

To: Clegg, Patsy M SCC-DCS/22 <patsy.clegg@shell.com>
From: Galvin, Jennifer B <Jennifer.B.Galvin@conocophillips.com>
Cc:
Bcc:
Received Date: 2007-02-09 17:52:07 GMT
Subject: FW: Shanghai Health Study - Materials for the conference call Friday, February 9, 10 AM EST

Patsy,
Per your request, the only change I saw in Brian's document was the addition of the blue word "continued" which he substituted for "development". I think this is a good catch. The rest appeared unchanged.

Thanks,
Jennifer Galvin
918-661-3865
918-662-1139 (fax)
918-519-6302 (cell)

-----Original Message-----

From: Galvin, Jennifer B
Sent: Friday, February 09, 2007 10:56 AM
To: mfitzsim@steptoe.com
Subject: FW: Shanghai Health Study - Materials for the conference call Friday, February 9, 10 AM EST

Here is the only change on this document that I heard the OC recommend. Thanks for your help and taking the "hot seat".

Thanks,
Jennifer Galvin
918-661-3865
918-662-1139 (fax)
918-519-6302 (cell)

-----Original Message-----

From: brian.e.doll@exxonmobil.com [mailto:brian.e.doll@exxonmobil.com]
Sent: Thursday, February 08, 2007 10:01 PM
To: BHRC Communications Committee; BenzConsort-OC@listserve.api.org; BenzConsort-TC@listserve.api.org; Howard Feldman; Russell White
Subject: Re: Shanghai Health Study - Materials for the conference call Friday, February 9, 10 AM EST

We would like to propose an alternative to the draft letter to Dr. Irons that Russ had distributed previously which we believe includes some incorrect information. The alternative draft is shown below along with the attachment that contains a few minor revisions. I look forward to discussing this with you tomorrow.

Regards,
Brian Doll

ExxonMobil

Dear Dr. Irons,

I am writing on behalf of the group of companies supporting the scientific and clinical research you are conducting in China. We appreciate your serving as principal investigator of this unique project in Shanghai. We are preparing funding in the amount of \$6,159, 864 (?) in response to your request for additional support.

We assume that the substantive provisions of our original agreement will be in any subsequent contracts necessary to enable completion of the study. We are also providing additional funding for QA/QC as was outlined in your original proposal. As you have suggested, Dr. Jerry Rice, chair of the Scientific Review Panel, as well as other colleagues, have agreed to assist in this effort as well.

We would also appreciate receiving a contract proposal from CinPathoGen and its agreements with the University of Colorado and Fudan University. Please forward at your convenience.

Sincerely,

(See attached file: Shanghai Health Data and Process Quality Assurance2.doc)

"Russell

White"

<whiter@api.org

To

g>

<BenzConsort-OC@listserve.api.org>,

<BenzConsort-TC@listserve.api.org>,

"BHRC Communications Committee"

02/06/07 02:33

<benzconsort-cc@listserve.api.org>

PM

cc

"Howard Feldman" <Feldman@api.org>

Subject

Shanghai Health Study - Materials

for the conference call Friday,
February 9, 10 AM EST

<<Shanghai Letter to Irons RDW edits.DOC>> <<Shanghai Health Data and
Process Quality Assurance.doc>>

Attached is a draft of the "conditions letter" and the QA team charter
for
discussion on Friday.

There is a conference call scheduled for Friday, February 9, at 10 AM
EST

to discuss the Shanghai Health Study.

Draft Agenda

- 1) Establish quorum and note taker - Patsy
- 2) Antitrust reminder - Mark
- 3) Communications Committee update - Trisha
- 4) Conditions letter update - Jennifer/Russ
- 5) Contract issues update - Howard
- 6) QA Team update - Jennifer
- 7) Next call or meeting - 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 [attachment "Shanghai Letter to Irons RDW edits.DOC"
deleted by Brian E Doll/Fairfax/Mobil-Notes] [attachment "Shanghai
Health

Data and Process Quality Assurance.doc" deleted by Brian E
Doll/Fairfax/Mobil-Notes]

Attachments:

Shanghai Health Data and Process Quality Assurance2.doc

Shanghai Health Study**Charter: *Data and Process Quality Assurance Team***

Purpose: The purpose of this team is to facilitate the successful completion of the Shanghai Health Study through continued implementation and management of a rigorous data, process quality assurance and control program and timely successful transition of data to the principal investigators(PI).

A multi-year study, the Shanghai Health Study has three principal investigators (PI), study databases in two countries, a clinical diagnostic laboratory delivering information to a hematologist, an investigative industrial hygiene team and an epidemiologist.

The team will be made up of the following members:

Members:

- Dr. Jerry Rice, Chairman, Chair of SRP
- Dr. Richard Irons – Hematologist, PI
- Dr. Otto Wong – Epidemiologist, PI
- Dr. Judy Baldwin – Quality Assurance Expert
- Dr. Helmut Greim – Toxicologist, SRP
- Dr. Rob Schnatter – Epidemiologist, Adjunct PI

****Others can be added as the team recognizes the need**

Team and PI Responsibilities:

- Ensure a rigorous system for data and process quality assurance and control is implemented and functioning (defined processes, roles and responsibilities, process reviews, project timeline with goals & milestones, and key metrics to provide oversight and assurance for:
 - (1) data and process quality control are robust and sustained
 - (2) data capture, analyses and transfers are done in a timely, accurate, complete, consistent and secure manner
 - (3) data tracking and progress reporting is on-time and accurate
 - (4) effective communications and collaboration among investigators occurs in a way that facilitates study completion
 - (5) Processes clearly define roles and responsibilities
 - (6) QA/QC procedures will result in enhanced communication and scientific excellence
 - (7) The PI's will implement recommendations of the QA/QC team

Deliverables:

1. QA/QC metrics, goals & milestones
2. Progress tracking, submission of status against metrics, goals and milestones to the Oversight Committee on the 15th of each month.

3. Metrics, goals and milestones which reflect the progress of the study and may include:

- Documentation of data flow and data entry
- Accrued Cases¹: AML and Lymphoid Neoplasms (WHO)
- Number of consent forms and questionnaires signed, entered into database, presented in running cumulative total
- Regular, periodic review of usable data and processes
- Progress on key milestones and goals
- Process: Timeliness and accuracy of data collection, analyses and entry into databases
- Number of data audits, process reviews, and QA review meetings
- Continuation of QA/QC program for remainder of study
- Indicator of staff training and continuity
- Other metrics deemed necessary by this team

Timeline: First metrics report – March 15, 2007

Note: Semi-annual, written progress reports as specified in original protocols will continue to be provided.

Draft Authors: J.B.Galvin and M.Bird

Revisions

0:	Dec. 15, 2006
1:	Jan. 12, 2007
2:	Jan. 22, 2007
3:	Jan. 31, 2007

¹ Definition of “accrued cases” indicates only those cases that will be used in the case control study for the Shanghai Health Study.