials, and correlative studies of interest. DF/HCC investigators are invited to apply, using the Project Team Member Application (PTMA) form, to be a clinical, translational, and/or basic scientist Project Team member.

Project Team Membership represents a tremendous opportunity to contribute to the Drug Development Plan, with the prioritization and design of clinical trials and associated biomarker assays that are distinct from industry plans for the specific agent under study. To date, DF/HCC has been represented in nearly all of the Project Teams.

In general, it is advisable to discuss any planned PTMA with Drs. Shapiro, Kufe or Flaherty.

Junior investigators with mentors are encouraged to apply under the designation of Career Development Applications (CrD PTMAs). The vast majority of successful clinical PTMAs are from junior investigators, paired with senior mentors. In this case, only the junior investigator completes the PTMA, but both the junior investigator and the senior mentor provide biosketches with personal statements detailing why they should be chosen for the project team. Typically, these statements indicate interest in leading one of the clinical trials outlined in the preliminary CTEP plans detailed in the PTA, although concepts for other trials may be mentioned as well. See the Procedure Section for additional specifics.

Although most team members are chosen from submitted PTMAs, on occasion, CTEP leadership will directly solicit applications from DF/HCC clinical, translational and basic scientists. In this case, a PTMA is usually completed, but there is an implied guarantee of team membership. DF/HCC members who are approached by CTEP for team membership should notify Drs. Shapiro, Kufe and Flaherty. Because only a limit number of Harvard members can be on any one team, the UM1 leadership can apprise other applicants of the strength of their PTMAs and the likelihood of success.

PTMAs for team membership as a clinician require signature from Drs. Shapiro, Kufe or Flaherty. DFCI and BIDMC applications may be signed by Dr. Shapiro or Dr. Kufe; MGH applications are signed by Dr. Flaherty. These signatures indicate that our UM1 grant will provide support for the trial to be conducted in the ETCTN.

Translational scientist and basic scientist PTMAs do not require additional signatures. Translational scientist applications typically detail the types of correlative assays that can be performed by the applicant; basic science applications indicate the types of preclinical models available and experiments that can be conducted to support the clinical trials proposed by the Project Team. Available grants that support these activities should be listed.

If selected to be part of the Project Team, the DF/HCC investigator(s) will attend web-based meetings over the course of approximately 8 weeks during which the Drug Development Plan (and associated Biomarker Assay Development Plan) will be finalized. Attendance at these meetings is required and a commitment to attend must be in the biosketch statement. There may be additional calls conducted by a subset of team members regarding specific trials that comprise the Drug Development Plan. Project Team members subsequently present the Drug Development Plan to the Investigational Drug Steering Committee (IDSC). Team leaders usually attend the IDSC meetings, which occur at the Shady Grove campus, but most team members can participate in the IDSC meeting via webinar.

After the Drug Development Plan has been approved by the IDSC and the NCI, ETCTN clinician members of the Project Team are typically invited to submit individual Letters of Intent (LOIs); however, Project Team participation is not an absolute guarantee that team members will lead a trial or lead a laboratory correlative study. Junior clinicians who were paired with senior mentors on the team will submit a Career Development LOI (CrDL). Details regarding the submission of CrDLs can be found on the CTEP website: https://ctep.cancer.gov/protocolDevelopment/letter_of_intent.htm#instructions.

Of note, basic science team members may be offered supplemental funding to conduct preclinical experiments thought important by the Team to support the various clinical trials, if other sources of funding to complete these studies are not readily available.

For additional information, refer to the NCI Drug Development Project Teams Overview: https://ctep.cancer.gov/initiativesPrograms/project_teams.htm

Procedure

1) NCI releases a Notification of Formation of a Project Team and requests PTMA submissions for team membership as a clinical, translational, and/or basic scientist. (Sometimes this request may be sent directly to individual investigators at DF/HCC, in which case Drs. Shapiro, Kufe and Flaherty should be notified).
2) The DF/HCC investigator completes the PTMA form provided by the NCI. The most recent version of the PTMA form must be used; this is typically distributed with the request for PTMAs.
   a) Refer to the DF/HCC ETCTN CTEP Submission Requirements Guide for details regarding how the PTMA form and supplemental documentation should be prepared.
   b) All PTMAs require submission of an NIH biosketch. The personal statement should indicate the applicant's qualifications and specific contributions the applicant can bring to the team. If appropriate, the applicant should detail which trial(s) listed in CTEP's preliminary plans in the Project Team Announcement (PTA) are of greatest interest. Other trials that applicants wish to conduct may also be mentioned. The personal statement should also indicate that the applicant will adjust their schedule in order to participate in all team meetings.
   c) In addition to the PTMA form and biosketch, CrD PTMAs also require the applicant's curriculum vitae, a letter of commitment from the faculty mentor and an institutional letter of support. Applicants from DFCI and BI should contact Dr. Geoffrey Shapiro or Dr. Donald Kufe to request the letter of support, and applicants from MGH should contact Dr. Keith Flaherty. For CrD PTMAs, the faculty member does not need to fill out a separate PTMA form. Instead, the faculty member should provide the mentor letter and a biosketch with an appropriate personal statement about participation in the team. Faculty mentors are also required to attend all team meetings and the personal statement should reflect this commitment.
   d) Applications from clinical scientists must be signed by one of the UM1 Grant PIs to include Drs. Shapiro, Kufe, or Flaherty.
   e) Applications from clinical scientists must include the UM1 Grant number and DF/HCC LAO code. This information will be supplied by the PI signing the form.
   f) Applications from translational and basic scientists may list other grant support that will contribute to work they will conduct as a team member.
3) Investigator will email the complete PTMA submission to CTEP at CTEPPTMASubmissions@mail.nih.gov.
4) CTEP will review the PTMAs and notify applicants if they have been selected to participate on the Project Team.
5) Project Team members complete financial conflict of interest forms, and subsequently attend teleconference/web-based meetings and work to develop the drug and biomarker assay development plan.

6) The Project Team presents the drug and biomarker assay development plan to the Investigational Drug Steering Committee (IDSC). After IDSC approval, the plan is subsequently fully approved by NCI-CTEP.
7) DF/HCC clinician members of the Project Team may be invited to submit individual LOIs based on trials developed by the Project Team. Investigators who were members of the team based on a Career Development PTMA go on to submit a Career Development LOI (CrDL).

Links

NCI Drug Development Project Teams Overview:
https://ctep.cancer.gov/initiativesPrograms/project_teams.htm

CTEP's Career Development Program:
http://ctep.cancer.gov/protocolDevelopment/letter_of_intent.htm#instructions