

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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Date

2:00 PM ET

Operator: Welcome and thank you all for standing by. Participants will be in a listen-only mode for the duration of today's call. Today's call is being recorded. If there are any objections you may disconnect at this time. I would now like to turn the call over to Miss Melissa, I'm sorry, Mr. Henry Ciolino. Sir, you may begin.

Henry Ciolino: Well good afternoon and welcome to the Office of Cancer Centers webinar information series. My name is Henry Ciolino, from the Office of Cancer Centers. Today's topic is Opportunity for Cancer Trial Support Unit Support for Collaborative Multi-Center Phase 2 Trials Led by NCI-Designated Cancer Centers, and SPOREs.

Operator: This is the operator. May I have your passcode please?

Henry Ciolino: ... housekeeping details, the webinar will stream most efficiently to your computer if you close all other applications. We are being recorded and this will be posted on the Office of Cancer Centers website after the presentation. You are in listen-only mode. To submit questions please use the question and answer box on the upper right hand of your screen. Dr. Petryshyn, take it away, please.

Dr. Petryshyn: Thank you very much. I hope everybody can follow along with my slide set as we go along. And first of all I would like to thank the Office of Cancer Centers for providing me this opportunity to talk about this relatively new program, although it has been about for about a year. So again, my name is

Raymond Petryshyn, I'm from the Coordinating Center [for] Clinical Trials and that is in the Office of the NCI Director.

So today over this session I plan to give a brief overview of the program, some eligibility and evaluation process. I'll try to answer any questions you have that may arise. However I really do encourage anyone who is interested in this opportunity to visit our website and you'll see that on the slide set on the next slide and to contact me if there are any further questions on this.

Again, I hope you can follow along with this slide set. I'm not sure but I did provide a copy of the new announcement for 2012, which may have been sent out or will be posted on the website for sure. This announcement will also be distributed to the offices of the Cooperative Groups, the Cancer Center - Offices of the Cancer Centers and the SPOREs and also to the Center for Cancer, the NCI Center for Cancer Research. So this distribution will be made very broadly in the next couple weeks or so, I think.

So I'm going on now to slide 2 and again I – the first thing I want to point out is that the website is given at the top and I, again, I would encourage you to visit this website if you have interest in this program. [*Ed Note:* <http://ccct.cancer.gov/files/CTSUSHarmonizationAnnouncement.pdf>]

This program is an opportunity for cancer trial support, for [Clinical] Trial Support Units, supports or CTSU. This announcement is also sometimes referred to as the CTSU Harmonization Announcement and I will describe why that is shortly. And as I mentioned this announcement has already been - the previous has been in the works for about a year and is being renewed – and has been actually renewed in late November, coming out actually in, coming out this week actually.

So um, it highlights an opportunity for Cooperative Groups, NCI-designated cancer centers, NCI Center for Cancer Research center, which is CCR and that's new for 2012, and Specialized Programs of Research Excellence (SPORE) investigators to develop collaborative trials through discussions with NCI's Steering Committees. I will describe those steering committees later on in the program.

There really [are] two aspects to give this: one is to give credit for review and that pertains to the harmonization of the guidelines among SPOREs, Cancer Centers and Cooperative

Groups. And the second is to provide support through the Clinical Trials Support Unit.

So if we go to the next slide, which is slide 3, this describes the overall purpose of the program and really it's to encourage collaborations and hand-offs between Cooperative Groups, NCI-designated Cancer Centers and SPORE investigators related to clinical trials through discussions with the NCI's Scientific Steering Committees.

Part two of this, which I will discuss later, really deals with our collaborations, which is really an important underpinning of NCI's effort to harmonize review guidelines in the three mechanisms, that is, the SPOREs, Cancer Centers and Cooperative Groups. And as I mentioned earlier, the Center for Cancer Research investigator – the NCI Center for Cancer Research investigators, they [will] become eligible in this program as collaborators in 2012.

The new guidelines, the new guideline changes, which are coming that NCI is doing as encouraging collaborations and it is expected that the major forces will have collaborations and this provides one of the opportunities in this program to give credit for these types of collaborations. Upon review of either the SPORES, the Cancer Centers, and the Cooperative Groups.

So it's also – it represents - the program also is an opportunity for credits for – credits that we'd be giving for developing, developing collaborations. Obviously, this particular program, the support is limited. It's not intended for every type of trial but for those that are quite important enough and that need multi-center collaboration and/or hand-offs to succeed. So NCI felt that there is a value in this opportunity to foster trans-mechanism collaborations, especially in those uncommon tumors.

I'll go through the next slide, which is slide four. Again, there are two specific opportunities that are described here. The first opportunity is to allow investigators from the SPOREs, CCR and NCI-designated cancer centers to bring their ideas and bring their concepts for clinical trials or ideas for clinical trials to the NCI Steering Committee to seek input and discussion and to form collaborations with Cooperative Groups and among themselves, which could lead to review credit under the harmonization guidelines for the SPOREs, Cancer Centers and Cooperative Groups.

Secondly, on a limited basis NCI will be able to provide support for CTSU services for phase II trials that are

recommended by the Scientific Steering Committees and approved by NCI's Clinical and Translational Research Operations Committee or CTROC.

The remainder of this – of this presentation will focus on that component of it. And if we move on to the next slide, I want to talk a little about the eligibility for CTSU support under this, we're calling it the Revised Announcement, since it's been recently revised.

In the past, the eligibility required phase II trials, randomized multi-c – randomized multi-center treatment trials having at least four accrual sites with less than – greater than or equal 100 and less than 200, that is 199 total patients led by a SPORE, NCI-designated cancer center, or as the new changes have occurred, CCR investigator.

However, after some discussions with SPORE PIs, disease-specific committees and their task forces and other stakeholders in clinical trials, it was clear we needed to add some flexibility because in many cases the investigators were interested in smaller trials that were difficult to do - where it would be difficult to get 100 patients or more on these trials.

So for 2012 we did make the program more flexible and as it states in the red outline on the slide, there will be circumstances, and this will be a case by case basis, when there is a unique opportunity for important improvement to clinical outcomes, concepts of less than 100 patients and/or single arm or non-randomized concepts will also be considered. And this again is to provide essentially, I mean, to provide opportunity for the uncommon tumors where patient accrual, sufficient patient accrual may be an issue.

There is a requirement for collaborations with either another SPORE or an NCI-designated Cancer Center or a Cooperative Group. Those are the three that are mechanisms where the guidelines are being harmonized for credit and with the CCR as well.

I would like to say, it should be pointed out that those networks that already have access to the CTSU or other multi-center trial coordination support is really ineligible for this program. For example, if there is already access to CTSU then you wouldn't expect to get support or access through this program.

The next slide, actually, is slide number 9, discusses how the evaluation practice takes place. Actually slide 9 and slide 10 are essentially the same. Slide 10 has more detail. I just put in

there so you can have a little bit more information, but for the sake of this discussion, we'll focus on slide 9.

Essentially clinical concepts are submitted to the steering committees. But if steering committees as about half of them have, and I'll, again, I'll come back and I'll discuss steering committees, have task forces, then the first course of events would be to send this idea for CTSU support concept to the task force of a steering committee where they will undergo discussion of the concept.

This discussion with the task force could lead to some possible revisions or recommendations that before submission to the steering committee that the PIs might want to consider, um, consider after discussing it with the task force members.

The task force, of course, [is] part of the steering committee, but they represent a group of experts that do pre-discussion, um, pre-development of concepts. Once the concept, once the concept is ready for submission to the steering committee, it is submitted to, with CTEP [Cancer Therapy Evaluation Program], through its PIO, to be – the PIO is the Protocol Information Office - so that it can be logged in and then it will be sent to a particular disease-specific steering committee for evaluation.

The disease-specific steering committee can recommend the concept for approval, or it can have a pending, in which case it can go back and forth and undergo revision, or the third option, of course, would be disapproval of the concept, after which it would not be considered further.

For those concepts that are approved or get final approval, they are then sent to the NCI's Clinical and Translational Research Operations Committee for programmatic evaluation and prioritization. Actual funding for this program comes from the Office of the Director. CTROC, or as it is known as the Clinical Trials Research Operations Committee, is the body that is responsible for that decision out of the Office of the Director. And of course they could disapprove it or they could approve it, in which case if it is approved, then a protocol would go on for development and would have support on the CTSU.

Again, I just reiterate that other, the next slide number 7, really is just a little bit more verbiage of what I described. As I say, steering committees have relevant task forces that need to look at this, at least once before it goes through steering committee to present their comments and their recommendations.

I will say that once the protocol is submitted to the protocol information office it does fall under the Operational Efficiency Working Group timeline or clock and I'm not sure you're familiar with that, but there is a timeline for opening of protocols once – after for concept review and for opening of protocols to accrual that is outlined by the Operations and Efficiency Group.

So let me just move on to slide number, um, I don't think I have the right slides on here, but I did actually have a couple of additional slides that I wanted to talk about steering committees for those that weren't familiar with them. The NCI-designated disease-specific steering committees have been formed through our office, the Coordinating Center for Clinical Trials, and the earliest ones from as long as 2006 when the GI Steering Committee was formed and the GYN Steering Committee. They're actually – we're up to now about 11 disease-specific steering committees: GI, GYN, Head and Neck, etc., down to Pediatrics Steering Committee.

These steering committees are composed of the major clinical trial stakeholders, which include CTEP, Cooperative Group members, patient advocates, translational scientists, statisticians, clinical trialists, etc. And their job is to evaluate and prioritize the national, all of the national trials – late-stage national trials and these are mainly have come in the past from the Cooperative Groups, and large Phase II trials as well.

But half of all of the steering committees have these task forces, which I discussed in the previous slides and their job is to actually have a discussion of the concepts or ideas for concepts with the PI, making any recommendations they think will strengthen the trial and also to advise the steering committee on those concepts. The steering committees, of course, vote to approve, disapprove or pending as I described on the previous slide.

In addition to the disease-specific steering committees, there are also five related scientific steering committees that are not disease specific. These include the investigational drug steering committee, the clinical imaging steering committee, symptom management and health-related quality of life steering committee, and the patient advocate steering committee. And all of these help form our clinical trials steering committee system.

These steering committees and their chairs can be found on the CCCT website for those that are interested in looking at that.

I'm sorry I didn't have the slides added to the set that you're looking at.

So if we go on then to slide – whoops I'm going backwards here – so if we go on then to the slide that's up there now, slide number 11 I think it is, this describes what sort of services are provided through the CTSU Harmonization announcement. I want to emphasize that this is not a grant. It provides a suite of services from the CTSU menu. This is really in-kind support; salaries, traditional direct and indirect costs, etc., are not supported through this program.

The types of supports that one can get from these are regulatory support – are listed on the slide – regulatory support, website document hosting, protocol coordination, patient registration, study coordination and those others, clinical database development, as needed. All of these are time-consuming, difficult tasks. But I think the most, one of the most important ones that I can point out is that this, that this program does provide support for capitation at the current rate of reimbursement for, that is provided now for phase II trials.

I do want to point out that there are a few things that are not, that are not eligible for CTSU support and these include investigational new drug (IND) applications and statistical support, data safety monitoring, auditing services are also not available through CTSU. It is expected that these services will come as part of the multi-site, will be available through other means through these multi-site connections.

Finally, I would just like to summarize this and provide some, for those interested, some reminders and advice as to what's required to apply for these. And it's a bit of a summary of what I presented. We, currently we think that there will be support for up to trials this year. Concepts – that's two trials total, I'm afraid to say. Concepts must be, you know originally the concepts were phase II randomized multi-center treatment trials with 100 and less than – between 100 and less than 200 total patients that are led by a SPORE, designated cancer center, or CCR investigator.

Of course we, as I mentioned earlier, we've modified these to give consideration to concepts for trials of less than 100 patients that may be single arm or non-randomized. And these will also be considered on a case-by-case basis to help accommodate the uncommon cancer sites, tumors.

The concepts must represent a collaboration of a lead institution with another SPORE or NCI-designated cancer center and with a cooperative group or the CCR.

In slide number 13, this continues, letters, you know, to make the process smoother and to make sure there's no doubt in the evaluators about how well this multi-site has been arranged, I think it is wise to have your letters of agreement and understanding from each of the collaborator sites available at the time of submission and evaluation. This makes the process simpler from the get-go.

Those concepts that are likely to get favorable consideration are ones that there is strong rationale for being funded through this program and not led by one or more Cooperative Groups.

Again, this program – in the beginning, before, when these slides were sent out, we weren't sure about whether an announcement was going to be reissued, but it is going to be reissued and it has been reissued, so this funding is available. This program is available and I would encourage you to contact me either through phone or through my email if you have any questions on this, further questions on this program.

And again, in the last slide then I just want to point out where the website is again so that you can, uh, and I would encourage you to go to that website to read about it in further detail.

And I'll thank you very much. I think that concludes this portion of it and I'll take any questions.

Henry Ciolino:

Raymond, how many proposals do you expect to see submitted per year in this program?

Raymond Petryshyn:

It's difficult to say. The program has only been available for one year. During that period of time, we – and that was the first year it was available, so it's brand new, we received three proposals last year. We expect, we've always expected to fund at least two trials. That's the amount of resources we have available, but I think most people know that the NCI is flexible and if there's a really important opportunity for funding, more than hopefully two that we can fund, we'll certainly consider and do our best in these tight times.

Henry Ciolino:

Is there a template for protocol submission to the Steering Committee Task Force?

Raymond Petryshyn:

Yes, there absolutely is. It's outlined in the announcement, which can be found on the website. We are using the CTEP standard concept submission template and you can download that from the available website.

Henry Ciolino: You mentioned that you expect there to be at least four accrual sites. But wouldn't you expect many more accrual sites?

Raymond Petryshyn: Oh yes. Four is the minimum. It's great if you have more collaborators. That's intended. Sorry I wasn't quite clear on that.

Henry Ciolino: You mentioned that under special circumstances, single-arm studies, studies with less than 100 patients could be funded under this program, what's -

Raymond Petryshyn: Yes.

Henry Ciolino: Could you describe the special circumstances?

Raymond Petryshyn: Oh, I would think it depends on the need for that, um, I wouldn't be making those decisions out of our office. We would be facilitating it. It would be the opinion of the Steering Committee, and I could see where there's a rare tumor, say something like most recently a Burkett's Lymphoma, where it's a relatively rare tumor. You would need a lot of sites. You have a good idea that will really improve the treatment.

That may not be the best example, but that just came to my head. But where there's really an opportunity for improvement of treatment that needs to be done and needs multiple sites. So that would be considered a special circumstance or at least an opportunity the NCI would like to fund. Areas where there's a real need in the NCI portfolio, where a Cooperative Group by itself would not or could not be able to take on, be able to do that kind of study would be another example where this kind of consideration would take place.

Henry Ciolino: Considering that this is a requirement, collaboration between SPOREs, cancer centers, Cooperative Groups, or CCR, could you ever envision accrual sites out of the country? Especially for rarer countries?

Raymond Petryshyn: So another country? So that's interesting. I think the way it's outlined right now, it's domestic. I think that we'd have to consider that possibility. I understand that for very rare tumors, international collaborations might be very important. This is a very small program right now and I think at least for the time being, international collaboration has not been considered, but it may be something to think about. So I don't have a definitive answer on that, but the way the program is put together now, it's for the SPOREs, cancer centers and Cooperative Groups, and Center for Cancer Research.

Henry Ciolino: Well, if there are no other questions, I'd like to thank our presenter, Dr. Petryshyn, today for his presentation. I'd like to

remind the registrants that the slides will be posted on the Office of Cancer Center website. Also that registered participants will be receiving a brief evaluation from. We ask that you complete this and send it back to us so that we can continue to improve our webinar series. And I'd like to thank you for joining us today.

Raymond Petryshyn:

Thank you very much.

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