



February 2017 Newsletter

Volume 5, Issue 2

A Letter from the Founder, Dr. Christine Brezden-Masley

Since the launch of the CCTC in 2011, the consortium has remarkably expanded to over 200 members across 28 institutions, including 12 of the major cancer centres in Ontario.

We greatly value any input, feedback, and suggestions in order to make your experience with the site as user-friendly as possible. E-mail us at cometrials@smh.ca and we will be more than happy to assist.

Sincerely,

Dr. Christine Brezden-Masley
Founder, CCTC

A Letter from the Project Manager, Caroline Illmann

Hello CCTC Members,

We would like to thank everyone that stopped by our booth at the Best of San Antonio Breast Cancer Symposium in Toronto on January 13th. We are continuing to grow with over 260 members and 31 institutions.

Feel free to share this newsletter with any cancer care colleagues that may be interested, as we are always happy to have new members join the CCTC network.

As always, please contact me at cometrials@smh.ca any time with questions, comments or concerns.

Kind Regards,

Caroline Illmann
Project Manager, CCTC

ARTICLE RECOMMENDATION

Novel Methodology for Comparing Standard-of-Care Interventions in Patients with Cancer

John Hilton, MD, Sasha Mazzaello, Dean Fergusson, MHA, PhD, Anil A. Joy, MD, Andrew Robinson, MD, Angel Arnaout, MD, Brian Hutton, PhD, Lisa Vandermeer, MSc, and Mark Clemons, MD

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Purpose

The current clinical trials development and conduct process is cumbersome and expensive, with the majority of studies focusing on either the development of new agents or new indications for established agents. Unfortunately, research comparing standard-of-care interventions is rarely performed, leaving many important and practical patient-centered questions unanswered. Novel clinical trial methodologies and approaches are needed.

Methods

We have identified simple key components that, when combined, enhance the ability to both perform and increase accrual for studies that compare standard-of-care interventions. These include selection of clinically relevant and practical questions, demonstration of clinical equipoise through surveys of knowledge users and completion of systematic reviews, appropriate study design and simply defined study end points, use of an integrated consent model incorporating oral consent, efficient research ethics board approval, Web-based randomization in the clinic, real-time electronic data capture and management, and regular formal team feedback.

Results

We have demonstrated the feasibility of this model in a pragmatic trial comparing two standard-of-care interventions (growth factor support or ciprofloxacin) for the primary prophylaxis of febrile neutropenia in patients with breast cancer receiving adjuvant docetaxel with cyclophosphamide chemotherapy. Research ethics board approval took 3 months, and 110 (72%) of 153 potentially eligible patients have agreed to participate in the study. When surveyed, 81 (85%) of 95 patients were completely satisfied with the integrated consent model process.

Conclusions

Our proposed model contains elements that, when used alone or in combination, may allow efficient and cost-effective comparison of standard-of-care interventions.

TRIALS SNAPSHOT

Trial Type	Breast	CNS	GI	GU	GYN	Head & Neck	Heme	Lung	Mel	Total
Imaging Study	2	-	-	-	-	-	-	-	-	2
Observational	3	-	-	1	-	-	-	-	-	4
Prevention	-	-	1	-	-	-	1	-	-	2
Radiation	4	-	3	3	-	-	-	4	-	14
Surgical Therapy	1	2	-	1	1	1	-	1	-	7
Systemic Therapy	15	2	9	15	5	1	1	9	9	63
Therapeutic	-	-	-	1	-	-	2	-	-	3
TOTAL	25	4	13	21	6	2	4	14	9	98



TRIALS OF THE MONTH

Type	Acronym	Study Title	Description	Site (s)
Breast	<u>KEYNOTE-355</u>	Study of Pembrolizumab (MK-3475) Plus Chemotherapy vs. Placebo Plus Chemotherapy for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer (MK-3475-355/KEYNOTE-355)	<ul style="list-style-type: none"> Metastatic Systemic Therapy 	North York General Hospital
CNS	<u>Intelligence 1</u>	A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 With Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects With Newly Diagnosed Glioblastoma (GBM) With Epidermal Growth Factor Receptor (EGFR) Amplification	<ul style="list-style-type: none"> Systemic Therapy 	London Health Sciences Centre
GU	<u>REC 3</u>	A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib, Crizotinib, Savolitinib, and Sunitinib) in Metastatic Papillary Renal Carcinoma (PAPMET)	<ul style="list-style-type: none"> Renal Cell Carcinoma Systemic Therapy 	London Health Sciences Centre
Heme	<u>Bridging ITP</u>	Treatment of Thrombocytopenia with Eltrombopag or Intravenous Immune Globulin (IVIG) Before and During Invasive Procedures in Patients with Immune Thrombocytopenia	<ul style="list-style-type: none"> Therapeutic 	Odette Cancer Centre
GYN	<u>RTOG 1174</u>	A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: The OUTBACK Trial	<ul style="list-style-type: none"> Cervical Systemic Therapy 	London Health Sciences Centre
Lung	<u>ATLANTIS</u>	Phase III Randomized Clinical Trial of Lurbinectedin (PM01183)/Doxorubicin (DOX) Versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as Treatment in Patients With Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line	<ul style="list-style-type: none"> Small Cell Lung Cancer Systemic Therapy 	Southlake Regional Health Centre
Mel	<u>MASTERKEY 265/KEYNOTE 034</u>	A Phase 1b/3, Multicenter, Trial of Talimogene Laherparepvec in Combination With Pembrolizumab (MK-3475) for Treatment of Unresectable Stage IIIB to IVM1c Melanoma (MASTERKEY-265/KEYNOTE-034)	<ul style="list-style-type: none"> Systemic Therapy 	London Health Sciences Centre
GI	<u>KEYNOTE 177</u>	A Phase III Study of Pembrolizumab (MK-3475) vs Chemotherapy in Microsatellite Instability-High or Mismatch Repair Deficient Stage IV Colorectal Cancer	<ul style="list-style-type: none"> Systemic Therapy 	Mount Sinai Hospital





MEMBERSHIP UPDATES

265 members

31 institutions

98 accruing trials



ACKNOWLEDGEMENTS

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CONTACT US

Do you have any questions, feedback, suggestions? Please do not hesitate to contact us.

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INSTITUTIONS

Institution	Location	Members	Trials
Cambridge Memorial Hospital	Cambridge	3	3
Grand River Hospital	Waterloo	8	1
Humber River Regional Hospital	Toronto	5	1
Kingston General Hospital	Kingston	3	3
Juravinski Cancer Centre	Hamilton	7	-
Lakeridge Health Corporation	Oshawa	20	-
London Health Sciences Centre	London	9	55
Mackenzie Health Hospital	Richmond Hill	5	-
Markham Stouffville Hospital	Markham	3	-
Mount Sinai Hospital	Toronto	2	4
North York General Hospital	Toronto	12	3
Odette Cancer Centre/Sunnybrook	Toronto	56	32
Ontario Institute for Cancer Research	Toronto	4	-
Ontario Hospital		1	-
Ottawa Hospital	Ottawa	2	-
Princess Margaret Cancer Centre	Toronto	24	1
Quinte Health Care	Belleville	1	-
Rouge Valley Health System	Ajax	3	-
Royal Victoria Regional Health Centre	Barrie	24	17
Scarborough General Hospital	Toronto	1	-
Southlake Regional Health Centre	Newmarket	20	12
St. Joseph's Health Centre	Toronto	4	-
St. Joseph's Healthcare	Hamilton	4	-
St. Michael's Hospital	Toronto	14	7
Sudbury Regional Hospital	Sudbury	1	-
Thunder Bay Regional	Thunder Bay	2	-
Toronto General Hospital	Toronto	3	1
Toronto East General Hospital	Toronto	5	-
Trillium Health Partners	Mississauga	16	-
William Osler Health Systems	Brampton	4	-
Windsor Regional Hospital	Windsor	1	-
Wingham and District Hospital	Wingham	1	-