# NCIC CLINICAL TRIALS GROUP

# **GYNECOLOGY**

# DISEASE SITE COMMITTEE MEETING AGENDA

DELTA CHELSEA HOTEL, TORONTO, ON ROOM: Churchill B

SATURDAY MAY 2, 2015 – 9:00 A.M. - 3:30 P.M.

CHAIRS: MICHAEL FUNG KEE FUNG AND HAL HIRTE (3:30 p.m. – 4:15 p.m. Executive Committee Meeting – Room: Baker - Closed)

#### CME Credits:

Credits for Specialists: This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada, and approved by Queen's University.

### Learning Objectives:

To provide an update of ongoing and recently completed trials and an understanding for the rationale for studies that are proposed or in the process of being activated.

To provide an understanding of oncolytic viruses and how they could be applied therapeutically to gynecologic malignancies

To provide a framework for the design and conduct of clinical trials in the era of personalized medicine.

To understand the role of patients and and their advocates in the development and execution of clinical trials.

#### 9:00 a.m. Opening remarks and outline of the meeting

M. Fung-Kee-Fung / H. Hirte

- 1. Review of minutes and follow-up items from Spring Meeting 2014
- 2. Overview of Gyne Trials Landscape and update on ecosystem blueprint/roadmap and Strategic Plan for the Gynecologic Disease Site Committee

## 9:30 a.m. Clinical Trial Updates

1. OV.21 (15 min)

D. Provencher /H. MacKay

2. CX.5 / SHAPE (15 min)

M. Plante

3. OV.23 (30 min)

A. Oza/M. Masour/N. Berinstein

## 10:45 a.m Planned/Proposed Trials for Presentation and Feedback

1. MAGNUM Endometrial Basket Trial (20 min)

S. Welch

2. Ovary Prevention Study Proposal (OV.24 – STICs and STONES)

A. Oza

(20 min)

3. Innate NK and T cell checkpoint inhibitor in Ovary (20 min)

A. Tinker

4. Other (15 min)

TBD

## 12:00 p.m. **LUNCH**

### 1:30 p.m. Gyne Oncology – State of the Art Presentations (presenter bios attached)

1. Session 1 (30 minutes) – Going Viral in Gynecologic Cancers Brian Lichty

2. Session 2 (30 minutes) - Biomarkers in Early Phase Clinical

Trials - New Realities in Trial Design

Bill Brady

## 2:30 p.m. Working Group Updates

1. Ovary (10 min)

D. Provencher/H. MacKay

2. Cervix (10 min)

M. Plante/C. Doll

3. Endometrium (10 min)

M. Bernardini/S. Welch

4. Correlative Sciences and Tumour Biology (10 min) A. Mes-Masson/M. Butler

## 3:15 p.m. Other Updates

- The patient's role in trial participation/preliminary results
  M. Manojlovich from patient survey (10 min)
- 2. Other Gyne DSC Rep Reports (5 min)
- NCI US GCSC and Ovarian Cancer Task Force (posted on NCIC-CTG website)
- 4. GCIG (posted on NCIC-CTG website)
- 5. Other

### 3:30 p.m. ADJOURN

Closed meeting of Gyne Executive Council to follow in the Baker Room.

# **Gyne Oncology – State of the Art Presentations**



Going Viral in Gynecologic Cancers

Dr Brian Lichty did his undergraduate degree at the University of Guelph and his PhD at the University of Toronto. He joined Dr John Bell's lab in Ottawa, Canada for his postdoctoral studies and was involved in the discovery that type I interferon signalling defects in cancer cells can be targeted by certain viruses. He is currently Associate Professor at the McMaster Immunology Research Centre at McMaster University in Hamilton Ontario since 2004 where he is developing these oncolytic vectors as tumour vaccines and cancer immunotherapies.



Biomarkers in Early Phase Clinical Trials - New Realities in Trial Design

William Brady earned his MS in Statistics from the University of Wisconsin (UW) in 1993 and his PhD in Biostatistics from the University at Buffalo, The State University of New York (UB) in 2012. He joined the Roswell Park Cancer Institute (RPCI) faculty and was appointed Director of the Biostatistics Core Resource in 2012. Prior to joining the RPCI Biostatistics department as a biostatistical consultant in 2005, he spent nine years in the pharmaceutical industry—most recently at Merck & Co., Inc. Dr. Brady has collaborated on studies ranging from translational research and preclinical work at RPCI to phase I and II clinical trials at the Gynecologic Oncology Group (GOG) (now NRG) to phase III and IV

industry trials, including contributions to three successful New Drug Applications (NDAs) to epidemiologic studies at RPCI, GOG, and UW.

Dr. Brady's statistical methods research focuses primarily on phase I and II clinical trial design and the application of exact methods to binary data.

Dr. Brady currently serves on RPCI's Phase I Committee, Scientific Review Committee, and Cancer Center Support Grant Steering Committee, and previously served on its Institutional Review Board (IRB). He has served or does serve on the NRG/GOG's Developmental Therapeutics, Phase I, Rare Tumor, Comparative Effectiveness, and Health Outcomes Research Committees.