

This document spells out the expectations of API and the Study sponsors with regard to the contract for supplemental funding to CinPathogen for completion of the Shanghai Health Study. Consistent with the original scope of work for the Study and grant, the design, performance and conclusions of the Study are in the sole control of the principal investigators. The milestones laid out in this document are not intended to change that, or in any way to request or require divulgence of data or interim results to the sponsors or API prior to acceptance of manuscripts for publication in scientific journals. The purpose of requesting the milestone reporting set forth herein is for the sole purpose of allowing API and the Study Sponsors Oversight Committee to fulfill their obligations to monitor costs and the progress of the study, with numbers of cases reported and other factors used as benchmarks of study progress.

1. Short-term milestones to be achieved in the second quarter, 2007.

- a. In May 2007, provide an update of the numbers of AML and NHL¹ cases that can be used in the case-control study.
- b. Reestablish case accrual at participating Shanghai Hospitals
 - i. Provide an accounting of the number of participating hospitals before and after the transition to IBS.
 - ii. Provide an estimate for case accrual in 2Q (AML and NHL), 3Q, and 4Q (lymphoid only – should this be NHL?) and provide an update of the numbers of cases that can be used in the case-control study on a quarterly basis (approximately July, October, and January 2008.)
 - iii. Within the new administrative structure, provide arrangements for continued review of original work history questionnaires by Dr. Otto Wong and his associates.²
- c. Continue necessary exposure assessment activities for completion of the job-exposure matrix.
 - i. Provide expectations for exposure assessment activities until June 2008 and quarterly reports on progress toward those goals to the QA team.
- d. Cooperate with the independent QA/QC team to fulfill the elements of the QA/QC team charter.

2. Long-term milestones to complete the case accrual work by the end of 2007 and the entire study by the end of 2008.

- a. Provide to Applied Health Sciences by mid-September 2007³ a test data set consisting of all diagnosed and verified AMLs and NHLs and their matched controls, including detailed subtype diagnostic classifications, potential confounders and available exposure information (such as medical histories, family histories, lifestyle information, etc.) for testing the case-control protocol and for developing analytical programs.
- b. Provide to Applied Health Sciences by July 1, 2008³ a final data set consisting of all diagnosed and verified AMLs and NHLs and their matched controls, including detailed subtype diagnostic classifications, potential confounders and exposure assessment data, and all questionnaire information (such as medical histories, family histories, lifestyle information, etc.) for completion of the case-control protocol.

¹ Defined here as The WHO classification for lymphoid neoplasms.

² In cooperation with the independent QA/QC team.

³ Based on a timeline agreed upon in cooperation with the independent QA/QC team.

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- c. Complete a study cohort of those cases diagnosed prior to December 31, 2007 of hematopoietic and lymphoid neoplasms (should this be NHL?) and individually matched (2x) sets of controls selected randomly from the entire patient populations at the participating hospitals in Shanghai. Cases characteristics will also include:
 - i. Case selection following eligibility criteria in the March 18, 2007 DPME proposal, Section 8.1
 - ii. Documented informed consents and work history questionnaire administration for all cases and controls
 - iii. Cases of AML will be accrued through June 30, 2007
 - iv. Cases of NHL will be accrued through December 31, 2007
- d. Complete a benzene job-exposure matrix for cases and controls used in the case-control study. The matrix will consider job, task, industry and time period in developing exposure estimates to benzene. Data sources for exposure assessment including the IPHS data set, Yang Pu database, the Chinese literature, real-time monitoring in selected factories and simulations.
- e. Submit for publication to appropriate scientific journals manuscript(s) presenting the findings of the Disease Progression protocol following the guidelines in the March 18, 2007 DPME proposal, Section 3.1-A by November 1, 2008
- f. Submit for publication to appropriate scientific journals manuscript(s) presenting the findings of the Molecular Epidemiology protocol following the guidelines in the March 18, 2007 DPME proposal, Section 3.1-A by November 1, 2008.
- g. Implement the recommendations of the independent QA/QC team.
- h. Provide semi-annual progress reports to the Scientific and Ethics Review Panelists, Shanghai Health Study sponsors, and API. The update should include a cumulative list of papers submitted to the SRP/ERP for their review.