Wednesday, January 14, 2009

Trans-NCI working group for international collaboration in clinical trials

1. Welcome and introductions
2. Update on March 17, 2009, meeting with EORTC and UK NCRN
    a. Agenda attached
3. Follow-up on EU Clinical Trials Directive
    a. Request to Denise Jobin Welch at US Mission to EU for NCI visit to EC staff in conjunction with March 17, 2009, visit
4. Trans-NIH working group to develop international framework to facilitate international collaboration in public and academic trials (similar to International Conference on Harmonization)
    a. Core group: large NIH institutes with large portfolio of international trials (NCI, NHLBI, NIAID, etc) and appropriate NIH staff
        i. NHLBI: Susan Shurin
        ii. NIAID: Jorge Tavel
    b. Plan organizational meeting with reps from DHHS, Department of State, FDA, etc, when new administration in place (2-3 months)
    c. Plan meeting with new FDA reps to EU Mission (Dr. Linda Tollefson) and to EMEA (Dr. Janice Soreth) in early February
5. Strengthen global intergroups
    a. Discussion between CCCT and CIB pending
        i. Charge steering committees with responsibility for international liaison
        ii. Need to identify modest funding for steering committee reps to attend international intergroup meetings occurring outside US
    b. Ascertain ASCO meetings
6. Update for group chairs conference call January 21st
    a. Working group with 2 reps from each group to develop strategy for international membership (how to foster synergy, keep costs down, address regulatory barriers, boost accrual, and strengthen science)
        i. One rep for science, one for administrative/logistical issues
    b. Plan to share best practices for collaboration with groups outside US
7. Public information for website, including FAQs
    a. How the US NCI supports clinical trials
        i. Grants, contracts, cooperative agreements
        ii. Partnership with industry: CTAs, CRADAs, etc
        iii. RAID and RAPID
    b. Mechanisms for international collaboration
        i. Joint trials with groups outside US
        ii. International sites joining US groups
        iii. Individual patient-data meta-analyses
        iv. Links to US group websites
        v. Model SOPs
    c. US regulatory issues

        i. FDA 1572 forms
        ii. IRB registration with OPRR
        iii. FWA with OPRR
        iv. NCI-required audits
    d. Summary of regulatory issues in other countries
        i. Legal definitions and requirements of sponsorship
8. Follow-up from 2008 meeting with EORTC, NCIC, UK, and cooperative groups
    a. Documents summarizing options for joint trials and trial development process for EORTC, NCIC, UK, and NCI/US groups
        i. Need input from NCIC and UK
        ii. How best to share information and update
        iii. Mike Montello, Anastassia Negrouk, UK, NCIC
    b. Guidelines for working with industry
        i. Sherry Ansher, Richard Silvester, Remy von Frankell, BRB
    c. List of trials conducted by EORTC, NCIC, UK groups, US groups, NCI, which lead to licensing approval
        i. 2006 NCI list currently being updated
        ii. Need similar lists from EORTC, NCIC, UK groups
    d. Data ownership, access, and intellectual property issues
        i. Are these spelled out in the CEO Roundtable model contracts?
        ii. Need to summarize and post on websites
        iii. Sherry Ansher, Anastassia Negrouk, Wilma Hoffman (RTOG), Mary Steele (ECOG), Belinda Vandersluis (NCIC), other group
    e. Tissue collection
        i. Need to summarize and post information with links
    f. Informed consent documents
        i. Need to summarize and post information with links
    g. Data protection requirements
    h. IT/pharmacovigilance/ data management workspace recommendations
        i. CTCAE revisions
        ii. caAERs
        iii. CBIIT
9. Country and region-specific issues
    a. Austria: wants to open GOG 219, awaiting decision from new company on additional funding
    b. French NCI (INCA)
        i. Considering LOI for IND agent
        ii. Formal Letter of Intent for ongoing collaboration lost at US State Department
        iii. Participation in ACRIN studies?
        iv. Need FWAs, IRB registration, 1572 forms
    c. Germany
        i. Need follow-up from 2006 mtg at US Embassy Berlin
    d. Italy
        i. Check with Silvia Marsoni re QP

ii. Need to follow-up on signed agreement with ISS

e. Japan
   i. Currently planning joint workshop in Tokyo, 2009, with US Embassy and Japanese National Cancer Center
f. Korea
   i. National Cancer Center developing DTP-IDB type program; want to send staff to spend time at DTP and CTEP
g. Scandinavia
   i. Wants to join GOG 219, awaiting decision from new company
h. UK
   i. Need to touch base with new person at NCRN/ CRUK (not yet on board)
   ii. Per Rick Kaplan: no obvious QP
   iii. How to increase collaboration