

To: Cagen, Stuart Z SHLOIL-SHOIL-SHS <stuart.cagen@shell.com>
From: ottowong@aol.com <ottowong@aol.com>
Cc: whiter@api.org <whiter@api.org>
Bcc:
Received Date: 2007-04-28 06:40:36 GMT
Subject: Fwd: Shanghai Health Study - DRAFT deliverables

Dear Stuart:

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Editorial Board, Regulatory Toxicology and Pharmacology

Tel: 1 (650) 347-7898
Fax: 1 (650) 344-6887
Email: OttoWong@aol.com

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

From: ottowong@aol.com
To: whiter@api.org; jarnotb@api.org
Cc: Jmricewas@aol.com
Sent: Mon, 16 Apr 2007 9:03 AM
Subject: Re: Shanghai Health Study - DRAFT deliverables

Dear Russ and Bruce:

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

From: whiter@api.org
To: OttoWong@aol.com ; Jmricewas@aol.com ; BenzConsort-TC@listserve.api.org
Sent: Thu, 12 Apr 2007 1:54 PM
Subject: Shanghai Health Study - DRAFT deliverables

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Otto - I have also attached the enrollment criteria for the case-control study, both the original text and the recent version from Cinpathogen. Let me know if you have any suggested changes in the Cinpathogen protocol. (FYI - Figure 8.1 was not included in the document we received from Cinpathogen. While Dr. Iron's said it was in the original version, I could not find it.)

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Attachments:

DRAFTModifiedDeliverables from WONG 2007-04-16.doc

SHELL-MCCLURG-054936

Case Control Study

- Cases diagnosed prior to December 31, 2007 of hematopoietic and lymphoid neoplasms (WHO, 2001) and a individually matched (2x) sets of controls selected randomly from the entire patient populations at the participating hospitals in Shanghai that will include:
 - Case selection following criteria ("eligibility") in Cinpathogen's March 18, 2007 DPME proposal, Section 8.1
 - Documented informed consents and work history questionnaire administration for all cases and controls
 - Verified diagnoses of approximately 500 - 600 cases of AML
 - Cases of NHL (i.e., lymphoid neoplasms) will be accrued until December 31, 2007
- An account of all eligible AML and NHL 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. [Note: This information is vital in assessing whether there is any selection bias between participating and non-participating, but otherwise eligible, AML and NHL patients.]
- A benzene job-exposure assessment matrix (JEM) for all study cases and controls for use in the case-control protocol. The matrix will consider task, 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. Supporting and other relevant documents of the JEM will also be provided.
- A substantial-preliminary test data set (including consisting of all available AMLs and NHLs diagnosed by WHO and ICD-9 criteria and their matched controls), including detailed subtype diagnostic classifications, confounders and job-exposure assessment 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*.
- A final data set (including consisting of all AMLs and NHLs diagnosed by WHO and ICD-9 criteria and their matched controls), including detailed subtype diagnostic classifications, confounders and job-exposure assessment 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*.

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

To: whiter@api.org <whiter@api.org>
From: ottowong@aol.com <ottowong@aol.com>
Cc: Cagen, Stuart Z SHLOIL-SHOIL-SHS <stuart.cagen@shell.com>
Bcc:
Received Date: 2007-04-28 14:43:33 GMT
Subject: Re: Shanghai Health Study - DRAFT deliverables

Dear Russ:

Thank you for the quick response (working on Saturday morning!).

I think we should wait and see how Rich Irons reacts to the final deliverables. Hopefully, he will be able to meet most of them and there will be no major issues going forward with the new schedule/timeline.

When I talked with Rob Schnatter on Thursday, he did not think the deliverables were unreasonable. I also talked with Tom Armstrong last week as well, and he is willing to give me at least some preliminary exposure estimates in the test data sets as soon as possible. All it takes is Rich Irons' approval.

Certainly I will not insist on something that's unreasonable or infeasible. I simply want to know what will be available to me by when, so that I can realistically plan the timeline of completing the case-controls study.

Thanks your help.

Otto

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

From: whiter@api.org
To: ottowong@aol.com; stuart.cagen@shell.com
Sent: Sat, 28 Apr 2007 4:34 AM
Subject: RE: Shanghai Health Study - DRAFT deliverables

Otto,
While Rich Irons has seen the "draft" deliverables, the final version should be available this Tuesday. I'll make sure you and Rich get a copy.

From: ottowong@aol.com [mailto:ottowong@aol.com]
Sent: Saturday, April 28, 2007 2:40 AM

SHELL-MCCLURG-054939

To: stuart.cagen@shell.com
Cc: Russell White
Subject: Fwd: Shanghai Health Study - DRAFT deliverables

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Cc: Cagen, Stuart Z SHLOIL-SHOIL-SHS <stuart.cagen@shell.com>
Bcc:
Received Date: 2007-05-04 14:47:14 GMT
Subject: Re: Shanghai Health Study - DRAFT deliverables

Russ:

Thank you for the update. I will contact Rich Irons regarding the deliverables for the case-control study after he has looked at them.

Otto

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Cc: stuart.cagen@shell.com
Sent: Fri, 4 May 2007 6:21 AM
Subject: RE: Shanghai Health Study - DRAFT deliverables

Otto,

Sorry for the delay. There were comments from company members that forced a second draft to be circulated. The final document should be done on Monday (May 7).

From: ottowong@aol.com [mailto:ottowong@aol.com]
Sent: Thursday, May 03, 2007 10:58 AM
To: Russell White
Cc: stuart.cagen@shell.com
Subject: Re: Shanghai Health Study - DRAFT deliverables

Dear Russ:

Just to follow up your email last week, have you sent out the revised version of the deliverables to Rich Irons? I would like to see a copy as well.

Many thanks,

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