To: BenzConsort-OC@listserve.api.org <BenzConsort-OC@listserve.api.org>; BenzConsort-TC@listserve.api.org <BenzConsort-TC@listserve.api.org>; BHRC Communications Committee <benzconsort-cc@listserve.api.org>; myron.c.harrison@exxonmobil.com <myron.c.harrison@exxonmobil.com>
From: Russell White <whiter@api.org>
Cc: Bob Greco <Greco@api.org>
Bcc:
Received Date: 2007-04-14 18:45:17 GMT
Subject: Shanghai Health Study - conference call on Monday, April 16 at 5 PM EDT

There will be a Oversight Committee conference call to discuss the Shanghai Health Study at 5 PM EDT (4 Central, 2 Pacific) on Monday, April 16.

Attached is a draft set of potential deliverables for the contract with Cinpathogen. I reviewed most of them yesterday with Dr. Irons. I should have a draft gap analysis for you before Monday's call.

Draft agenda
1) Establish quorum and notetaker - Patsy
2) Antitrust reminder - Mark
3) Review and modify agenda - Patsy
4) Update on acknowledgement of API letter - Howard
5) Review draft deliverables - Russ
6) Review draft gap analysis - Russ
7) Next call - Patsy

>

Conference call:

Toll Free Dial-In Number: (866) 443-0059
International Dial-In: (770) 765-9147

Enter this code at the prompt: 202 682 8344#
Operator-Assisted Service:
Toll-Free Dial-In Number: (800) 572-9844
International Dial-In Number: (706) 643-1733
Call Participant Functions
*0 Operator assistance
*6 Mute your own line

Russell White
Regulatory and Scientific Affairs
American Petroleum Institute
1220 L Street NW
Washington, DC 20005-4070

Tel: 202-682-8344
Fax: 202-682-8270

Attachments:

CINPATHOGEN DELIVERABLES DRAFT 4-14-07.doc

Within five calendar days of the receipt of funds, Cinpathogen will identify progress milestones to be achieved in the second quarter, 2007;

1. Update of the estimated NHL case numbers by ICD-9 classification in May 2007. [I would recommend dropping this deliverable and instead request updates based on lymphoid neoplasms (WHO) with documented informed consents and work history questionnaire administration for all cases and controls.]
2. Documentation of data flow and data entry for QA team
   a. Including review of SOP for data handling of work history information by the QA/QC team (including data-out, e.g., the virtual link between diagnostic data and exposure history data.)
3. Reestablish case accrual at participating Shanghai Hospitals
   a. Finalize arrangements for review of original work history questionnaires by Dr. Otto Wong or his associates as necessary*
4. Reestablish necessary exposure assessment activities for completion of exposure matrix

*In cooperation with the independent QA/QC team and Dr. Otto Wong.

Within fourteen calendar days of the receipt of funds, Cinpathogen will delineate deliverables and milestones to be utilized in the potential development of a contract with Cinpathogen to successfully complete the case accrual work by the end of 2007 and the entire study by the end of 2008. These deliverables and milestones should be consistent with the enhanced Quality Assurance/ Quality Control program and tie back to the partial Cinpathogen proposals of March 18, 2007 and April 5, 2007. Both the laboratory transition task and costs and the post study costs for the continued publication of study findings should be explicitly recognized by the Cinpathogen response.

Case Control Study

1. Cases diagnosed prior to December 31, 2007 of hematopoietic and lymphoid neoplasms (WHO, 2001) and a matched (2x) set of controls from participating hospitals in Shanghai that will include:
   a. Case selection follows criteria in Cinpathogen's March 18, 2007 DPME proposal, Section 8.1
   b. Documented informed consents and work history questionnaire administration for all cases and controls
   c. Cases of AML will be accrued until June 30, 2007
   d. Cases of lymphoid neoplasms will be accrued until December 31, 2007

2. A benzene exposure assessment matrix for all study cases and controls. The matrix will consider job, industry and time period in developing exposure estimates to benzene. Data sources for exposure assessment including the IPHS data set, Yang Pu database, the Chinese literature, real-time monitoring in selected factories and simulations will be used to arrive at credible benzene exposure estimates.

3. A substantial preliminary data set (including AMLs and lymphoid neoplasms by WHO criteria, confounders and the exposure assessment matrix) for testing the case-control protocol to Applied Health Science by September 2007*. [No ICD-9 classifications are being delivered for the case-control study.]

4. A final data set (including all cases of AML and lymphoid neoplasms diagnosis during the study by WHO criteria, confounders and the exposure assessment matrix) for completion of the case-control protocol to Applied Health Sciences by June 2008*. [No ICD-9 classifications are being delivered for the case-control study.]

*Based on a timeline agreed upon in cooperation with the independent QA/QC team and Dr. Otto Wong.

Disease Progression Studies

1. Publication quality manuscript(s) presenting the findings of the Disease Progression protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Molecular Epidemiology Study

1. Publication quality manuscript(s) presenting the findings of the Molecular Epidemiology protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Project Management

1. Implementation of the conditions in the agreement for advance funding for Cinpathogen (Red Cavaney to Richard Irons, April 11, 2007).

2. Implementation of recommendations from the independent QA/QC team.

3. Update of estimated NHL case numbers per ICD-9 classification in May 2007. Periodic updates throughout 2007 linked to diagnostic reviews which are on a nominal quarterly basis (approximately July, October, and January 2008.) [I would recommend dropping this deliverable and instead request updates based on lymphoid neoplasms with documented informed consents and work history questionnaire administration for all cases and controls.]