2021 PANCREATIC CANCER ACTION NETWORK

PRECISION PROMISE CLINICAL TRIAL CONSORTIUM SITES

Guidelines and Application Instructions

PANCREATIC
CANCER
ACTION
NETWORK
®

CONTENTS

Please direct questions to:
Lynn Matrisian, Chief Science Officer
Pancreatic Cancer Action Network
lmatrisian@pancan.org

I. GUIDELINES

BACKGROUND

Precision Promise^{SM} is the Pancreatic Cancer Action Network (PanCAN)'s groundbreaking initiative to accelerate new treatment options for pancreatic cancer patients. Precision Promise is designed to serve as a catalyst to facilitate and accelerate pancreatic cancer drug development, de-risk industry participation and transform clinical research for this hard-to-treat patient population. The overarching goal of Precision Promise is revolutionizing treatment for every pancreatic cancer patient.

Precision Promise is now open for patient enrollment at top cancer institutions across the country. More information on the background and vision of Precision Promise is found at www.pancan.org/precision-promise.

The purpose of this Request for Applications is to expand the geographic, racial and ethnic diversity of the Precision Promise Clinical Trial Consortium by adding five additional sites across the U.S.

PRECISION PROMISE

At the center of Precision Promise is an adaptive randomized Phase II/III registration-ready clinical trial (NCT04229004). Focused on first and second-line therapies for patients with metastatic pancreatic adenocarcinoma, multiple investigational arms are compared to two standard-of-care treatment arms using Bayesian adaptive randomization to provide efficiencies of scale and maximize the chance that patients receive effective novel treatments. The primary endpoint for the trial is overall survival, allowing for a registration-ready package with a maximum of 175 patients per investigational arm and dramatically lowering cost and accelerating progress. The Precision Promise Master Protocol calls for pre- and on-treatment biopsies and blood samples for extensive molecular analysis to ensure learning from every patient. Supportive care, a hallmark of the study, is provided for all patients and studied extensively. Precision Promise is designed to be able to learn quickly, reassess and constantly evolve the treatment options based on our learnings.

Precision Promise is governed by a Steering Committee composed of a Chair and leads of key Committees: Arm Selection, Biomarker, Supportive Care, Translational Research and the Clinical Trial Consortium. Berry Consultants provide the innovative statistical design; trial execution is supported by Covance, Inc; and Tempus, Inc provides expert molecular analysis. Industry members are an essential stakeholder of Precision Promise. The Guiding Principles for decision-making within the Precision Promise Steering Committee include:

- Patient centricity, through the entire pancreatic cancer journey

- Bold, audacious goals

- Sense of urgency

- Flexibility

- Iterative between science and medicine

- Sustainable

Operations

IND holder: PANCREATIC CANCER ACTION NETWORK

CRO: COVANCE SOLUTIONS MADE REAL

Statistical design: Berry Consultants Statistical Innovation

Genomics sequencing and analysis: TEMPUS

Infrastructure

Steering Committee

Diane Simeone, MD (Chair)   Vincent Picozzi, MD
Andrew Hendifar, MD   Gregory Beatty, MD, PhD
Manuel Hidalgo, MD, PhD   Anirban Maitra, MBBS

Translational Research | Biomarker | Supportive care | Arm Selection | Operations | Clinical Trial Consortium

Industry

Current Members

abbvie
angiodynamics
AstraZeneca
IPSEN   Pfizer
RAFAEL   TEMPUS
TriSalus LIFE SCIENCES   TYME

Founding Precision Promise Members

AstraZeneca
Celgene   Bristol-Myers Squibb
Halozyme   janssen Oncology

PRECISION PROMISE CLINICAL TRIAL CONSORTIUM SITES

The Precision Promise Clinical Trial Consortium (CTC) consists of 15 U.S. clinical sites. PanCAN is interested in growing the geographic, racial and ethnic diversity of the Precision Promise CTC. The purpose of this Request for Applications is to expand the Precision Promise CTC to up to 20 sites across the U.S.
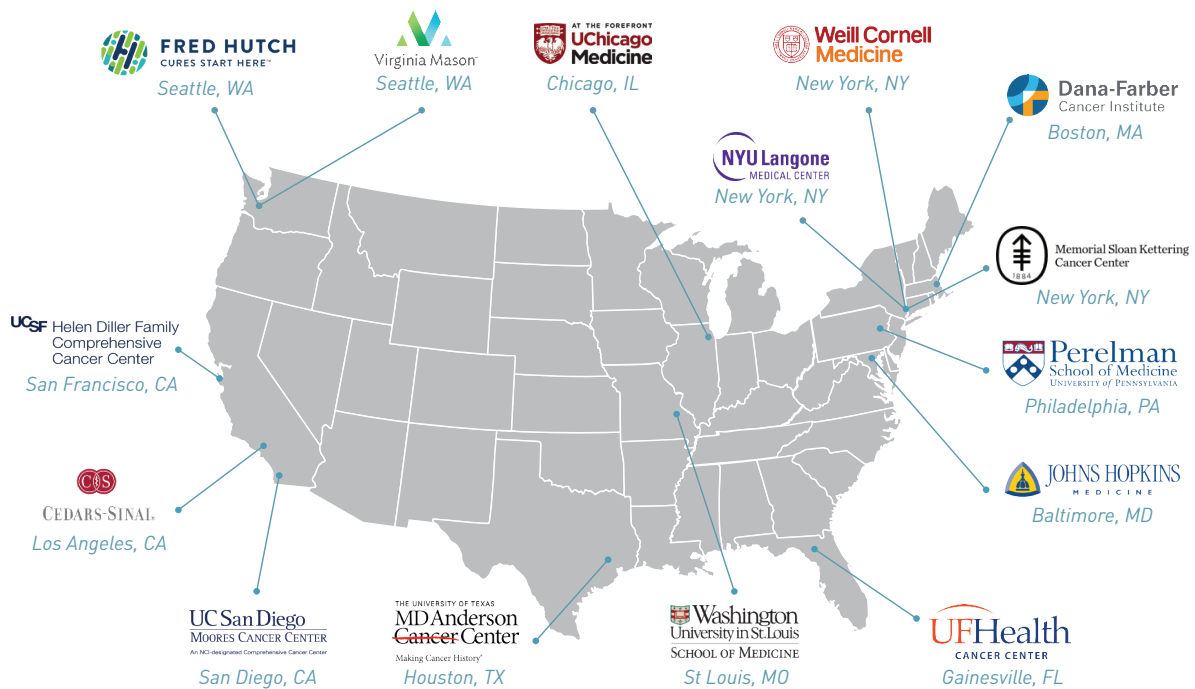
Each CTC site is required to open the Precision Promise Master Protocol and to open each Precision Promise Arm Appendix as it becomes available. The CTC meets monthly by videoconference for scientific and operational updates and discussions. PanCAN will provide $50,000 direct cost to support start-up costs to open the Master Protocol and initiate ongoing Precision Promise activities for the first term. Per-patient costs are determined during the negotiation of a Site Agreement.

Eligibility

• The site must be in the United States.

• The contact principal investigator (contact PI) must be an independent researcher with a medical degree (including MD, DO or equivalent) in oncology with expertise in pancreatic cancer.

• The site must be willing to rely on a single IRB (Western IRB).

Use of funds

This grant will provide $50,000 to support site start-up activities. Up to an additional 20% ($10,000) is allowed for indirect institutional costs. Per-patient site costs will be determined during the negotiation of a Site Agreement and each Arm Appendix. An up-front payment of $25,000 plus $5,000 indirect costs can be disbursed on July 1, 2021. The remaining funds will be available upon completion of the site initiation visit. Future supplements to this grant are anticipated to support Arm Appendix start-up or other significant protocol modifications.

EVALUATION OF APPLICATIONS

PanCAN is interested in expanding the geographic, racial and ethnic diversity of the Precision Promise CTC. Proposals will be evaluated based on the following criteria:

Feasibility

- Does the site have sufficient patient volume to accrue pancreatic cancer patients to the Master Protocol and sub-studies?

- Is there a history of successful accrual to pancreatic cancer trials?

- Is the infrastructure for successful trial implementation available?

- Are appropriate safety and compliance processes in place?

Leadership

- Does the PI have a track record that supports their role as a CTC leader?

- Have they been able to successfully interact with others in a consortium-like environment?

- Is there evidence that they are willing to "revolutionize" pancreatic cancer clinical trials and support the mission to transform outcomes and put the patient at the center of every decision?

Culture

- Does the institution have a culture that is conducive to the execution of clinical trials built upon a philosophy of cooperation and learning that puts the patient at the center of every decision?

II. APPLICATION INSTRUCTIONS

IMPORTANT DATES

Application deadline: Applications must be submitted by midnight Eastern Standard Time (9 p.m. PST) on Monday, Feb.15, 2021, using the proposalCENTRAL website at https://proposalcentral.altum.com.

Decision date: Funding decisions will be made in May 2021.

Contract term: The contract to be a Precision Promise CTC site is renewable on a yearly basis, dependent on reaching specified milestones of patient enrollment and data quality.

APPLICATION PROCEDURES

Required application materials

To submit a complete application, the contact PI (applicant) needs to enter information directly into the online application platform as well as upload a number of documents. The following instructions provide an overview of information that needs to be entered and the materials that need to be uploaded.

Information to be entered directly into proposalCENTRAL

- Contact PI (Applicant) Information

- Institution and Contacts

- Organization Assurances

Templates to be downloaded, completed and uploaded

- Site Information

- Statement of Interest

Non-template materials to be uploaded

- Biographical Sketch of Contact PI

- Letters of Institution Support (Please provide letters from individuals representing the institutional entities responsible for oversight of CTC activities, e.g., Cancer Center Director, Chair of PI's department and/or others as needed.)

- Appendix (if needed)

Materials to be downloaded, printed, signed, scanned and uploaded

- Application Signature pages

GETTING STARTED IN proposalCENTRAL

If you are a new user of proposalCENTRAL, follow the "REGISTER" link and complete the registration process. After you register, complete your Professional Profile (green tab, second tab from the left) before starting an application.

If you are already registered with proposalCENTRAL, access the site and log in with your Username and Password. If you have forgotten your password, click on the "Forgot your password?" link. Supply your User ID or email address in the space provided; your password will be sent to you by email.

To start an application, select the "Grant Opportunities" tab (gray tab furthest to the right). A list of applications will be displayed. Find the Pancreatic Cancer Action Network "Precision Promise Clinical Trial Consortium Sites" and click the "Apply Now" link (second-to-last column) to create your application.

Complete all fields in the application and all templates that are provided. Upload all requested documents in portable document format (PDF). For more information, see the proposalCENTRAL FAQ section: https://docs.proposalcentral.com/User%20FAQs.pdf.

If you have difficulty registering, logging in or creating your application, contact proposalCENTRAL Customer Support. Phone: (800) 875-2562 or (703) 964-5840; email: pcsupport@altum.com.

*Important note: To ensure your PDF files upload in their entirety, please avoid: replacing files multiple times, using files that were once password-protected or encrypted and combining multiple scanned documents or files into one PDF. Review your full application before submitting to check that all pages of your PDF files are displaying properly.

COMPLETING THE APPLICATION

The following information is required to submit a complete application.

1. Download Template and Instructions. The Guidelines and Application Instructions document, the Contract Terms and Conditions and all templates must be downloaded from this page.

    An Application Packet Checklist is also available to download from this page. The checklist does not need to be uploaded to the application but provides a guide for all materials that need to be submitted.

    The following two templates must be downloaded and completed: Site Information Template and Statement of Interest Template.

    - Click the "Download" link to save each of the templates to your computer.

    - Use your word-processing software (e.g., MS Word) to complete the templates and then convert the templates to PDF format. You do not need to be connected to the Internet or proposalCENTRAL while working on the templates.

    - Upload the completed template files to your online application.

    The following additional attachments, for which a template is not provided, are also required: Biographical Sketch of Contact PI and Letters of Institutional Support.

2. Contact PI (Applicant) Information. Enter information for the contact PI directly into the proposalCENTRAL system. The contact PI is required to update his/her Professional Profile, including contact information, other support and publications.

3. Institution and Contacts. Enter information for the contact PI's institution and the designated signing official directly into the proposalCENTRAL system.

4. Organizational Assurances. Select the appropriate assurances options for your proposed research and complete the Approved or Pending Date field. If a grant is awarded, you will be required to submit the regulatory and compliance documents to the Pancreatic Cancer Action Network.

5. Application Documents. Formatting Instructions:

    - Type size. 12-point Times New Roman for the text, and no smaller than 9-point type for tables and figures or other images.

    - Spacing. Single-spaced format, and indent to begin new paragraphs.

    - Margins. No less than 0.75 inch on each side.

    Using the templates where provided, prepare and upload the following documents into your application in portable document format (PDF):

    A. Site Information. Complete in the template available from the proposalCENTRAL website.

        I. Pancreatic cancer patients and research: Provide details about the proposed Precision Promise CTC site's patients and research by answering each of the questions in the template.

II. Clinical trial infrastructure: Provide detailed information about the site's clinical trial infrastructure by answering each of the questions in the template.

III. Regulatory: Provide the institution's regulatory information by answering each of the questions in the template.

B. Statement of Interest. Complete in the template available from the proposalCENTRAL website. Each question in this template should be answered in half a page or less, and the full Statement of Interest document should not exceed three pages.

C. Biographical Sketch of Contact PI. The biographical sketch must be in English. The NIH Biographical Sketch Form (PHS 398/2590 [Rev. 06/09]) and (OMB No. 0925-0001/0002 [Rev. 03/20]) are both acceptable. The contact PI must adhere to the page limits and requirements specific to the biographical sketch format used (four pages for the Rev. 06/09 format, five pages for the Rev. 03/20 format).

D. Letters of Institutional Support. The letters must be written on letterhead by individuals representing the institutional entities responsible for oversight of CTC activities; e.g., Cancer Center Director, Chair of PI's department and/or others as needed.

E. Appendix (if needed). Appendix may include results of an FDA audit.

F. Application Signature Pages. In order to ensure the appropriate parties have approved the application, the signature pages must be printed and signed. The signed signature page (with original signatures) must then be scanned and uploaded into the online application in the section for attaching files. Signatures that are electronically transmitted shall have the same force and effect as original signatures.

Uploading the attachments into your application. All attachments must be converted to PDF files. To ensure your PDF files upload in their entirety, please avoid replacing files multiple times, using files that were once password-protected or encrypted and combining multiple scanned documents or files into one PDF.

Once converted, the next step is to upload the files to your online application.

- Make certain that the converted PDF files are closed on your computer.

- Open your application and go to the section for attaching files.

- Enter your own description of the file in the "Describe Attachment" field.

- Select the appropriate type of attachment from the dropdown list. NOTE: After selecting attachment type, the screen will show the file types (e.g., PDF, .doc) that are allowed for that type of attachment. Only PDF attachments are permitted for this application submission.

- Click on the "Browse" button to select the file from your computer.

- A "Choose File" dialog box opens for you to search for the template file on your computer's hard disk or local area network.

- Select the file and click "Open."

- The file location and name will display in the window adjacent to the "Browse" button.

- Click on the "Upload Attachment" button. You will get a confirmation message on your screen that the file was uploaded successfully. You also will see that your file is now listed in the "Uploaded Attachment" section of the screen. Two links are available in each row of an uploaded attachment: DEL and SHOW. "DEL" allows you to delete the file, if necessary, and "SHOW" opens the uploaded file. ***Open and review your uploaded files.***

In the section for attachments, all the required attachments are listed in the middle of the screen, just below where you upload your files. This list helps you track completion and uploading of your required attachments. Once you upload a required attachment, that attachment type will be removed from the required list and will be displayed in the "Current list of uploaded attachments."

If you wish to modify the attached file, make the revisions to your original file on your computer (offline), convert the file to PDF and use the same process above to attach the newly revised file. *Delete any previously submitted versions of the file before submitting your application.*

SUBMITTING THE COMPLETE APPLICATION

1. Contact PI Data Sheet. This is an automatically populated data sheet based on the contact PI's proposalCENTRAL profile.

2. Validate. Validate the application on proposalCENTRAL. This is an essential step. "Validate" checks for required data and required attachments. You will not be able to submit the application if all the required data and attachments have not been provided.

3. Signature Pages and Print Application. After completing these sections of the online application, you may print the Signature Pages. Click the "Print Signature Pages" button.

   NOTE: Data that you entered in previous sections of the online application are automatically included in the Signature Pages. If information is missing in the Signature Pages, it could be because you have not entered the information in one of the proposal sections or because the information is not required for this grant. If the institution's Employer Identification Number (EIN) is not completed on the Signature Pages, please request your institution to provide that information in their proposalCENTRAL profile.

   The option "Print Signature Pages" prints the Signature Pages and Application Contacts. Please review the application in its entirety by selecting the "Print Signatures Pages and Attached PDF Files" option to ensure that it contains all the required uploaded materials.

   Obtain required signatures. The Pancreatic Cancer Action Network requires that the completed application and Signature Pages with original signatures be uploaded into the Application Documents. Signatures transmitted by electronic means shall have the same force and effect as original signatures.

   Upload the signed Signature Pages into the application.

4. Submit. After successfully passing the validate check and printing your documents, click the "Submit" link. An email will be sent to you confirming your submission.

   Once your application is submitted, you may view it by accessing the "Submitted" link under the "Manage Proposals" tab. The status column will show "Submitted" and the date submitted. You may need to refresh your browser screen after submitting the application to see the updated status.

CHANGING YOUR APPLICATION

Withdrawal of application

Please advise the Pancreatic Cancer Action Network promptly, in writing, should you decide to withdraw your application.

Your email (or letter) should include your name, the title of the proposal and the reason for withdrawal.

Change of address

Notify the Pancreatic Cancer Action Network in writing of any changes of address, email or phone number, following the submission of an application. Include your name and the application number.

INQUIRIES

Inquiries or technical issues regarding proposalCENTRAL and the online application process should be directed to customer support at (703) 964-5840 or toll-free at (800) 875-2562 or by email at pcsupport@altum.com.

Inquiries about the Precision Promise Clinical Trial Consortium Sites guidelines and application materials should be directed to Lynn Matrisian, Chief Science Officer, Pancreatic Cancer Action Network, at lmatrisian@pancan.org.

PANCREATIC CANCER ACTION NETWORK ®

THE PANCREATIC CANCER ACTION NETWORK

leads the way in accelerating critical progress for pancreatic cancer patients. We take bold action by funding life-saving research, providing personalized patient services and creating a community of supporters and volunteers who will stop at nothing to create a world in which all pancreatic cancer patients will thrive.