April 11, 2013

COORDINATION OF CANCER CLINICAL TRIALS
FOR ADOLESCENTS AND YOUNG ADULTS (AYA)

Thursday, April 25, 2013
1:00 – 9:00 pm

Thank you for agreeing to participate in this special meeting designed to think through how, as an investigative community, we can better address the needs of adolescent and young adult (AYA) cancer patients through the conduct of high-quality multi-centre clinical trials. This meeting is linked to the NCIC CTG Annual Spring Meeting of Participants, and we welcome colleagues from the Canadian C17 Group, the US Children’s Oncology Group, and the National Cancer Institute’s Cancer Therapy Evaluation Program.

This meeting is based on the premise that AYA cancer patients have unique and unmet needs. Our general objective is to address the special requirements and facilitate the conduct of cancer clinical trials for the AYA population as is based on the following observations or assumptions:

i) While cancer outcomes of pediatric and adult patients have improved, similar improvements have not been observed in the AYA population;

ii) The AYA population is under-represented in cancer clinical trials;

iii) Health care delivery systems for managing pediatric and adult cancer patients are dichotomized;

iv) While there are well-developed cancer clinical trials networks, and these have relatively sophisticated international coordination processes among pediatric networks and among adult networks, there is poor coordination between pediatric and adult networks;

v) Separate from scientific priorities that address AYA cancer patients, substantial barriers are associated with the operational aspects of conducting cancer clinical trials for this population;

vi) Complex regulatory compliance issues exist and addressing these issues across the dichotomized pediatric/adult health care delivery systems and across their separate trials networks represent special barriers to the conduct of trials that include the AYA population; and,

vii) Operational complexities associated with AYA cancer clinical trials are generic to the cancer clinical trials enterprise and strategies to address these issues for this population represent a “pilot effort” to address broader operational, including regulatory, requirements associated with the entire enterprise.

From these assumptions, we identified a number of priorities that might be addressed in a single 1-day meeting that could have the potential to result in specific conclusions being reached and bridges being
built, including: alignment of respective scientific committees, trial prioritization and activation processes, regulatory and operational aspects associated with trial conduct, and information technology (IT) capabilities. From these items, we concluded that, in order to ensure we have a durable platform of success, our priority should be to address the last two items: regulatory / operational and IT supports. Our (ambitious) hope is that we successfully address these issues so that, by the end of 2013, two new clinical trials accessible to the entire AYA population across the pediatric/adult communities would be activated.

The range of experience and perspectives of attendees is very broad. The format of the meeting is intended to be informal and interactive and based on the recognition that much knowledge will exist ‘around the table’. Thus, after some initial presentations to set the stage, the meeting will include two main components:

1. An open session associated with a ‘matrix’ of topics (see Table). While we recognize the importance of each cell varies and that the optics of the table may undervalue the interactions among some stakeholder groups, the intent of the table is to facilitate discussion. Next week we will post an updated Table, which will include “assignment of attendees” to, we hope, reflect your area of expertise. A Central Office staff member will be assigned to each cell who will be tasked with summarizing the discussion.

2. Subsequent sessions will aim to synthesize what we anticipate to be wide-ranging discussions associated with the cells within the table.

Hopefully, the attached agenda makes all of this clear.

Again, thank you for attending. We look forward to seeing you and to a lively and fruitful discussion.

Yours sincerely,

Ralph M. Meyer, MD, FRCP(C)
Edith and Carla Eisenhauer Chair in Clinical Cancer Research
Director, NCIC Clinical Trials Group
Professor, Departments of Oncology, Medicine, and & Community Health and Epidemiology

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Table: Agenda Item – Operational Issues of Trial Conduct

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Questions to consider:

1. What are the items that belong in each cell?

2. What are the issues associated with each item that create a vulnerability for:
   • competency?
   • efficiency?

3. What items / cells require activities that:
   • must be done in duplicate?
   • are best done in duplicate?
     ○ when duplicate systems exist, how are these best coordinated?
   • might be better done under one system?