

The NCI Office of Cancer Centers Learning Series

Opportunity for CTSU Support for Collaborative Multi-Center Phase 2 Trials Led by NCI Designated Cancer Centers, SPORES, and CCR

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December 5, 2011

2:00pm ET

Moderator:

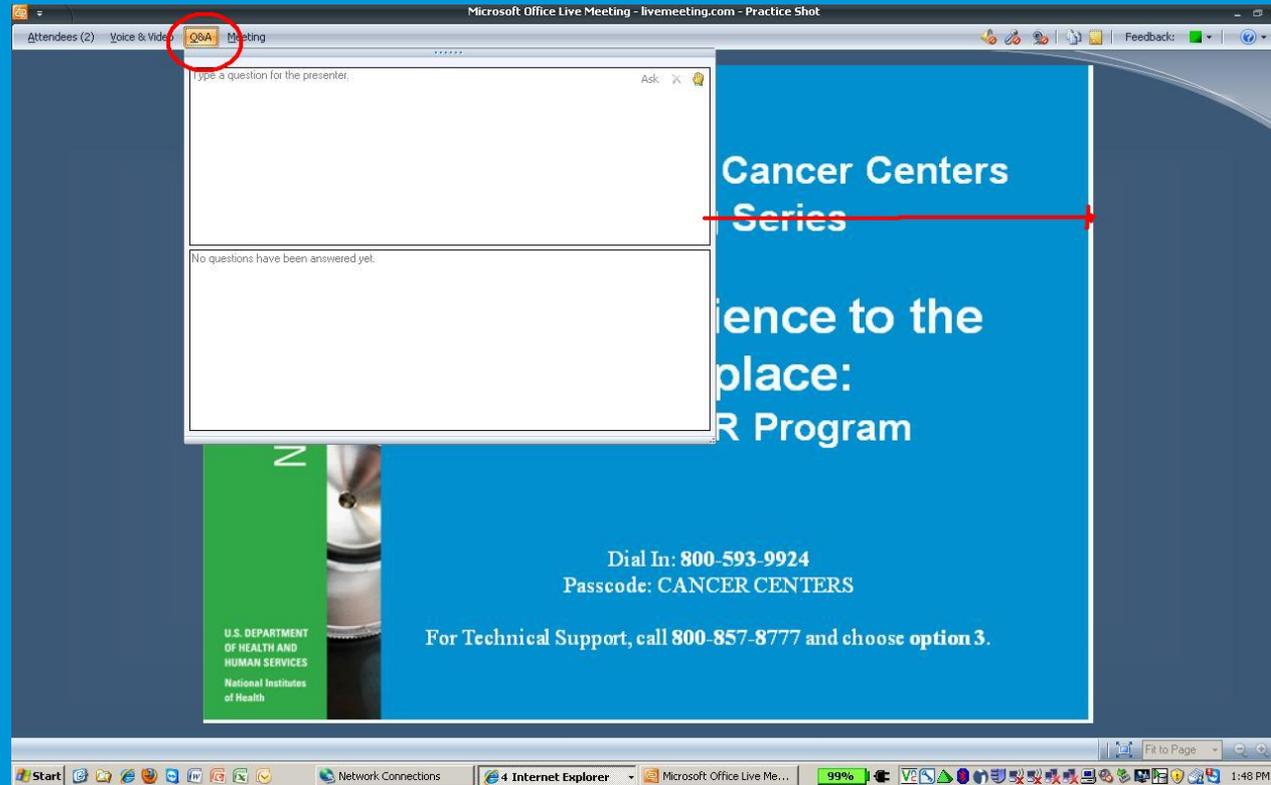
Henry Ciolino, PhD
Program Director
Office of Cancer Centers
National Cancer Institute
National Institutes of Health
Bethesda, MD

Featured Presenter:

Raymond Petryshyn, PhD
Program Director
Coordinating Center for Clinical Trials
Office of the Director, NCI
National Institutes of Health
Bethesda, MD

A Quick Guide to Your Screen

- Please submit your question via the Q & A box on the right hand side of your screen. If you do not see the Q&A box, you can expand it by clicking the Q&A on the top navigation panel and dragging it to the right side of your screen.



Opportunity for CTSU Support for Collaborative Multi-Center Phase 2 Trials Led by NCI Designated Cancer Centers, SPORES, and CCR

(CTSU/ Harmonization Announcement)

December 5, 2011

Raymond Petryshyn, PhD
Coordinating Center for Clinical Trials
Office of the Director, NCI

CTSU/ Harmonization Announcement

<http://ccct.cancer.gov/files/CTSUSupportUnitAnnouncement.pdf>

Purpose:

This announcement highlights an opportunity for Cooperative Group, NCI Designated Cancer Center, NCI's Center for Cancer Research Center (CCR) and Specialized Programs of Research Excellence (SPORE) investigators to develop clinical trial collaborations through discussions in NCI's Scientific Steering Committees. Collaboration is an important underpinning of NCI's efforts to harmonize review guidelines across NCI's these three grant mechanisms and with CCR. For clinical trial collaborations requiring multi-center coordinating support that is not otherwise available through existing networks, NCI will prioritize requests for in-kind coordination support through its Cancer Trials Support Unit (CTSU). While most Cooperative Group study PIs are familiar with Scientific Steering Committees and CTSU capability, this announcement provides important details for how study PIs at NCI Designated Cancer Centers, CCR and SPOREs can interact with Scientific Steering Committees and request access to CTSU services for highly meritorious clinical trials. It is anticipated that CTSU support will be provided for up to two multi-center phase 2 trials per year under this announcement.

CTSU/ Harmonization Announcement

Overall Purpose:

- Encourage collaborations and hand-offs (bench-to-bedside and back) between Cooperative Group, NCI Designated Cancer Center, and SPORE investigators related to clinical trials through discussions in NCI's Scientific Steering Committees.
- *Collaboration is an important underpinning of NCI's efforts to harmonize review guidelines across the above three grant mechanisms.*
- CCR Investigators eligible in 2012

CTSU/ Harmonization Announcement

Two specific opportunities:

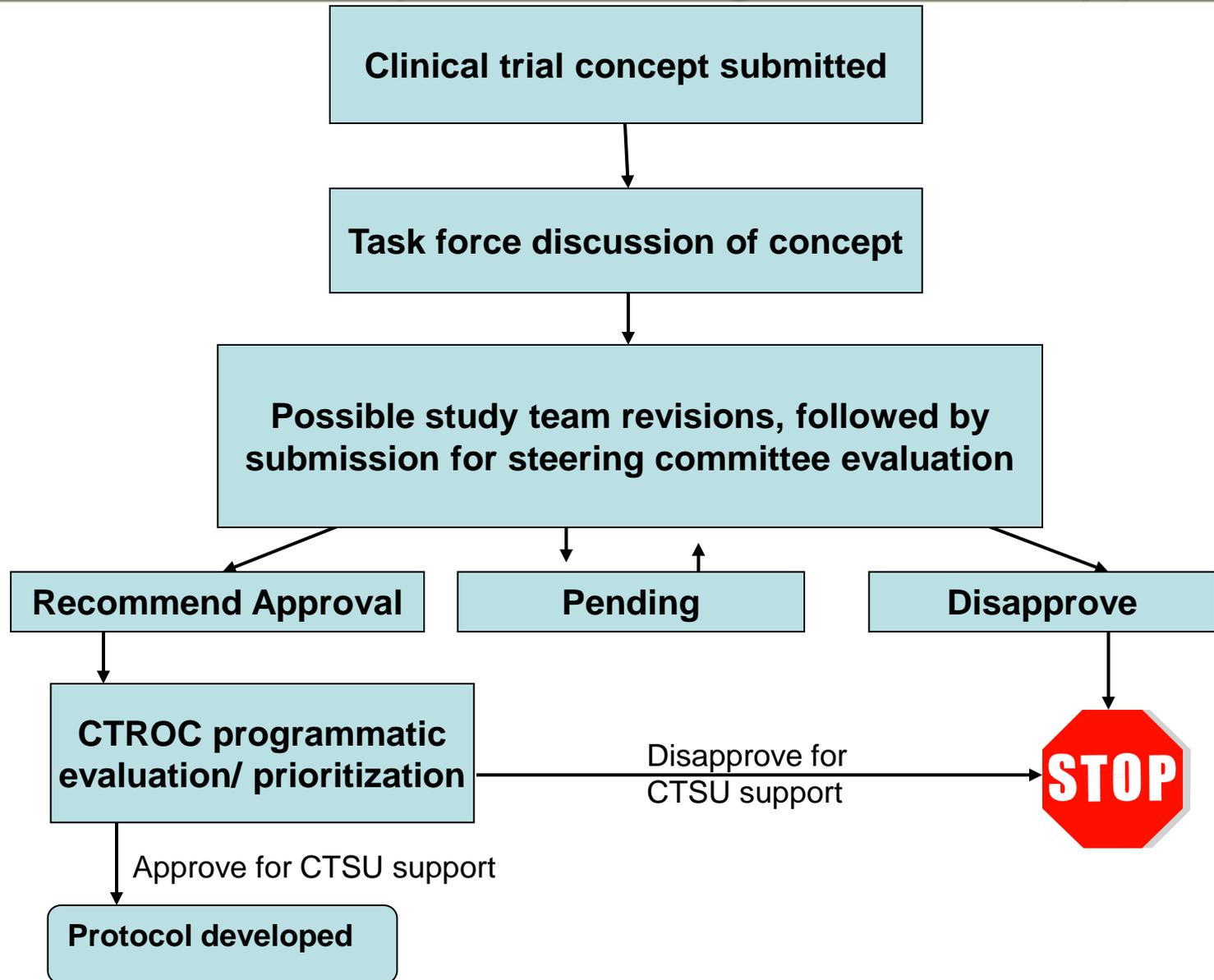
- SPORE, CCR, and NCI Designated Cancer Center Investigators may wish to bring ideas for clinical trials or components (e.g., biomarkers) to NCI Scientific Steering Committees for input and to seek collaboration; could lead to “review credit” under harmonized guidelines for SPOREs, NCI Designated Cancer Centers, and Cooperative Groups
- On a limited basis NCI will provide support for CTSU services for Phase 2 trials recommended by a Scientific Steering Committee and approved by NCI’s Clinical and Translational Research Operations Committee (CTROC); remainder of slides focus on this component

CTSU/ Harmonization Announcement - Revisions

Eligibility for CTSU Support under Revised Announcement

- Phase 2 randomized multi-center treatment trial (at least four accrual sites) with ≥ 100 and < 200 total patients led by a SPORE, NCI Designated Cancer Center, or CCR investigator. Under special circumstances when there is a unique opportunity for important improvement to clinical outcomes, allow concepts of less than 100 patients and/or single arm or non-randomized concepts.
- Requires collaboration with either another SPORE or NCI Designated Cancer Center, or Cooperative Group (i.e., mechanisms with harmonized guidelines), or CCR.
- A trial proposed by a network with access to CTSU or other multi-center trial coordination support is ineligible.

Evaluation Process for Eligible Trial Concepts Seeking CTSU Support



CTSU/ Harmonization Announcement - Revisions

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CTSU/ Harmonization Announcement

Multi-Center Coordination Services available from CTSU under current announcement:

- Regulatory support
- Website document hosting
- Protocol coordination
- Patient registration
- Study coordination
- Clinical database development
- Data management
- Data processing
- Information technology
- Capitation

Investigational New Drug (IND) application & statistical support, data safety monitoring, and auditing services are not available through the CTSU.

Reminders/Advice

- Support available for up to two trials this year
- Concepts must be for Phase 2 randomized multi-center treatment trials (with at least four accrual sites) with ≥ 100 and < 200 total patients led by a SPORE, NCI Designated Cancer Center, or CCR investigator
- Concepts of < 100 patients and/or single arm or non-randomized may be considered under special circumstances
- Concept must represent a collaboration of the lead institution with another SPORE or NCI Designated Cancer Center, Cooperative Group, or CCR

Reminders/Advice

- Letters of agreement / understanding from each of the collaborating sites at time of submission/evaluation
- Concepts likely to receive favorable NCI programmatic consideration will make a strong case for why the proposed trial cannot be lead by one or more Cooperative Groups
- Anticipate reissuing the announcement in November, with possible modifications, such as revised eligibility for trials involving rare tumors
- Questions? Contact Dr. Raymond Petryshyn at [301-594-1216](tel:3015941216) or petryshr@mail.nih.gov

CTSU Harmonization Website

<http://ccct.cancer.gov/files/CTSUHarmonizationAnnouncement.pdf>

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Raymond Petryshyn, PhD
Program Director
Coordinating Center for Clinical Trials
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National Institutes of Health
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Disclosures

- Raymond Petryshyn, PhD:
 - No relevant financial relationships with commercial interest



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If you have further questions, please contact:

Raymond Petryshyn, PhD

petryshr@mail.nih.gov

This webinar was created by the Office of Cancer Centers in the National Cancer Institute

<http://cancercenters.cancer.gov/>

For information about the --- program through the National Cancer Institute, please visit

<http://ccct.cancer.gov/files/CTSUHarmonizationAnnouncement.pdf>

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