

From: Bruce Jarnot <jarnotb@api.org>
Sent: Tuesday, May 15, 2007 7:16 PM (GMT)
To: BenzConsort-OC@listserve.api.org
Cc: BenzConsort-TC@listserve.api.org; Howard Feldman <Feldman@api.org>
Subject: BHRC-OC... for 5/17 Conf Call: Rev timeline & budget for CC study
Attach: Letter to Bruce Jarnot 2007-05-12.pdf; AHS additional budget for 2007 & 2008 (2007-05-12).pdf

BHRC Oversight Committee (OC) –

First of 2 new items for Thursday's BHRC-OC conference call agenda ...

Dr. Otto Wong revised the timeline and budget (see attached letter, budget file) for AHS's completion of the Case Control (CC) study, to be synchronized with the new Cinpathogen-UCHSC timeline for CC study deliverables:

- Test set data: Cinpathogen expects to deliver "test set" data to UCHSC or its designee by Sept 15, 2007; Adding an estimated 2 weeks for UCHSC or its designee to compile & deliver the data to AHS = October 01, 2007 estimated availability to Dr. Wong / AHS;
- Final AML/NHL/control data: Cinpathogen expects to deliver a final, complete set of study data to UCHSC or its designee by July 31, 2008; adding 4 weeks estimated for UCHSC or designee to compile study data & deliver to AHS = August 31, 2008 estimated availability to Dr. Wong / AHS.

Best Regards – Bruce.

From: ottowong@aol.com [mailto:ottowong@aol.com]
Sent: Saturday, May 12, 2007 7:29 PM
To: Bruce Jarnot
Subject: Revised timeline & budget for CC study

Dear Bruce:

I have prepared a revised timeline and additional budget for the CC study (attached). I am being somewhat optimistic in projecting the date of completion. According to your email, the final dataset will be ready for us by the end of August 2008. We need about four to six months for data editing, analysis and report preparation, depending on the status of the final dataset. Most likely we will be able to submit our report around the end of 2008 or the beginning of 2009. I hate to be the first one to even mention "2009." Therefore, I have set the end of 2008 as our goal and we will try our best to meet that goal.

If you have any questions, please let me know. I am leaving for Hong Kong tomorrow. I will be teaching there for a week and then go to Shanghai to work on SHS. I can be reached by email.

Thank you for your help.

Regards,

Otto

Otto Wong, Sc.D., F.A.C.E.

Fellow, American College of Epidemiology

Chief Epidemiologist, Applied Health Sciences, San Mateo, California, USA

Adjunct Professor of Epidemiology, University of North Texas, Fort Worth, Texas, USA

Adjunct Professor of Community Medicine, Chinese University of Hong Kong

Honorary Professor of Community Medicine, University of Hong Kong

Visiting Professor of Occupational Epidemiology, Fudan University, Shanghai

Associate Editor, Annals of Epidemiology

Editorial Board, Regulatory Toxicology and Pharmacology

Tel: 1 (650) 347-7898

Fax: 1 (650) 344-6887

Email: OttoWong@aol.com

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

From: jarnotb@api.org

To: OttoWong@aol.com

Sent: Fri, 11 May 2007 9:53 AM

Subject: Please call me... 202-682-8473 (W) or 410-535-9846 (H)

Dear Otto –

Please call me at your earliest convenience, either at work (before 12:30pm PDT Friday, or Monday: 202-682-8473) or at home (after 3:00pm PDT Friday, or anytime over the weekend: 410-535-9846)...

I want to submit the AHS contract amendment request as soon as possible (i.e., by early next week); to do this, I need you:

- 1) to e-mail a copy of the latest AHS revised proposal / revised budget to me; and
- 2) to confirm that the timeline in this latest AHS revised proposal / revised budget is synchronized with the new Cinpathogen-UCHSC timeline for Case Control study deliverables...
 - a. Test Set Data available by Oct 1st, 2007: Cinpathogen is expected to deliver “test set” data to UCHSC or its designee (Gail Jorgenson under contract to UCHSC) by Sept 15, 2007; add 2 weeks for UCHSC/designee to compile data & deliver to AHS = Oct 01, 2007.
 - b. Final AML/NHL/Control data available by August 31, 2008: Cinpathogen is expected to deliver the final, complete data set to UCHSC or its designee (Gail Jorgenson under contract to

UCHSC) by July 31, 2008; adding 4weeks for UCHSC/designee to compile data & deliver to AHS =
August 31st, 2008.

With Very Best Regards - Bruce.



size=2 width="100%" align=center>

AOL now offers free email to everyone. Find out more about what's free from AOL at AOL.com.

Applied Health Sciences, Inc.
Post Office Box 2078
San Mateo, California 94401
USA

Otto Wong, Sc.D.
Fellow of American College of Epidemiology
Associate Editor of *Annals of Epidemiology*
Adjunct Professor of Epidemiology
University of North Texas Medical Center, Fort Worth, USA
Adjunct Professor of Community & Family Medicine
Chinese University of Hong Kong, Hong Kong, China
Honorary Professor of Community Medicine
University of Hong Kong, Hong Kong, China
Visiting Professor of Occupational Epidemiology
Fudan University Medical Center, Shanghai, China
Editorial Board, *Regulatory Toxicology & Pharmacology*

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

12 May 2007

Bruce M. Jarnot, Ph.D., DABT
Senior Toxicologist
Regulatory and Scientific Affairs
American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

Re: Revised timeline and additional budget for the completion of the case-control study

Dear Bruce:

I am writing to follow-up our recent discussions of revising the timeline and budget estimate for the completion of the case-control study of AML and NHL.

As a result of the new timeline of deliverables from Cinpathogen, both the timeline and the budget for the case-control study will be significantly affected, and both need to be revised. I have been asked, for the purpose of projecting a new timeline and estimating additional budget for the case-control study, to assume that AML case accrual will end by June 2007 and that for NHL patients by December 2007. Your email dated 10 May 2007 further indicates that we will receive from Cinpathogen a comprehensive test dataset by the end of September 2007 and the final dataset with complete diagnostic, exposure and questionnaire information ready for analysis by the end of August 2008.

Based on these newly projected dates of deliverables, I have revised the timeline for the completion of the case-control study (see below). I am being slightly optimistic and project that we may be able to complete our analysis and report within four months after we receive the final dataset. However, I must emphasize that I am being optimistic. The actual date of completion of the case-control study will depend heavily on the date of delivery and the status of the final dataset, but for planning purposes I will set the end of 2008 as our goal.

Revised timeline for the case-control study

Tasks	Date
Test dataset to AHS*	September 2007
Exploration of test dataset	October-November 2007
QA/QC of test dataset	November-December 2007
End of patient accrual*	December 2007
Development of analytical programs/plans	December 2007-May 2008
Final diagnoses of all patients completed*	March 2008
Interviews of all patients completed*	March/April 2008
Questionnaire data entry completed*	May 2008
Exposure assessment completed*	July 2008
Final dataset ready for analysis to AHS*	August 2008
Final QA/QC and data editing	September-October 2008
Statistical/epidemiological analysis	September-November 2008
Preparation of draft report	September-November 2008
Consultations with SRP members	September-December 2008
Preparation of final report	December 2008

* activities not under AHS control.

As indicated in the timeline above, some of our most important tasks can be carried out in 2008 only after patient accrual has been completed, diagnoses have been finalized and exposure classifications have been assigned. In projecting the above timeline, we assume that we will receive a final dataset with complete information ready for analysis by August 2008. Any delay in receiving the final dataset or any unanticipated additional preparation or processing of the final dataset will have an impact on the projected timeline.

At this moment, there is no budget for the case-control study at all for 2008. (Please refer to the contract amendment signed between American Petroleum Institute and Applied Health Sciences in November 2006, Contract No. 2004-101153, Amendment No. 1.) Additional funding will be needed. Attached is a spreadsheet detailing the additional budget needed to complete the case-control study. Again, the budget estimate is based on the assumptions and timeline outlined above. Any changes in our assumptions will likely affect the budget.

Additional amounts needed by year (2007 and 2008) are itemized and justified in the attached budget (dated 2007-05-12). We are requesting the following additional amounts by year:

Year 2007	\$184,695
Year 2008	\$703,505
Total	\$888,200

These amounts are needed in addition to those already approved in the November 2006 amendment (Contract No. 2004-101153, Amendment No. 1.).

I am assuming that I will continue to be assisted by Professor Fu's group in connection with the case-control study, particularly with my QA/QC activities in Shanghai. Professor Fu's graduate assistants are also assisting me in a literature review of occupational and non-occupational risk factors of subtypes of AML and NHL. I anticipate that Professor Fu's group will also participate in analysis and report preparation. For the past years, Professor Fu had a separate contract with API to assist me in these activities. If Professor Fu's contract is not renewed, then we need to explore other appropriate alternatives.

Please note that I have reserved both time and budget for interacting with members of the SRP in the last quarter of 2008. I anticipate that I will seek advice and suggestions in both analysis and report preparation from SRP members in the final months of the study. By the same token, API should budget separately some time for the SRP members to interact with me.

If you have questions, please let me know.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Otto Wong', written in a cursive style.

Otto Wong, Sc.D.
Chief Epidemiologist

Enclosure: AHS additional budget for 2007 & 2008