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From: Wong, Zachary (ZachWong) <ZachWong@chevron.com>
Cc:
Bcc:
Received Date: 2007-01-16 18:36:50 GMT
Subject: FW: My Input on Shanghai Quality Team Charter!

Hi Patsy. I had meant to copy you on my comments to Jennifer on the Charter. Zach

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From: Wong, Zachary (ZachWong)
Sent: Monday, January 15, 2007 9:07 PM
To: 'Jennifer.B.Galvin@conocophillips.com'; 'Russell White'
Subject: My Input on Shanghai Quality Team Charter!
Importance: High

Hi Jennifer. As we discussed on Friday, I have provided my input on some essential "project management" elements that I feel would help our chances for a successful completion of the study. See attached revised Charter with my edits in blue. Thanks....and pls confirm receipt. I'm out on Tuesday but in the office on Wed and Thursday this week. Regards, Zach

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Attachments:

Shanghai Health Data and Process Quality Assurance.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. This team will facilitate progress of this study by developing and instituting a rigorous data and process quality assurance program for data management.

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:

(I think the team is too large – 5 would be better)

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 – Industrial Hygienist, SRP
Dr. Rob Schnatter – Epidemiologist, Adjunct PI

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

Team Responsibilities:

This team will ensure a system is in place (defined processes, roles and responsibilities, process reviews, project timeline with goals & milestones, and key metrics) to provide oversight for:

- (1) data and process quality control
- (2) data capture, analyses and transfers are done in a timely, accurate, complete, consistent and secure manner
- (3) data tracking and progress reporting
- (4) effective communications and collaboration among investigators

Ensure that data and process quality are maintained; facilitate study timeline and data transfer between principal investigators. The quality of the data and processes will be assured by using fully *reviewed and documented* data quality and data transfer processes and periodic audits. Processes will be developed to further delineate roles and responsibilities. These procedures will result in enhanced communication and scientific excellence.

Deliverables:

The team will determine appropriate metrics, goals & milestones and track progress, and submit them to the team *(which team? Is this the Oversight team?)* on the 15th of each month. There should be both process and result

metrics which reflect the progress of the study and may include:

- **Regular, periodic review of data and processes**
- **Documentation of data flow and data entry**
- **Cases accrued: AML and NHL**
- **Progress on key milestones and goals**
- **Process: Timeliness and accuracy of data collection, analyses and entry into database**
- **Number of data audits, process reviews, and QA review meetings**
- **Process: Level of investigator satisfaction**
- **Percent of consent forms and questionnaires signed**
- **Percent of consent forms/questionnaires entered into database**
- **Development of QA/QC program for final year**
- **Other metrics deemed necessary by the team**

Timeline: First metrics report – March 15, 2007

The PI's will implement recommendations of the QA/QC team.

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

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