

ACC Coordinating Center Q2 Quarterly Progress Report April – June 2008

Executive Summary

The Coordinating Center is pleased to submit this quarterly report for your review. We have just completed a very productive Q2, with substantial progress made by both the ACC and the Coordinating Center. We accomplished the majority of the goals we set for ourselves while deferring a few tasks to Q3.

The quarter began with a successful Spring meeting in San Diego, CA, on April 11th, with representatives from Korea, Singapore, Malaysia, Taiwan, IARC (Iran), University of Chicago (Bangladesh), Japan, Vanderbilt (China), and NCI. ACC participants addressed a range of issues including a possible pilot project to study BMI and overall mortality in Asian populations.

During this quarter, a working group of a dozen ACC and CC members was established to coordinate this pilot project. Working group participants have addressed initial study design and project concerns, and will conference regularly as the project progresses. The BMI pilot project will be the first ACC collaborative endeavor and is expected to provide insight for optimizing future collaborative activities.

Essential to reviewing future collaboration potential, data-sharing and harmonization efforts have continued with the receipt of sample data from Singapore and Korea. The CC received IRB approval to access data from ACC-affiliated sites and has begun assessing data management, CDE and data-mapping strategies.

To further coordinate these current and prospective ACC activities, the CC has completed development of a secure web-based portal. The portal will be online shortly to facilitate communication, exchange information, and monitor progress as the next quarter begins.

Specific objectives for Q3 include the development of an external communications plan, continued CDE development, delivery of a new-cohort packet, and preparation for the Fall meeting. The CC will facilitate the ACC in these efforts and looks forward to a productive quarter.

Full Report

As the first quarterly progress report for submission, this report includes specific ACC and Coordinating Center (CC) objectives for both Q1 and Q2.

Coordinating Center Developments

In Q1 and Q2, the CC focused on hiring staff and putting goals and objectives, as well as policies and procedures, in place. Betsy Rolland, MLIS, was hired as the Coordinating Center Project Manager and Briana Smith, MPH, joined the CC as the Program Assistant. Both are based at the Fred Hutchinson Cancer Research Center in Seattle, WA, USA.

Spring Meeting in San Diego, California

The ACC held a successful Spring meeting on April 11th in San Diego, CA. The meeting was attended by 20 collaborators, including representatives from the FHCRC, Korea, Singapore, Malaysia, Taiwan, IARC (Iran), University of Chicago (Bangladesh), Japan, NCI, and Vanderbilt (China). Attendees collaboratively restructured the organization and responsibilities of working groups as well as the Steering and Executive Committees. They also defined membership requirements, reappointed current co-chairs, and reviewed short- and long-term goals.

Policies and Procedures Manual

Conclusions from the Spring meeting were incorporated in the newly drafted Policies and Procedures Manual, which received ACC approval in Q2. The CC has deferred the development of a CC Protocol for use in grant submissions and IRB renewal documentation to Q3.

Cohort Development

Existing cohorts continued to actively recruit study participants and conduct planned analyses throughout the quarter, as presented at the Spring meeting. No new cohorts have formally joined the ACC in Q2; however, the CC is preparing a new-cohort packet for Q3 delivery. This packet will evolve into a resource for new cohorts who want to join the ACC, providing information on minimum standards for biospecimen collection, standard consent forms and common data elements for data collection.

Working Group Activities

The BMI WG was established to coordinate a pilot project to study BMI and mortality, as proposed at the Spring meeting. The WG is chaired by Drs. Wei Zheng of Vanderbilt University and Paolo Boffetta of IARC and is comprised of twelve participants representing ACC members, CC staff, and other potential collaborators. This is the only WG currently active in the ACC. It was agreed at the Spring meeting that WGs would form and meet only in response to pilot projects or other perceived needs.

Pilot Project(s)

On June 5th, the BMI WG held a conference call to kick-off the BMI pilot project. Eleven WG members and CC staff participated. Participants addressed issues of authorship, IRB approval, study design and cohort recruitment.

The following timeline has been proposed:

April 11, 2008	Concept proposal discussed and approved
June 6, 2008	Conference Call
June 30, 2008	Finalize prioritized contact list and inclusion criteria
July 1, 2008	Begin surveying selected cohorts (approx. 6 weeks)
August 18, 2008	Finalize list of included cohorts
September 1, 2008	Begin data collection processes and pooled analysis

As Q3 begins, the CC will continue to facilitate IRB certification, cohort surveys, and additional activities to advance the project according to the proposed schedule. We are also engaged in defining the process of proposing and executing a pilot project within the ACC.

Harmonization Efforts

Deanna Stelling and Peter Lin of the CC developed Common Data Elements (CDEs) and mapping algorithms for questions on physical activity, reproductive history, alcohol consumption, tobacco use, and medical history. The CC will continue to explore solutions to harmonization barriers in these areas for the ACC to consider. CDE development on the remainder of harmonization areas identified at the Fall 2007 meeting will also continue into Q3. For more information on Deanna and Peter's presentation on CDEs, please see the minutes from the Spring meeting.

Specimen collection procedures were reviewed for future use opportunities during the Spring meeting. The development of harmonized procedures based on that review has been postponed until Q3.

The CC reviewed protocol documents on file from member cohorts, including IRB approvals, institutional assurances, QC procedures, protocols and informed consents. The CC delayed requesting any available revisions of these documents from cohorts until IRB approval with current documentation was approved. The CC evaluated the content of informed consent forms from Korea, Singapore and Malaysia, and notified these members on areas of divergence; the potential for harmonization will be revisited as necessary.

Data-sharing & Analysis

The CC IRB application was submitted and approved, permitting the CC to receive and analyze data for cross-cohort projects. Sample data were submitted to the CC from Singapore and Korea with accompanying certification letters, which authorize CC use of the data. Preliminary data analysis has begun to assess the feasibility of future data-sharing, as well as evaluating the

security and data containment structures developed by the CC. The CC is scheduled to begin pooled analysis on the BMI pilot project data later this year.

Communication

Streamlining communications and developing an online space for collaboration are two of the primary goals of the CC. To that end, the CC registered the domain “www.asiacohort.org” for the ACC. Mailing lists for individuals associated with the ACC, members and BMI working group participants were established in order to coordinate communication at various levels. In addition, the secure members’ portal was developed and the CC is finalizing content and access authorization for Q3 delivery. The external section of the portal and finalization of an external communications strategy have been rescheduled for Q3, as it will require further input from the ACC.

An account for conference calls was established for WG, Steering Committee and other necessary meetings. The CC will continue to refine procedures for coordinating conference calls, including scheduling and action item follow-up.

Q3 Objectives

The following objectives have been proposed for Q3:

ACC

- Work towards the harmonization of data collection instruments and continue appropriate Common Data Elements (CDEs) development.
- Identify other areas where harmonization of procedures may be advantageous.
- Establish strategy for external communications regarding the ACC.
- Develop other possible pilot projects and a process to evaluate them.
- Identify and plan for 2009 goals at fall meeting.

CC

- Organize fall meeting.
- Draft External Communications Plan based on the ACC-established strategy.
- Draft Internal Communications Plan.
- Provide support for harmonization of data collection instruments and development of appropriate CDEs.
- Create data mapping algorithms for smoking and exercise data.
- Facilitate discussion of 2009 goals at Fall meeting.
- Propose new-cohort packet.

*We welcome your feedback and comments.
Thank you for your contributions to the success of the ACC.*