Population Tracking Users Group

Date: Thurs., March 18, 2004
Time: 9:00–11:00 a.m.
Location: Rockledge 2, Room 3087
Chair: Carlos Caban

Next Meeting: April 15, Thurs., 9–11 a.m., Rockledge 2, Room 9100

Introductions

Carlos Caban introduced Michael Martin, the new technical analyst. Michael has worked on the eRA project for a number of years and brings that experience to the support of Population Tracking. Maria Koshy will continue as the business analyst for Population Tracking.

Additionally, Melissa Hirsch, as announced last month, has taken a new position and is phasing out of her Population Tracking efforts. Carlos thanked her for her excellent work.

CRISP vs. Population Tracking Data

Carlos reported that Dr. Zerhouni expects that he should have data that tells him, on any given day, how many NIH-sponsored clinical trials are being conducted that have human-subjects research. It currently is not available. Dr. Zerhouni wants to see more rigorous data so that this information is available.

There are two places at NIH that identify clinical trials: the Population Tracking Module and CRISP. CRISP indexers determine and code grants they determine meet the NIH criteria as a clinical trial. These determinations result in data that is different than the data in the Population Tracking Module, since not all clinical research is tracked in the Pop Tracking module. There is a clear discrepancy between the two, with a higher level of accuracy in Pop Tracking, which includes population counts. It was suggested that the data of both systems be coordinated or integrated.

Another area of discrepancy surrounds the definition of a Phase III clinical trial. The NIH defined Phase III trial differs from the FDA criteria, which many PIs use as a standard. ICs and Program Officers are supposed to make the final determination when a Phase III trial is an NIH-defined Phase III trial, which then has additional requirements from the inclusion policy. NIH requires all clinical trials to have a data and safety monitoring plan, and to have a data and safety monitoring board for multicenter trials based on risk to subjects. During the discussion it was noted that program officials often think that any Phase III requires a DSMB, that they have to convene, and to avoid this, they often won't define it as Phase III. There needs to be more education of program officials and NIH staff on these issues.

There is a new Knowledge Management tool for scientific coding that may help to sort out the discrepancies in data.

There were two suggestions:

- Add a box on the front page for PIs to check to indicate that it is a clinical trial.

- The NIH should make the determination whether or not it is a clinical trial based on NIH definitions, and not leave the decision to the PI.

It was noted that the electronic competitive grant application process (CGAP) allows for submission of multiple protocols.

Recommendations

Carlos gave the background for the convening of an ad hoc subcommittee of the Inclusion Tracking Committee, which met on March 4. Many Principal Investigators (PIs) try to upload their population tables through eSNAP but are unsuccessful because they are not coded 00. It is important that the NIH retrieve population tracking data for designated clinical research but, at the same, it is important that whatever issues are internal to the NIH regarding this data be transparent to the PI.

What and how should we tell the PI that won't discourage the PI from continuing to comply with the inclusion policy and reporting to NIH, even if they are informed that NIH is not tracking their study data in its tracking system? The group discussed the following recommendations of the ad hoc subcommittee:

Recommendation	**Discussion**
1. Both paper and electronic applications will be received for years while the electronic application process is implemented. The same information should be available to the Principal Investigator in both versions for the inclusion policies and Population Tracking System.	• agree
2. Not all mechanisms require reporting of inclusion data. If a mechanism does not require reporting of inclusion data, the Principal Investigator and Institution should be notified in the Just-in-Time letter, and also in the Notice of Grant Award. See mechanisms list http://impacii.nih.gov/popdoc/Mechanisms_Requiring_Pop_Tracking_03-05-04.pdf	• Delete phrase: "in the Just-in-Time letter" • This is silent on the subject of exception codes. • Add a reminder why not tracking tables for PIs, e.g., this mechanism does not require data. However, PI often has been sending data, so there is a disconnect.
3. For each study that is funded under a mechanism that requires reporting of inclusion data, IC Staff must create a Protocol in the Population Tracking Module and Enter Target Enrollment Data before award, or, by the end of October for awards made at the End of the Fiscal Year (September). These will then be available for the PI to update in the eSNAP submission.	• Delete phrase "reporting of inclusion data" and substitute with "tracking." Add a reminder why not tracking tables for PIs.
4. ICs should monitor the "List of Grantee Organizations Registered in NIH eRA Commons" at	• This is reasonable

Recommendation	Discussion
http://impac2.nih.gov/tools/comorg/ipf_com_org_list.cfm and focus initially on entering protocols into the Population Tracking System for all mechanisms that are reporting inclusion data from these organizations, so that the protocols will be available for PIs when they need to submit eSNAPs.	

The current criteria for allowing eSNAP submission of population enrollment tables are:

- 00 tracking code
- the activity code is tracked
- Human Subjects code is not 10 or 98.

Discussion and suggestions:

- Modify numbers 1 and 2 to include exception codes and mechanisms.
- If IC wants to track data, even though it is not required by NIH, code as IC or 00 and it will be in eSNAP.
- Have the PI submit the data regardless of requirements and have the NIH decide what to do with it.

Dr. Caban will present this report for discussion at the next Inclusion Tracking Committee meeting and seek their approval of specific recommendations that will then be presented to the NIH functional committees for approval.

Attendance

Bailey, Eric (NCMHD)
Bashir, Karen (NIA)
Bates, Angela (ORWH)
Burge, Lori (NIGMS)
Caban, Carlos (OER)
Chan, Ivy (NCMHD)
Davis, Trenita (NIDCR)
Delcore, Sandi (NICHD)
Douglas, Clarissa (NCI)
Everett, Donald (NEI)
Fobbs, Tinera (NIBIB)
Hirsch, Melissa (OER)
Koshy, Maria (OER)
Lamar, Charisee (NIAMS)
Lee, Delores (NCRR)
Manischewitz, Jack (NIDA)
Martin, Michael (OD)
Matala, John (NIGMS)
Michel, Mary Ellen (NINDS)
Mowery, Richard (NIDCR)
Palagi, Sharry (NHLBI)
Prince, Mary Lou (NIMH)
Richardson, Carmen (NIAAA)
Schafer, Susan (NIAID)
Seppala, Sandy (PCOB)
Witherspoon, Kim (NCI/CTEP)