Population Tracking Users Group

Date: Thurs., February 19, 2004
Time: 9:00–11:00 a.m.
Location: Rockledge 2, Room 9100
Chair: Carlos Caban

Next Meeting: March 18, Thurs., 9–11 a.m., Rockledge 2, Room 9100

Action Items

1. (All) Review the Population Tracking Module Bugs and Enhancements List and send additions and corrections to Carlos Caban with a copy to Melissa Hirsch.
2. (Carlos Caban) Write a memo explaining the two types of subproject codes, which ones are used for what, and who can change them.
3. (Melissa Hirsch, Carlos Caban) Post on the Web the list of people in each IC who have override permissions.
4. (Carlos Caban) Get determination for correct cumulative counts: from the start of the project or from the last funding.
5. (Carlos Caban) Prepare the options for what data needs to be collected and present it to the Inclusion Tracking Committee.

Welcome and Introductions

Carlos welcomed the group to the second meeting of the year. Several new people were in attendance and Martha Barnes joined the meeting by telephone.

Bugs and Enhancement List

Carlos explained that the eRA project is starting to get underway again after the contract and development-process changes. Consequently, he, Maria Koshy and Melissa Hirsch prepared a Population Tracking Module Bugs and Enhancements List, which they also prioritized. The new eRA development system requires this type of list, which is submitted into the system for consideration. Each item has to be approved and then added to a task list, which will be periodically updated and maintained.

Consideration will be given to the enhancements based on the following:

- Will the enhancement or bug fix affect only the Population Tracking Module? If yes, the change can be made quickly.
- Will the enhancement or bug fix affect other eRA modules? If yes, the change will be on a slower track because more changes and modules will be affected.

Action: (All) Review the Population Tracking Module Bugs and Enhancements List and send additions and corrections to Carlos Caban with a copy to Melissa Hirsch.

This list will be the baseline for further enhancements and bugs from which we can work.

Referring to number 10 on the list—*Subprojects tracking code not being rolled forward once generated from the previous year. Needs analysis of which would be valid to make 00 and which to leave alone. Eventually all the pop tracking information will have to be on a subproject level instead of grant level. Involves other analysts*—there was some discussion regarding the two types of categorization for subprojects:

- Subprojects in CRISP are given a particular code and data rolls forward when refreshed.
- Type P subprojects are given a code by the IC and the data does not roll forward. The numbering uses a different convention than that of the CRISP numbering convention.

There are two fields for subproject codes:

- Subproject ID, which is the CRISP number
- IC Subproject ID, which is the IC number

It was suggested that the PI name be included on page 2 of the Snapshot report and system screen. The issue of the PI of the protocol, who may be different than the grant PI was discussed. At present there is no field in the database.

The population tracking module also needs to be integrated with the Program Module.

Action: (Carlos Caban) Write a memo explaining the two types of subproject codes, which ones are used for what, and who can change them.

eSNAP Process for Internal Population Tracking Users

The eSNAP Process draft, originally written by Dan Hall and presented by Kim Witherspoon, was distributed separately by email and now reviewed and discussed. It was agreed to make the following changes:

- Move the last paragraph, *How to Learn about eSNAP*, to the beginning and add the commons demonstration link
- Get updated numbers for users and eSNAPs
- Add URL for the guide notice
- Add URL for the list of eSNAPs that have been received
- Add URL for system tools

Carlos said that there are 56 institutions in the eSNAP pilot now and 609 eSNAPs, but the pilot is going to expand soon and the number of eSNAPs will increase exponentially. Members of the Federal Demonstration Partnership are invited to participate in the expanded pilot. The FDP is a cooperative initiative among federal agencies and institutional recipients of federal funds. It was established to increase research productivity by streamlining the administrative process and minimizing the administrative burden on principal investigators while maintaining effective stewardship of federal funds. The FDP does testing for many of our processes and systems.

eSNAPs have a status code of either "I" for initiated or "S" for submitted (see screens on pp. 7 & 8 of the Process document). Melissa Hirsch cautioned the group about a "glitch" in the system that is being fixed. In the meantime, she asked that people do NOT refresh records if they are in a protocol that has a status of "I." There is an issue when the protocols have not been updated and a Principal Investigator (PI) wants to post a progress report. The system generates a new protocol for the progress report, which doesn't get linked back up with the original protocol. This is why it is important to be sure that all protocols are up to date.

It was suggested that, with the process becoming more and more complicated, specific roles or skill sets be determined so that one person can become an expert in that area. This would relieve the PI and the Program Official (PO) from having to attend to new processes that do not directly pertain to the science. Carlos noted that the data-entry function is part of the Most Efficient Organization (MEO) process at this time. However, within the new Program Module, separate roles for program approval, program assistant/analyst, and read-only are being defined.

The issue of getting help with the process was raised. Currently, any calls that come into the Helpdesk are copied to Melissa Hirsch and Mark Siegert. There was some discussion about the ability to override entries made by the PI. Melissa pointed out that most members of this group have override permissions. However, it was agreed that a list of people in each IC who have override permissions be made available on the Web site.

Action: (Melissa Hirsch, Carlos Caban) Post on the Web the list of people in each IC who have override permissions.

Another suggestion was that the PI's name be printed on the second page of the SNAP (snapshot) report. It was noted that the PI's name and email address are on the Protocol screen (see p. 4 of the eSNAP Process document).

There is a possibility that a report could be available using QVR that would show enrollment and target approval box data. Carlos noted that this information could be made available in the Program Module, where there will be defined roles and the ability to find a PO's portfolio. Melissa reminded the group that if anyone has a problem using QVR to retrieve population tracking data, she and the Helpdesk will not be able to provide support because QVR is not an eRA System module. QVR support is provided by CIT: Thor Fjellstedt, Cathy Buckley and Don Tiedemann.

The Clinical Trials checklist is available as a report through the Program Module. However, to fill out a checklist, one must print the Checklist itself, available in PDF format on the Population Tracking Module. It was suggested that an excellent enhancement to the Program Module might be to provide the ability to fill out all checklists on-line through it.

Policy Issues

Dr. Caban distributed a list of issues dated 2/19/04 for discussion. Issues in notification of PI and whether tracking will be done.

- Need a standard part of the just-in-time letter explaining why not tracking and encouraging the PI to still incorporate sex/gender and race/ethnicity in study and track as necessary. Will need to address in future studies.
- Or need separate notification to PI about tracking status before award.
- If to be tracked, need Program Official to approve so protocol can be entered at time of award. Do we need a "Y/N tracked?" box?
- For delayed onset studies, they should send in the tables and research plan and program will decide whether it will be tracked.
- For progress reports, PI may still include tables even if not officially tracked.
- eSNAP will not allow PI to enter tables if protocol is not tracked. Do we need a better message?
- Need to get policy approval and present to GMAC and POPOF and EPMC
- Should the new target data be entered before award or should there be a time limit (3 mo) after award to get it in.? This will distribute the workload over the year and have the information available when the PI goes to use eSNAP.

Discussion:

Notification of PI at time of award when NIH determines that PI does not need to provide enrollment tables to NIH. Linkage to Commons and eSNAP.

Need entry of Target Population information within x months of award

Currently, only grants with "00" coding appear in eSNAP.

With the change from hard-copy applications to electronic applications, more data will be available to the public and will be logged into the system. It is important to determine what information is needed from the PIs and to provide clear communication to the PIs as to what they are expected to do. For example, a letter might say the following:

> "We've evaluated your protocol in relation to the tracking of human subjects (and etc.) and we are not going to include it in the population tracking system. However, please continue to send your tracking forms as attachments for possible future use."

The message would link to eSNAP.

The issue here is that if the protocol is not officially tracked, the PI will not be allowed to electronically enter the tables.

Furthermore, the PI needs to clearly understand that if the grant that is to be awarded to them requires population tracking, certain information is required from them by the NIH and other information is required of them by the IC. The data will be required either electronically or in hard copy. The PI does not need to know how the data will be used. For example, a letter might say the following:

"You are about to be awarded a grant that is population trackable. The rules of the NIH require this data from you, and, in addition, the IC requires this data."

There was some discussion about Type 1 and 2 grants. For Type 2 grants, which are for the sixth support year, the target table would be the same as the initial grant. Should the PI want to increase the target population numbers, he/she would have to have that approved by the IRB because it changes the original scope of the research. The issue of cumulative counts was discussed and there was some disagreement as to whether cumulative meant from the beginning of the project or from the last funding.

Action: (Carlos Caban) Get determination for correct cumulative counts: from the start of the project or from the last funding.

It was agreed that Carlos should draft the options, with assistance from a working group similar to Miriam Kelty's subgroup, for what data needs to be collected and present it to this user group and to the Inclusion Tracking Committee. Any recommendations would need to be reviewed and approved by the relevant NIH functional committees, including EPMC.

Action: (Carlos Caban) Prepare the options for what data needs to be collected and present it to the Inclusion Tracking Committee.

Attendance

Barnes, Martha (NIEHS)
Bashir, Karen (NIA)
Caban, Carlos (OER)
Doherty, Margaret (NIAMS)
Douglas, Clarissa (NCI)
Fobbs, Tinera (NIBIB)
Freeman, Julia (NIAMS)
Goodman, Mike (OER)
Hirsch, Melissa (OER)
Koshy, Maria (OER)
Lee, Delores (NCRR)
Lingham, Angela (NIA)
McClure, Shelia (NCRR)
Meskill, Lauren (NIDDK)
Mowery, Richard (NIDCR)
Palagi, Sharry (NHLBI)
Parker, Marie (NIAID)
Schafer, Susan (NIAID)
Seppala, Sandy (LTS/PCOB), recorder
Sewell, Dorita (NIAAA)
Whalin, Michael (NICHD)
Witherspoon, Kim (NCI/CTEP)
Yerg, Diane (NIAID)