Within five calendar days of the receipt of funds, Cinpathogen will identify progress milestones to be achieved in the second quarter, 2007;

1. Update of the estimated NHL case numbers by ICD-9 classification in May 2007. [I would recommend dropping this deliverable and instead request updates based on lymphoid neoplasms (WHO) with documented informed consents and work history questionnaire administration for all cases and controls.]
2. Documentation of data flow and data entry for QA team
   a. Including review of SOP for data handling of work history information by the QA/QC team (including data-out, e.g., the virtual link between diagnostic data and exposure history data.)
3. Reestablish case accrual at participating Shanghai Hospitals
   a. Finalize arrangements for review of original work history questionnaires by Dr. Otto Wong or his associates as necessary*
4. Reestablish necessary exposure assessment activities for completion of exposure matrix

*In cooperation with the independent QA/QC team and Dr. Otto Wong.

Within fourteen calendar days of the receipt of funds, Cinpathogen will delineate deliverables and milestones to be utilized in the potential development of a contract with Cinpathogen to successfully complete the case accrual work by the end of 2007 and the entire study by the end of 2008. These deliverables and milestones should be consistent with the enhanced Quality Assurance/ Quality Control program and tie back to the partial Cinpathogen proposals of March 18, 2007 and April 5, 2007. Both the laboratory transition task and costs and the post study costs for the continued publication of study findings should be explicitly recognized by the Cinpathogen response.

Case Control Study

1. Cases diagnosed prior to December 31, 2007 of hematopoietic and lymphoid neoplasms (WHO, 2001) and a matched (2x) set of controls from participating hospitals in Shanghai that will include:
   a. Case selection follows criteria in Cinpathogen's March 18, 2007 DPME proposal, Section 8.1
   b. Documented informed consents and work history questionnaire administration for all cases and controls
   c. Cases of AML will be accrued until June 30, 2007
   d. Cases of lymphoid neoplasms will be accrued until December 31, 2007

2. A benzene exposure assessment matrix for all study cases and controls. The matrix will consider job, 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 will be used to arrive at credible benzene exposure estimates.

3. A substantial preliminary data set (including AMLs and lymphoid neoplasms by WHO criteria, confounders and the exposure assessment matrix) for testing the case-control protocol to Applied Health Science by September 2007*. [No ICD-9 classifications are being delivered for the case-control study.]

4. A final data set (including all cases of AML and lymphoid neoplasms diagnosis during the study by WHO criteria, confounders and the exposure assessment matrix) for completion of the case-control protocol to Applied Health Sciences by June 2008*. [No ICD-9 classifications are being delivered for the case-control study.]

*Based on a timeline agreed upon in cooperation with the independent QA/QC team and Dr. Otto Wong.

Disease Progression Studies

1. Publication quality manuscript(s) presenting the findings of the Disease Progression protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Molecular Epidemiology Study

1. Publication quality manuscript(s) presenting the findings of the Molecular Epidemiology protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Project Management

1. Implementation of the conditions in the agreement for advance funding for Cinpathogen (Red Cavaney to Richard Irons, April 11, 2007).

2. Implementation of recommendations from the independent QA/QC team.

3. Update of estimated NHL case numbers per ICD-9 classification in May 2007. Periodic updates throughout 2007 linked to diagnostic reviews which are on a nominal quarterly basis (approximately July, October, and January 2008.) [I would recommend dropping this deliverable and instead request updates based on lymphoid neoplasms with documented informed consents and work history questionnaire administration for all cases and controls.]

To: BenzConsort-OC@listserve.api.org <BenzConsort-OC@listserve.api.org>; BenzConsort-TC@listserve.api.org <BenzConsort-TC@listserve.api.org>
From: Howard Feldman <Feldman@api.org>
Cc:
Bcc:
Received Date: 2007-04-16 21:06:43 GMT
Subject: FW: Shanghai Health Study materials

> >

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Attachments:

CINPATHOGEN DELIVERABLES DRAFT 4-14-07.doc
GAP analysis 4-14-07.doc

Within five calendar days of the receipt of funds, Cinpathogen will identify progress milestones to be achieved in the second quarter, 2007;

1. Update of the estimated NHL case numbers by ICD-9 classification in May 2007. [I would recommend dropping this deliverable and instead request updates based on lymphoid neoplasms (WHO) with documented informed consents and work history questionnaire administration for all cases and controls.]
2. Documentation of data flow and data entry for QA team
   a. Including review of SOP for data handling of work history information by the QA/QC team (including data-out, e.g., the virtual link between diagnostic data and exposure history data.)
3. Reestablish case accrual at participating Shanghai Hospitals
   a. Finalize arrangements for review of original work history questionnaires by Dr. Otto Wong or his associates as necessary*
4. Reestablish necessary exposure assessment activities for completion of exposure matrix

*In cooperation with the independent QA/QC team and Dr. Otto Wong.

Within fourteen calendar days of the receipt of funds, Cinpathogen will delineate deliverables and milestones to be utilized in the potential development of a contract with Cinpathogen to successfully complete the case accrual work by the end of 2007 and the entire study by the end of 2008. These deliverables and milestones should be consistent with the enhanced Quality Assurance/ Quality Control program and tie back to the partial Cinpathogen proposals of March 18, 2007 and April 5, 2007. Both the laboratory transition task and costs and the post study costs for the continued publication of study findings should be explicitly recognized by the Cinpathogen response.

Case Control Study

1. Cases diagnosed prior to December 31, 2007 of hematopoietic and lymphoid neoplasms (WHO, 2001) and a matched (2x) set of controls from participating hospitals in Shanghai that will include:
   a. Case selection follows criteria in Cinpathogen's March 18, 2007 DPME proposal, Section 8.1
   b. Documented informed consents and work history questionnaire administration for all cases and controls
   c. Cases of AML will be accrued until June 30, 2007
   d. Cases of lymphoid neoplasms will be accrued until December 31, 2007

2. A benzene exposure assessment matrix for all study cases and controls. The matrix will consider job, 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 will be used to arrive at credible benzene exposure estimates.

3. A substantial preliminary data set (including AMLs and lymphoid neoplasms by WHO criteria, confounders and the exposure assessment matrix) for testing the case-control protocol to Applied Health Science by September 2007*. [No ICD-9 classifications are being delivered for the case-control study.]

4. A final data set (including all cases of AML and lymphoid neoplasms diagnosis during the study by WHO criteria, confounders and the exposure assessment matrix) for completion of the case-control protocol to Applied Health Sciences by June 2008*. [No ICD-9 classifications are being delivered for the case-control study.]

*Based on a timeline agreed upon in cooperation with the independent QA/QC team and Dr. Otto Wong.

Disease Progression Studies

1. Publication quality manuscript(s) presenting the findings of the Disease Progression protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Molecular Epidemiology Study

1. Publication quality manuscript(s) presenting the findings of the Molecular Epidemiology protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Project Management

1. Implementation of the conditions in the agreement for advance funding for Cinpathogen (Red Cavaney to Richard Irons, April 11, 2007).

2. Implementation of recommendations from the independent QA/QC team.

3. Update of estimated NHL case numbers per ICD-9 classification in May 2007. Periodic updates throughout 2007 linked to diagnostic reviews which are on a nominal quarterly basis (approximately July, October, and January 2008.) [I would recommend dropping this deliverable and instead request updates based on lymphoid neoplasms with documented informed consents and work history questionnaire administration for all cases and controls.]

Within five calendar days of the receipt of funds, Cinpathogen will identify progress milestones to be achieved in the second quarter, 2007;

1. In May 2007, provide an update of the numbers of AML and lymphoid neoplasms (WHO 2001) that can be used in the case-control study.
2. Reestablish case accrual at participating Shanghai Hospitals;
   a. Provide an accounting of the number of participating hospitals before and after the transition to IBS.
   b. Provide expectations for case accrual in 2Q, 3Q, and 4Q and provide an update of the numbers of cases that can be used in the case-control study on a nominal quarterly basis (approximately July, October, and January 2008.)
   c. Finalize arrangements for review of original work history questionnaires by Dr. Otto Wong and his associates as necessary*
3. Reestablish necessary exposure assessment activities for completion of exposure matrix;
   a. Provide expectations for exposure assessment activities until June 2008 and quarterly reports on progress toward those goals to the QA team. [RDW - Talk to Rob Schnatter]
4. Documentation of data flow, data entry, and roles & responsibilities within the Shanghai Health Study for review by the QA team;
   a. A specific objective should be a review of the SOP for data handling of work history information (including data-out, e.g., the virtual link between diagnostic data and exposure history data.)

*In cooperation with the independent QA/QC team

Within fourteen calendar days of the receipt of funds, Cinpathogen will delineate deliverables and milestones to be utilized in the potential development of a contract with Cinpathogen to successfully complete the case accrual work by the end of 2007 and the entire study by the end of 2008. These deliverables and milestones should be consistent with the enhanced Quality Assurance/ Quality Control program and tie back to the partial Cinpathogen proposals of March 18, 2007 and April 5, 2007. Both the laboratory transition task and costs and the post study costs for the continued publication of study findings should be explicitly recognized by the Cinpathogen response.

Case Control Study

1. Cases diagnosed prior to December 31, 2007 of hematopoietic and lymphoid neoplasms (WHO, 2001) 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:
   a. Case selection follows eligibility criteria in Cinpathogen's March 18, 2007 DPME proposal, Section 8.1
   b. Documented informed consents and work history questionnaire administration for all cases and controls
   c. Cases of AML will be accrued until June 30, 2007
   d. Cases of lymphoid neoplasms will be accrued until December 31, 2007

2. An account of all eligible AML and lymphoid neoplasm patients at all participating hospitals, who did not agree to participate or who were not interviewed, including

their basic demographic information and reasons for non-participation/non-interview (if available) will be provided.

3. 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 will be used to arrive at credible benzene exposure estimates.

4. A test data set consisting of all available AMLs and lymphoid neoplasms (WHO 2001) and their matched controls, including detailed subtype diagnostic classifications, confounders and job-exposure matrix, and all questionnaire information (such as medical histories, family histories, lifestyle information, etc.) for testing the case-control protocol and for developing analytical programs to Applied Health Sciences by mid-September 2007*. [RDW – Talk to Rob Schnatter/Otto Wong]

5. A final data set consisting of all available AMLs and lymphoid neoplasms (WHO 2001) and their matched controls, including detailed subtype diagnostic classifications, confounders and job-exposure matrix, and all questionnaire information (such as medical histories, family histories, lifestyle information, etc.) for testing the case-control protocol and for developing analytical programs to Applied Health Sciences by by July 1, 2008*.

*Based on a timeline agreed upon in cooperation with the independent QA/QC team and Dr. Otto Wong.

Disease Progression Studies

1. Publication quality manuscript(s) presenting the findings of the Disease Progression protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Molecular Epidemiology Study

1. Publication quality manuscript(s) presenting the findings of the Molecular Epidemiology protocol by November 1, 2008 following guidelines in Cinpathogen's March 18, 2007 DPME proposal, Section 3.1-A.

Project Management

1. Implementation of the condition number one and number three in the agreement for advance funding for Cinpathogen (Red Cavaney to Richard Irons, April 11, 2007).

2. Implementation of recommendations from the independent QA/QC team.

3. Provide semi-annual progress report to the Scientific and Ethics Review Panalists and API. The update should include a running list of papers submitted to the SRP/ERP for their review. [How do we include a look at "projected" publications?]