2016 PANCREATIC CANCER ACTION NETWORK

PRECISION PROMISE
CLINICAL TRIAL
CONSORTIUM SITES

Guidelines and Application Instructions
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Please direct questions to:
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I. GUIDELINES

BACKGROUND

In recognition of the urgent need to accelerate scientific and medical breakthroughs in pancreatic cancer and with the guidance of our scientific advisors, the Pancreatic Cancer Action Network adopted a bold initiative to double survival for pancreatic cancer by the year 2020.

The Pancreatic Cancer Action Network believes the current approach to pancreatic cancer needs to be rewritten with a focus on what is best for an individual patient. Initiatives such as Patient Central, Clinical Trial Finder, Patient Registry and Know Your TumorSM are designed to empower the patient and facilitate access to information that provides the best opportunity for the individual as well as that contributes to advancing the field for future pancreatic cancer patients. The next step in this continuum of services and research projects is Precision Promise, an initiative created with the goal of revolutionizing treatment for every pancreatic cancer patient.

The mission of Precision Promise is to transform outcomes for all pancreatic cancer patients through a research and clinical trials platform that creates a culture of cooperation and learning among clinicians, researchers and drug developers, and that puts the patient at the center of every decision. Precision Promise has three components: a Coordinating Center, a Translational Research Grants Program and a Clinical Trial Consortium. The Coordinating Center will be responsible for the design of the Master Protocol to provide biomarker testing and stratification of patients for the clinical evaluation of biomarker-targeted therapies through a series of sub-studies. The Translational Research Grants Program will be offered through a competitive peer-review process to support clinically relevant research identified by the Coordinating Center that can inform and be applied through the sub-studies. The Clinical Trial Consortium will start with 10 U.S. clinical sites, but it is envisioned to expand to additional sites in the U.S. and globally and to incorporate just-in-time trial initiation in the future. Precision Promise is designed to be able to learn quickly, reassess and constantly evolve the treatment options based on our learnings. 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 constitute the Precision Promise U.S. Clinical Trial Consortium.

PRECISION PROMISE EXECUTIVE COMMITTEE AND WORKING GROUPS

The Precision Promise Executive Committee is responsible for the design of the Master Protocol, the selection of topics for Translational Research component funding announcements and the overall direction and oversight of Precision Promise. The Executive Committee consists of the following individuals:

- Andrew Biankin, MBBS, PhD, University of Glasgow
- Diane Simeone, MD, University of Michigan
- Anirban Maitra, MBBS, MD Anderson Cancer Center
- Sunil Hingorani, MD, PhD, Fred Hutchinson Cancer Research Institute
- David Chang, MBBS, PhD, University of Glasgow
- Vaibhav Sahai, MBBS, University of Michigan
- Lynn Matrisian, PhD, MBA, Pancreatic Cancer Action Network
- Julie Fleshman, JD, MBA, Pancreatic Cancer Action Network
The Guiding Principles for decision-making within the Precision Promise Executive Committee include:

- Patient centricity, through the entire pancreatic cancer journey
- Audacious goals
- Sense of urgency
- Flexibility
- Iterative between science and medicine
- Sustainable

The Master Protocol will provide for the screening of patients using a broad cancer panel for gene alterations, whole genome sequencing, RNA sequencing, immunohistochemistry and/or proteomic analysis. The goal is to have a high priority clinical sub-study for every pancreatic cancer patient enrolled in the Master Protocol. Working Groups are being convened to develop specific protocols for each sub-study. Bio-statistical support will be provided by Cancer Research and Biostatistics (CRAB). The initial sub-studies will focus on patients with metastatic disease and will be signal-seeking to inform subsequent registration trials. Three Working Groups will be convened to design the three initial sub-studies focusing on agents that 1) target DNA damage repair defects, 2) disrupt the stroma and 3) engage the immune system. All consortium members participating in Precision Promise will be expected to activate and enroll patients into all three initial sub-studies at their site or institution. The initial sub-studies will be designed so all participating patients will be eligible for at least one of the three sub-studies. Patients with identified low-prevalence genetic alterations will be assisted in enrolling in appropriate national basket trials.

**PRECISION PROMISE CLINICAL TRIAL CONSORTIUM SITES**

The Precision Promise U.S. Clinical Trial Consortium (CTC) will be established to realize the vision of Precision Promise. Up to 10 sites will be selected to form the inaugural CTC. The Pancreatic Cancer Action Network will support one-time upfront costs of $15,000 to establish each site and $100,000/year total for the principal investigator and/or site personnel to support the Master Protocol and general CTC activities. Each site will be required to open the Precision Promise Master Protocol to facilitate providing molecular screening to pancreatic cancer patients and to open each Precision Promise sub-study as it becomes available. It is envisioned that the Master Protocol and three sub-studies will be available in the fall of 2016 with the first patient enrolled in Q1 2017. Per-patient costs for the Master Protocol and each sub-study will be determined by a Precision Promise Working Group with representation from the CTC.

**Eligibility**

- The site must be in the United States.
- The contact principal investigator (contact PI) must be an independent researcher with a doctoral degree (including PhD, MD, DO, PharmD or equivalent) in the biomedical sciences or in a field applicable to health science research.

**Use of funds**

This renewable contract will support one-time upfront costs of $15,000 to establish each Precision Promise CTC site and $100,000/year total for the principal investigator and/or site personnel to support the Master Protocol and general CTC activities, including salaries and other costs related to patient accrual. Up to an additional 20 percent ($20,000/year) is allowed for indirect institutional costs. Due to anticipated differences in complexity, per-patient costs will be developed on a sub-study basis with input from CTC members.
EVALUATION OF APPLICATIONS

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 Noon, Eastern Daylight Time on Friday, July 1, 2016, using the proposalCENTRAL website at https://proposalcentral.altum.com.

Decision date: Funding decisions will be made in August 2016.

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
• Budget and Budget Narrative Template

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
• Signed Acknowledgement of Contract Terms and Conditions
• 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://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp.

*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.

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.
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 three templates must be downloaded and completed: Site Information Template, Statement of Interest Template and Budget and Budget Narrative 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 Contract Agreement Terms and Conditions must be downloaded and the last page signed by the contact PI and signing official from the sponsoring institution.

   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. Budget and Budget Narrative Template. Complete on the template available from the proposalCENTRAL application website.

Funds will be provided for one-time upfront costs of $15,000 to establish each Precision Promise Clinical Trial Consortium Site. $100,000/year total can be used for the principal investigator and/or site personnel to support the Master Protocol and general CTC activities, including salaries and other costs related to patient accrual. Up to an additional 20 percent ($20,000/year) is allowed for indirect institutional costs. Per patient costs will be developed separately and are not included in the Budget.

D. 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. 08/12]) 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. 08/12 format).

E. 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.

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

G. Signed Acknowledgment of Site Agreement Terms and Conditions. Applicants are required to read the Master Clinical Trial Site Agreement before completing the application form. A copy must be downloaded from the proposalCENTRAL application Web page. Appendix A – C of the Agreement will be dependent on the finalization of the Master Protocol and sub-studies and determination of associated per-patient costs. The final page of the document must be signed by the contact PI and sponsoring institution, indicating that they have read the document and agree in principle with the content. Any disagreement with the terms or conditions should be stated in writing at this time. A scanned copy of the signed page and comments on disagreements (if any) must be uploaded into the online application in the section for attaching files. This signature is not binding, and official recognition as a CTC site and initiation of annual fixed costs are dependent on finalized agreements between the site and the Pancreatic Cancer Action Network.

H. 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 Research Officer, Pancreatic Cancer Action Network, at lmatrisian@pancan.org or (202) 772-3373.

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**THE PANCREATIC CANCER ACTION NETWORK** is the national organization creating hope in a comprehensive way through research, patient support, community outreach and advocacy for a cure. The organization is leading the way to increase survival for people diagnosed with this devastating disease through a bold initiative — The Vision of Progress: Double Pancreatic Cancer Survival by 2020. Together, we can Wage Hope in the fight against pancreatic cancer by intensifying our efforts to heighten awareness, raise funds for comprehensive private research, and advocate for dedicated federal research to advance early diagnostics and better treatments and increase chances of survival.