

I hope you are all doing well and are enjoying (or will soon enjoy) the return of spring.

There has been a great deal of activity getting ready for I-SPY2. You might want to periodically browse our website (www.gemini-grp.com/ISPYHome.pdf) as we regularly add material relevant to the trial, as well as background information that is likely to be of interest to folks interested in the trial.

Over the past few months advocates have been assigned to all of the scientific working groups, and have begun to be actively engaged in many of them. In addition, three groups of advocates have begun work on other activities. One group, is reviewing an early draft of the trial protocol; we hope to put a version of it on the website sometime next month. Another group being led by Debbie Molis is working on patient materials, and a third group is working on training. We will also soon initiate two other advocate groups: 1) to work on a plan to assess all advocate activities; and 2) to work on a model for involving advocates at the trial sites. If you are interested in getting involved in any of these five groups, please send me an email message and we will add you to the list.

One of the activities that the training group is working on is a webinar series that will be available to any interested advocates. The webinars will be scheduled about every three weeks. Those who can attend live will have an opportunity to ask questions. However, given the variety of work schedules and time zones, we realize it will be difficult to meet everyone's needs. Thus, all of the webinars will be archived and available for viewing and listening at your convenience. Many of the webinars will be hosted by I-SPY investigators. The first of the I-SPY2 talks, which we are still trying to schedule will be done by Laura Esserman, the principal investigator and will provide an overview of the trial. This will be followed by other investigators who will talk in more detail about various topics (e.g., trial design, biomarkers, agents, imaging). In addition, we are scheduling a number of webinars that are more generic which should provide the background advocates need to understand clinical trials in general and I-SPY2 in particular. If there is a topic and/or speaker you think we should cover, please send me an email with your suggestion. The first general webinar is scheduled for:

WEDNESDAY, APRIL 15th at 3:00 eastern (2:00 central; 1:00 mountain; or noon pacific time)

Topic: Introduction to Clinical Trial Protocols and Protocol Review From the Advocate/Patient Perspective

Speaker: Barbara LeStage

Goal: At the end of the Webinar advocates will know what information must be included in NCI funded clinical trial protocols and how to effectively review a protocol to promote meaningful scientific research and trials to which patients will accrue.

Objectives: Advocates will know

1. that the purpose of a protocol is to describe the purpose of the trial and exactly how it is to be conducted.
2. what the elements of a clinical trial protocol are
3. how to review a protocol from the patient perspective
4. that tools have been developed by ACRIN, ECOG and RTOG to assist advocates in reviewing protocols
5. that an overview of the clinical trial process is available in the NCI Cancer Clinical Trial Basic Workbook.
6. that guidelines for authoring and submitting a protocol to NCI are available in a handbook from the Cancer Therapy Evaluation Program (CTEP) at NCI.
7. that the Components of a Protocol Document are listed in Section 3.1 of the CTEP handbook.
8. that CTEP has developed a template for Phase II clinical trials.

If you can participate live, please send me email to that effect so we can ensure there are an adequate number of ports. Following the webinar, I will send information about how to access the archive.

Dial-in procedures:

1. Prior to the call (like right now!) go to <https://www2.gotomeeting.com/join/928603461/10000000000814655> and launch the software. You may need to enable ActiveX and/or disable pop—up blockers to load and test the software; however, it is safe.
2. Five – ten minutes before the call:
 - Dial: 1-800-974-2164
 - Participant Access code: 9382660
 - Webinar ID: 928-603-461
 - You will be provided an ID which you should write down
3. Go to: <https://www2.gotomeeting.com/join/928603461/10000000000814655>
 - Assuming you pre-loaded the software, it should start up rapidly
 - If you are prompted for a Webinar ID, enter: 928-603-461
 - If you are prompted for a personal ID, enter the ID you received when you called in. This will allow the group system to show who is speaking

On another topic, many of you will be attending the NBCC annual training conference in Washington DC next month, and some of you suggested that we schedule an I-SPY2 networking get together. If you are attending and would like to join such a gathering, please send me a note to that effect including information about you time preferences.

Jane