

{ DATE \@ "M/d/yyyy" }

Shanghai Health Study

QA/QC Team summary report for March 16-April 27, 2007

Otto Wong has provided names of two individuals, himself and Fran Harris, who can serve as contact individuals for Judy Baldwin for purposes of checking the robustness of his computer system at Applied Health Sciences (San Mateo, CA). A conference call involving Otto, Judy, and Jerry Rice is planned but has not yet been scheduled.

Judy has discussed directly with Rich Irons what he needs to do to complete the study. She plans (as of 4/12) to compose an outline of the status of the QA/QC project with assignments of specific individuals to participate in each activity.

Jerry has participated in a conference call with Rob Schnatter and Tom Armstrong to discuss the status of exposure assessment activities, progress towards completion of the occupational exposure matrix on which detailed exposure assessments will be based, and the provision to Otto Wong of the first of the preliminary data sets (for AML) for the case-control study. Rob Schnatter will be Otto's contact person for this preliminary data set, rather than Gail Jorgenson, who retired from ExxonMobil on March 31.

Problems

Judy has recently experienced health issues and for the moment is not responding to email or voicemail messages.

Gail Jorgenson's retirement came as a surprise. Clearly she will not be available through her previous employer to make any site visits to Fudan University, as Judy had previously expected. It is not clear when she may be re-employed as a consultant to ExxonMobil to resume her previous activities within the SHS. Her future role(s) in the QA/QC team efforts remain to be established.

Apparently the status of Professor Fu Hua in the Shanghai Health Study and the status of the laboratory and office space occupied by the JCML within the Fudan Univ School of Public Health have not been resolved, and no substitute has been appointed to undertake Professor Fu's previous role as paymaster for patients enrolled in the SHS. This ongoing uncertainty is disruptive to the case accrual process and hampers clear lines of communication among the senior investigators.

Future Plans

Progress will depend largely on the extent to which Judy is able once again to direct SHS QA/QC activities during the coming weeks.

Respectfully submitted,

Jerry M. Rice, Chair, QA/QC Team

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. Helmut Greim – Toxicologist, SRP
- To be filled – Quality Assurance Expert

- Dr. Richard Irons, Cinpathogen – Hematologist, PI
- Dr. Otto Wong, Applied Health Sciences – Epidemiologist, PI
- Dr. Sherilyn Gross, U of Colorado – Toxicologist, PI
- Dr. Rob Schnatter, ExxonMobil – 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 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
 - 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.