

To: Clegg, Patsy M SCC-DCS/22 <patsy.clegg@shell.com>; Tsai, Shan P SHLOIL-SHS
<Shan.Tsai@shell.com>
From: Cagen, Stuart Z SHLOIL-SHOIL-SHS
</O=SHELL/OU=MSXSCC/CN=RECIPIENTS/CN=SC724012>
Cc:
Bcc:
Received Date: 2007-04-23 20:01:23 GMT
Subject: RE: Shanghai Health Study - follow up

Patsy:

Do you think it would be worthwhile for the three of us to talk before the next Oversight committee call ?

Stuart Cagen, Ph.D.

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-----Original Message-----

From: Cagen, Stuart Z SHLOIL-SHOIL-SHS
Sent: Sunday, April 22, 2007 1:45 AM
To: Clegg, Patsy M SCC-DCS/22
Cc: Snyder, Phil J SDIUS-DXX/9; Tsai, Shan P SHLOIL-SHS
Subject: FW: Shanghai Health Study - follow up

Patsy:

The implications of the response from Rich Irons are not clear. The deliverables and milestones were developed at the Oversight Committee meeting late last year and were reinforced by the API executive committee via the letter from API as conditions for the advanced payment. I did not think these were merely suggestions.

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 (AML and lymphoid), 3Q, and 4Q (lymphoid only) 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 the job-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. Provide documentation of data flow, data entry, and roles & responsibilities within the Shanghai Health Study for review by the QA team;
 - a. A specific objective of their review will be data handling of consent forms and work history information to ensure that potential cases are included in the case-control study.

*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. Provide 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. Provide 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.

3. Provide a test data set consisting of all diagnosed and verified 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]

4. Provide a final data set consisting of all diagnosed and verified 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 completion of the case-control protocol to Applied Health Sciences by July 1, 2008*.

5. Provide 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).

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

Disease Progression Studies

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

Molecular Epidemiology Study

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

Project Management

1. Implementation of the conditions one and 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 Panelists, Shanghai Health Study sponsors, and API. The update should include a cumulative list of papers submitted to the SRP/ERP for their review. [Dr. Irons - Is there a way to estimate the number of "projected" publications?]

Thanks

Stuart

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-----Original Message-----

From: Howard Feldman [<mailto:Feldman@api.org>]
Sent: Saturday, April 21, 2007 8:48 PM
To: Brenda Hargett; Bob Greco; Harry Ng; BenzConsort-OC@listserve.api.org
Cc: Russell White
Subject: Fw: Shanghai Health Study - follow up

----- Original Message -----

From: Richard.Irons@UCHSC.edu
To: Russell White
Cc: Howard Feldman; myron.c.harrison@exxonmobil.com ; brian.e.doll@exxonmobil.com
; brian.e.doll@exxonmobil.com
; Patsy.Clegg@shell.com
; Burnetdm@bp.com
Sent: Sat Apr 21 13:21:39 2007
Subject: RE: Shanghai Health Study - follow up

Dear Dr. White,

I want to thank you and the oversight committee for your suggestions for deliverables and milestones to be included in our budget proposals to the BHRC and the API. The actual deliverables and milestones that will be provided by Cinpathogen and the UCDHSC as part of our response to your request for budget proposals will reflect our expectations based on conditions in the field, our desire to conduct good science as well as our best

efforts to comply with the recommendations of the Scientific and Ethics Review panels.

Thank you,

RDI

From: Russell White [mailto:whiter@api.org]
Sent: Fri 4/20/2007 10:57 AM
To: Irons, Richard
Cc: Howard Feldman
Subject: Shanghai Health Study - follow up

Dr. Irons,

Were there any questions on the draft deliverables and milestones I sent yesterday? I will check email over the weekend, please contact me if necessary.

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Attachments:

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