To: john.moscari@cinpathogen.com <john.moscari@cinpathogen.com>; richard.irons@cinpathogen.com <richard.irons@cinpathogen.com>
From: Russell White <whiter@api.org>
Cc: BenzConsort-OC@listserve.api.org <BenzConsort-OC@listserve.api.org>; Howard Feldman <Feldman@api.org>; Linda Kangas <Kangas@api.org>; John Wagner <Wagner@api.org>
Bcc:
Received Date: 2007-05-24 21:13:19 GMT
Subject: Shanghai Health Study - Cinpathogen contract

Please find attached a draft contract (with Appendices) between API and Cinpathogen for completion of the Shanghai Health Study.

Mr. Moscari and Mr. Feldman are scheduled to discuss the documents tomorrow at 1:30 PM EDT.

> > > > >

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 2007-102814 Appendix A Business Plan.pdf
Cinpathogen 2007-102814 Appendix B Milestones 5-21-07.doc
Cinpathogen 2007-102814 Appendix C QA-QC team charter 4-27-2007.doc
Cinpathogen 2007-102814 Appendix D DPMEMaster Final3_18_07.doc
Cinpathogen 2007-102814 DRAFT 52407.doc

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. Therefore, this complex study needs a well understood process for the transfer of data from one investigator to another.

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 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 Cases[1]: AML and Lymphoid Neoplasms (WHO)
    - Number of consent forms and questionaires 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
    - Development of an 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.**