

FAQs for FOAs for NCI Pediatric in Vivo Testing Program ([RFA-CA-20-034](#) for in vivo testing programs and [RFA-CA-20-041](#) for the Coordinating Center for the Program)

November 4, 2020 Additional Questions/Answers

- 1) **How should the “Other Attachments” requested in the SF424(R&R) Other Project Information section be uploaded so that the file names appear as bookmarks?** There is an error in the application instructions for RFA-CA-20-034 and for RFA-CA-20-041 in Section IV. 2. under the “SF424(R&R) Other Project Information” subsection. This subsection provides instructions for applicants to provide specific additional supporting materials and states, “Upload these materials as a single PDF file using file names indicated in the list (these file names will become bookmarks in the application).” The correct instruction that will allow the file names of each PDF file to serve as bookmarks within the application is for each attachment to be uploaded as a separate PDF with the appropriate file name.

October 22, 2020 Additional Questions/Answers

- 1) **Will drugs be provided free of charge or do applicants need to budget for drugs?** Each experimental agent will be provided by the collaborating company at no charge as part of the MTA for each agent.
- 2) **If applicants are planning to propose combination therapy with standard of care agents, will these agents need to be purchased?** While in some cases, collaborating companies may provide SOC agents for combination testing, this is not always the case. Hence, it is appropriate to include funds for purchase of SOC agents.
- 3) **Do plasma and tumor pharmacokinetic (PK) studies need to be budgeted for?** When PK is incorporated into a research plan for a specific agent, the assumption is that the collaborating company will often have a validated assay established for the agent and will perform PK as part of the research plan agreed to in the MTA for the agent. Hence, applicants do not need to budget for performing PK studies. However, funds should be set aside to cover the animals that will be utilized to collect timed specimens that will be used to determine drug levels in plasma and/or tumor.

Note that applicants can provide their perspective on the overall contribution of PK studies to preclinical testing in the “Approach to Preclinical Testing” section of the Research Plan. As Program PIs will be responsible for developing the research plans for agents to be tested with input from the collaborating company, the perspective and expertise of PIs on issues such as the role of PK studies will be essential for developing scientifically robust research plans.

- 4) **How do pharmacodynamic studies need to be addressed in applications?** The PD studies that will be relevant to the agents that will be studied through the NCI Pediatric in Vivo Testing Program cannot be anticipated at this time given the wide range of candidate agents. Similar to PK studies, the assumption is that the collaborating company will often have validated assays for clinically relevant biomarkers that may be appropriate to incorporate into the research plan for an agent being tested by the Program. Hence, applicants do not need to budget funds for performing

PD/biomarker studies. However, funds should be set aside to cover the animals that will be utilized to collect specimens that will be used to evaluate relevant PD biomarkers.

Note that an exception is made for biomarkers that may be required to adequately assess the activity of agents and to fully evaluate their relevance to clinical testing within the context of the models proposed by an applicant. Such a biomarker(s) will apply across multiple types of agents and will not be restricted by the class of agent studied.

Note that applicants can provide their perspective on the overall contribution of PD/biomarker studies to preclinical testing in the “Approach to Preclinical Testing” section of the Research Plan. As Program PIs will be responsible for developing the research plans for agents to be tested with input from the collaborating company, the perspective and expertise of PIs on issues such as the role of PD studies will be essential for developing scientifically robust research plans.

- 5) **Web presence is important for coordinating center but URLs not allowed in NIH proposals. Are they allowed in the Resource Sharing plan?** For RFA-CA-20-041, URLs of publicly available websites may be cited for the purpose of demonstrating dissemination and outreach capabilities relevant to Research Plan (Subsection B) administrative and logistical responsibilities: “Creation and maintenance of a public web page for the Ped-In Vivo-TP”. Note that reviewers are not obligated to view linked sites. Note also that the actual URL text should be hyperlinked so that it appears on the page rather than hiding the URL behind a specific word or phrase [e.g., NIH (<http://www.nih.gov/>)].
- 6) **What expectation is there for management and analysis of prior datasets?** The prior funding periods for the Pediatric Preclinical Testing Program and Pediatric Preclinical Testing Consortium generated in vivo testing datasets on more than 100 agents. The expectation is that the Coordinating Center selected in response to RFA-CA-20-041 will be able to use these datasets to enhance the interpretation of new testing data when the same models are utilized or when similar classes of agents are studied. The basic data elements from previous testing studies that are anticipated to be utilized by the Coordinating Center may include weekly animal weights and weekly tumor volumes (or weekly human CD45% counts for leukemia models) as well as the analyzed results for each model for each agent tested using the current PPTC analytical pipeline. This expectation applies whether the Coordinating Center activity remains with the PPTC Coordinating Center or moves to another grantee. If the Coordinating Center is transferred, then the incumbent will be expected to provide the data in a format amenable for uploading into a new data system.
- 7) **Will testing centers do their own statistical analysis of response data in addition to the coordinating center?** While research teams are not prohibited from performing their own statistical analyses for internal purposes, funds are not set aside for this purpose and the expectation is that study reports for collaborating companies and that manuscripts for peer-reviewed publications will utilize statistical analyses performed by the Coordinating Center.
- 8) **What is the expectation for genomic data management in support of the testing centers?** The expectation of the Coordinating Center is that it will provide analytical capabilities to relate the in vivo testing results obtained by research teams to the genomic characteristics of models (e.g., RNA

expression, gene mutation, gene copy number change, etc.).

Note that through the Childhood Cancer Data Initiative (CCDI), NCI intends to establish a Pediatric Preclinical Data Commons that will be responsible for dissemination of genomic characterization data for preclinical models from successful applicants for RFA-CA-20-034 as well as characterization data that is available from other research teams.

- 9) **Is it expected that the coordinating center will provide guidance on new model development if this was needed?** New model development is not part of the research scope described for the research teams to be selected through RFA-CA-20-034. That said, research teams may develop new models during the course of their awards and the Coordinating Center should have the flexibility to incorporate these models (and data associated with them) into its workflow and data systems.
- 10) **Does the application include proposed investigator-initiated studies, or does it only include the 4 subsections A-D described?** Only the 4 subsections A-D are to be included in the Research Plan. Note that applicants can provide their perspective on the type of studies (including the types of agents/targets to be prioritized) that they think will be most informative and contributory in the “Approach to Preclinical Testing” section of the Research Plan. However, the agents to be tested through the in Vivo Testing Program will be determined by the Steering Committee based on opportunities that arise during the funding period, and they will not be restricted to the agents/targets described in the applications of the selected Research Teams.

Note that Research Team PIs will be responsible as members of the Steering Committee for prioritizing agents and developing the research plans for agents to be tested (with input from the collaborating company). Hence, it is important that PIs demonstrate a deep understanding of the therapeutic and research opportunities for the tumor types that they propose to study so that appropriate prioritization decisions are made and so that scientifically robust research plans are developed.

11) Please clarify responsibility for supporting travel to the annual face-to-face meeting.

RFA-CA-20-041 states: “Travel: Applicants are required to include travel support for an investigator from their research team to attend an annual face-to-face meeting. In the budget, a travel budget for one trip per year to these meetings must be included.” A comparable statement should have been included in RFA-CA-20-034 and was not. Applicants responding to RFA-CA-20-034 should include travel support for an investigator from their research team to attend an annual face-to-face meeting.

September 30, 2020 Questions and Answers

- 1) **Should a Specific Aims page be used?** Yes. As described in the [PHS 398 instructions](#), “The Specific Aims attachment (one page) is required unless otherwise specified in the FOA.”

- 2) **For the Research Strategy section, are descriptions for significance, innovation and approach needed with each of the specified Sub-Sections A-D?** No. Applicants can use the format that they find most appropriate to present their response for each of these Sub-Sections.
- 3) **Are multiple PDs/PIs acceptable?** Yes. However, note that the RFA specifies that testing is to occur at a single site to facilitate coordination and quality control.
- 4) **Is inclusion of effort to develop and characterize additional models acceptable/encouraged?** The primary focus of the NCI Preclinical in Vivo Testing Program will be testing of experimental agents. The continuing development and characterization of models is not requested in the RFA and is not a review criteria. While applicants may indicate their laboratory's plans to develop more models during the award period (e.g., as a way to help document their commitment to preclinical testing for the cancer(s) that they study), but funds should not be requested for this activity.
- 5) **The link for the Model MTA in RFA-CA-20-034 and RFA-CA-20-041 is for the MTA that is used for pharmaceutical collaborators. Where can the Model TMA that is used for the Testing Program Institutions and that is used for the Coordinating Center be found?** The Model MTA for Testing Program Institutions and for the Coordinating Center is embedded below.



PPTC

NCI-Institution MTA

- 6) **If genomic characterization work is ongoing, is it possible to submit additional genomic characterization of models after the submission deadline and before the review?**

Please refer to the [NOT-OD-20-163](#) about post submission materials during the COVID-19 pandemic. A one-page update with preliminary data as post-submission materials will be accepted, and hence additional genomic characterization data that becomes available post-submission can be provided. The deadline for submitting all post-submission materials, including preliminary data, will be 30 days before the study section meeting. All other materials listed in [NOT-OD-19-083](#) as acceptable post-submission materials will continue to be accepted if submitted 30 days before the study section meeting.