

- (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.