

From: Russell White <whiter@api.org>
Sent: Tuesday, April 3, 2007 3:12 PM (GMT)
To: Bruce Jarnot <jarnotb@api.org>; BenzConsort-TC@listserve.api.org
Cc: Jmricewas@aol.com; mfitzsim@steptoe.com
Subject: RE: BHRC-TC... *Pls Review* Revised QA/QC Team Charter
Attach: Shanghai Health Study QA-QC team charter April 2007 RDW.doc

Here are my (few) comments on the draft charter.

From: Bruce Jarnot
Sent: Tuesday, April 03, 2007 9:24 AM
To: 'BenzConsort-TC@listserve.api.org'
Cc: 'Jmricewas@aol.com'; Russell White; 'mfitzsim@steptoe.com'
Subject: BHRC-TC... *Pls Review* Revised QA/QC Team Charter
Importance: High

Benzene Health Research Consortium (BHRC) Technical Committee (TC) –

Jerry Rice has revised the QA/QC Team Charter (see attached file) to better reflect the scope and activities of this group. Please review this final draft and reply by COB Friday, April 6th with feedback if you take exception to something in (or to something not in) this final draft.

Best Regards – Bruce.

From: Jmricewas@aol.com [mailto:Jmricewas@aol.com]
Sent: Monday, April 02, 2007 9:16 AM
To: jennifer.b.galvin@conocophillips.com; Bruce Jarnot
Subject: QA/QC team charter

Jennifer, Bruce,

Pursuant to the March 15 conference call, I've modified the draft QA/QC team charter as indicated, to take account of some of the "points of order" that had been raised by certain team members, notably Richard Irons. I've also removed the DRAFT watermark. Importantly, I removed the "monthly" designation for submission of team reports; I think it's realistic to have monthly team conference calls, but I don't see a team with this mandate (for the SHS overall) being able to supply a table of numbers that would be updated monthly.

Please give this one last read-through, and if there are no further changes I will send it to team members and it can go into whatever contract or other documents you intend it for.

Best regards,

Jerry

Shanghai Health Study

Charter: *Data and Process Quality Assurance Team*

Purpose: The role of this team is to facilitate successful completion of the Shanghai Health Study through development, implementation and management of an independent data and process quality assurance and control program; to set definable milestones for study completion; and to assure timely transfer of information among investigators. The focus of the Team is to be on the Shanghai Health Study as a whole, rather than on specific protocols, and the team is not expected to duplicate or replace existing QA/QC measures that have already been established by individual principal investigators for individual protocols or other SHS elements.

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. Judy Baldwin – Quality Assurance Expert
 Dr. Helmut Greim – Toxicologist, SRP

Adjunct Members: Dr. Rob Schnatter – Epidemiologist, Adjunct PI
 Dr. Richard Irons – Hematologist, PI
 Dr. Otto Wong – Epidemiologist, PI

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

Team and PI Responsibilities:

- Ensure that a rigorous system for data and process quality assurance and control is in place and functioning (defined processes, roles and responsibilities, process reviews, project timeline with goals & milestones, and key metrics) to provide oversight and assurance addressing the following:
 - (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 a regular basis.**
- 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**
 - 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**
 - Development of additional external 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 by the Principal Investigators.

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