NCIC Clinical Trials Group
2004 Spring Meeting of Participants

Clinical Research Associates Committee
CRA Workshops & Disease Site Information Fair

Delta Chelsea Hotel, Toronto, ON
Friday, April 16, 2004, 10:30 a.m. – 4:30 p.m.

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<tr><th>Room:</th><th>Mountbatten B</th><th>Seymour</th><th>Stevenson</th><th>Scott B</th><th>Scott A</th></tr>
<tr><td>10:30-11:00</td><td rowspan="2">N/A</td><td rowspan="2">N/A</td><td rowspan="2">LY.12</td><td rowspan="2">Ethics & Regulatory Workshop</td><td>Preparing for an audit</td></tr>
<tr><td>11:00-11:30</td><td>Preparing for an audit</td></tr>
<tr><td>11:30-1:30</td><td colspan="5">CRA Information Fair - Churchill Ballroom
(Buffet Lunch Provided)</td></tr>
<tr><td>1:30-2:00</td><td rowspan="2"></td><td rowspan="2">SAEs</td><td></td><td rowspan="2">Ethics & Regulatory Workshop</td><td rowspan="2"></td></tr>
<tr><td>2:00-2:30</td><td>CTSU</td></tr>
<tr><td>2:30-3:00</td><td colspan="5">BREAK</td></tr>
<tr><td>3:00-3:30</td><td rowspan="2"></td><td rowspan="2">AdEERS</td><td rowspan="2">CRF Completion</td><td rowspan="2">MA.21</td><td></td></tr>
<tr><td>3:30-4:00</td><td></td></tr>
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CRA WORKSHOPS

Friday, April 16, 2004

Title: **CTCAE v.3 – Room: Mountbatten Salon 9:00 – 10:00 a.m.**
(Common Terminology Criteria of Adverse Events Version 3)

Speaker: Monica Bacon, Study Coordinator, NCIC Clinical Trials Group

Purpose: Educational

Description: "You Asked - We Deliver" At the October 2003, NCIC CTG meeting, a CTCAE v.3 education session was presented to one designate CRA per centre. Your feedback clearly indicated your desire to have this session presented to all CRAs. This one's for you!

Title: **LY.12 Trial Workshop – Room: Stevenson 10:30 – 11:30 a.m.**

Speaker: Nancy Paul, Study Coordinator, NCIC Clinical Trials Group

Purpose: Trial start-up workshop.

Description: This workshop will begin with a brief overview of the trial design and case report forms set, but move quickly to hands-on discussion of case scenarios. With two randomizations and various paths for patients to follow, LY.12 can be a challenge to navigate. Ruth Turner and Diane Taylor work with the study chair, Michael Crump, at Princess Margaret Hospital in Toronto; they will share their experience of having 11 patients already on trial. As well, the workshop will serve as a "launch" for the long-awaited Lost Productivity questionnaire to be completed by study patients during the salvage chemotherapy period. Nancy Risebrough, senior research associate with the Health Outcomes and PharmacoEconomics (HOPE) Research Centre, will review with workshop participants the health economics data collection goals of LY.12.

Title: **Test Your EQ… - Room: Scott B** **10:30 – 11:30 a.m.**
(what is your Ethics Quotient?) **1:30 – 2:30 p.m.**

Speakers: CRA ERI Subcommittee members:

Phyllis Bettello, Chair, CAPS
Nancy Pus, CANH
Tanis Coletti, CAVC
Tammy DeGelder, CALM
Judith Elise Marcoux, CAGS
Lois Crowe, CAKO
Wendie Templeton, CASA
Melanie Walker, NCIC CTG
Laurie Vaughan-Evans, NCIC CTG

Purpose: To provide an educational and interactive session on ethics and regulatory issues of relevance to Clinical Research Associates working in cancer clinical trials.

Description: NCIC CTG trials are subject to NCIC CTG policy as well as external guidelines and legislation as applicable to the given study. This has implications for the ethics review and regulatory adherence that a centre must abide by when participating in NCIC CTG trials.

Given the complex regulatory environment, the objective of this workshop is to provide an opportunity for CRAs to both 'test' their current knowledge and familiarity with ethics and regulatory policies and guidelines and to provide up to date and accurate information of
relevance to CRAs participating in NCIC CTG trials. This workshop will also provide CRAs with the opportunity to ask ethics and regulatory questions of interest to their centres.
The following external guidelines/legislation will be discussed in the workshop that will be presented in a 'quiz show' format:

- **ICH-Good Clinical Practice Guidelines**
- **Canadian Food and Drug Regulations**
- **Tri-Council Policy Statement**
- **U.S. Code of Federal Regulations** **(Title 45, Part 46: Protection of Human Subjects)**

Title: **Preparing for an Audit – Room: Scott A** **10:30 – 11:00 a.m.**
11:00 – 11:30 a.m.

Speaker: Nancy Page CCRP, Study Coordinator
The Ottawa Hospital Integrated Cancer Program

Purpose: To provide CRAs with helpful hints for preparing for an audit and what is expected of them.

Description: This workshop will cover:

- Why Audits are performed
- The objectives of NCIC audits
- What is expected of the CRA
- Review a check list to help CRAs prepare

Title: **SAE Reporting – Room: Seymour** **1:30 – 2:30 p.m.**

Speaker: Bryn Fisher, Study Coordinator, NCIC Clinical Trials Group
Paula Richardson, Study Coordinator, NCIC Clinical Trials Group

Purpose: Educational

Description: A power point presentation with question and answer time covering the following objectives:

1. To assist CRAs in understanding when and how to complete an SAE form in a timely manner.
2. To highlight the importance and reasons for full completion of SAE forms.
3. To provide answers to questions/problems relating to SAE form completion.

Title: **AdEERS Workshop – Room: Seymour** **3:00 – 4:00 p.m.**

Speaker: Jean Powers, Study Coordinator/AdEERS Coordinator, NCIC Clinical Trials Group

Purpose: Educational

Description: AdEERS (Adverse Event Expedited Reporting System) is a web-based application used to report serious adverse events on NCI US and CTSU trials. This workshop will provide some background and an introduction to the application and will walk the participants through the process of completing the on-line form, including helpful hints. Questions and discussion will be encouraged.

Title: **Updates from the CTSU – Room: Stevenson** **2:00 – 2:30 p.m.**
(Cancer Trials Support Unit)

Speaker: Stephen E. Riordan
Project Director, Cancer Trials Support Unit

Purpose: Educational/Informative

Description: Participants will learn about the current status of trials on the CTSU menu, highlighting on those available in Canada and those lead by the NCIC-CTG. Information will be provided to assist Canadian investigators with the process of opening CTSU trials at their centres and enrolling patients on trials.

Title: **MA.21 Trial Workshop – Room: Scott B 3:00 – 4:00 p.m.**

Speaker: Tiina Liinamaa, Study Coordinator, NCIC Clinical Trials Group

Purpose: Trial Update and Q & A

Description: A short presentation to update everyone on MA.21 (accrual, upcoming issues). The rest of the time will be open for questions and discussion (form completion, eligibility, etc.)

Title: **CRF Completion – Room: Stevenson 3:00 – 4:00 p.m.**

Speaker: Bev Koski, Quality Assurance Coordinator, NCIC Clinical Trials Group

Purpose: Educational

Description: The standard elements of NCIC CTG case report forms will be presented along with tips on completing the CRFs.