

From: Bruce Jarnot <jarnotb@api.org>
Sent: Thursday, April 12, 2007 3:21 PM (GMT)
To: Jmricewas@aol.com; BenzConsort-TC@listserve.api.org
Cc: Russell White <whiter@api.org>; OttoWong@aol.com; Howard Feldman <Feldman@api.org>; Fitzsimmons, Mark <MFitzsimmons@steptoe.com>
Subject: SHS... Rev Timeline & Conf Call reminder w/ Dr. Wong - Thurs 12 April, 1:30pm EDT
Attach: CC study timeline 2007-02-15.pdf

A reminder about today's PI conference call with Dr. Wong, along with a **revised timeline** (attached file) for discussion on the call:

AGENDA

- Antitrust review (M. Fitzsimmons)
- Case Control study update (O. Wong)
 - revised timeline

DIAL-IN INFORMATION

- Day/date: Thursday, April 12
- Start time: 1:30^{PM} Eastern / 12:30^{PM} Central / 10:30^{AM} Pacific
- Phone #: toll-free (866) 443-0059
- PIN Code: 202-682-8473-#

Best Regards – Bruce.

From: OttoWong@aol.com [mailto:OttoWong@aol.com]
Sent: Thursday, April 12, 2007 11:05 AM
To: Bruce Jarnot
Cc: Russell White; Jmricewas@aol.com
Subject: Re: SHS... Conf Call w/ Dr. Wong - Thurs 12 April, 1:30pm EDT

Dear Bruce:

Good morning.

I would like to discuss the revised timeline for the case-control study later today during our conference call. The revised timeline was attached to our last progress report dated 15 February 2007. For convenience, I have attached it to this email. I would appreciate it very much if you could send it out to all conference call participants before the call.

Many thanks,

Otto

Otto Wong, Sc.D., F.A.C.E.
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See what's free at <http://www.aol.com>.

Timeline for the Case-control Study

(from Applied Health Sciences progress report dated 15 February 2007)

The current understanding is that patient accrual will be extended to the end of 2007. Given the new end date for case accrual, final diagnoses, control selection, and interviews will most likely be completed around the end of the first quarter of 2008. Exposure assessment of newly enrolled patients (cases and controls) will be conducted in the first and second quarters of 2008. Assuming that both diagnostic and exposure data for all patients will be finalized and available by June 2008, Applied Health Sciences (AHS) will be performing epidemiologic analyses of the final data in the third quarter of 2008.

To facilitate data transfer/linkage and to develop plans for statistical analyses, however, AHS needs large and representative samples of study subjects with all questionnaire information, exposure estimates, and final diagnoses by mid-2007 (see the timeline table below). These samples will have sufficient details to allow AHS to develop plans for data QA/QC, data transfer/linkage and to test-run analysis programs.

The timeline of the case-control study depends heavily on the timing when diagnostic and exposure data (both test data samples and final complete data sets) are provided to AHS. The delay of any one event in the timeline will likely affect the others. The revised timeline below for the case-control study is based on the current understanding and assumptions above.

Revised timeline of the case-control study

Tasks	Date
Test data sets to AHS*	June 2007
QA/QC of test data sets	July-September 2007
Development of analytical programs/plans	October 2007-March 2008
End of patient accrual*	December 2007
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*	June 2008
Final QA/QC and data editing	July-August 2008
Complete final data to AHS*	End of June 2008
Statistical/epidemiological analysis	August-September 2008
Preparation of draft report	September-October 2008
Presentation of study results	October 2008
Discussion with SRP	October-November 2008
Preparation of final report	October-December 2008

* Activities not under the control of AHS.