



## March 2018 Newsletter

Volume 6 Issue 3

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

Dear CCTC Members,

It has been over 6 years since the CCTC was launched in October 2011. Thank you for your continued support of the website and use of the e-referral clinical trial portal. Our next phase is to develop an 'app' so the CCTC can be more accessible at your fingertips. Watch out for this in mid-2018.

We welcome and encourage suggestions so we can continue to improve the service of the CCTC. Simply please send us an email. Our goal is to showcase as many oncology clinical trials that are open in Ontario, providing ready access for your patients.

Sincerely,

Dr. Christine Brezden-Masley

### A Letter from the Project Manager, Alexandra Moskalewicz

Hello everyone,

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 our network!

Our 'Trials of the Month', featured on page 2 of this newsletter and on our website, is a great place to bring more emphasis to a trial that you or your institution would like to increase recruitment for. Please contact me any time at [comettrials@smh.ca](mailto:comettrials@smh.ca) to nominate a trial!

Kind regards,

Alexandra Moskalewicz

## ARTICLE RECOMMENDATION

### Challenges Facing Early Phase Trials Sponsored by the National Cancer Institute: An Analysis of Corrective Action Plans to Improve Accrual

Masset, H.A., Mishkin, G., Rubinstein, L., Ivy, S.P., Denicoff, A., Godwin, E., DiPiazza, K., Bolognese, J., Zwiebel, J.A. and Abrams, J.S.

[DOI: 10.1158/1078-0432.CCR-16-0338](https://doi.org/10.1158/1078-0432.CCR-16-0338) Published November 2016

**Abstract:** Accruing patients in a timely manner represents a significant challenge to early phase cancer clinical trials. The NCI Cancer Therapy Evaluation Program analyzed 19 months of corrective action plans (CAP) received for slow-accruing phase I and II trials to identify slow accrual reasons, evaluate whether proposed corrective actions matched these reasons, and assess the CAP impact on trial accrual, duration, and likelihood of meeting primary scientific objectives. Of the 135 CAPs analyzed, 69 were for phase I trials and 66 for phase II trials. Primary reasons cited for slow accrual were safety/toxicity (phase I: 48%), design/protocol concerns (phase I: 42%, phase II: 33%), and eligibility criteria (phase I: 41%, phase II: 35%). The most commonly proposed corrective actions were adding institutions (phase I: 43%, phase II: 85%) and amending the trial to change eligibility or design (phase I: 55%, phase II: 44%). Only 40% of CAPs provided proposed corrective actions that matched the reasons given for slow accrual. Seventy percent of trials were closed to accrual at time of analysis (phase I = 48; phase II = 46). Of these, 67% of phase I and 70% of phase II trials met their primary objectives, but they were active three times longer than projected. Among closed trials, 24% had an accrual rate increase associated with a greater likelihood of meeting their primary scientific objectives. Ultimately, trials receiving CAPs saw improved accrual rates. Future trials may benefit from implementing CAPs early in trial life cycles, but it may be more beneficial to invest in earlier accrual planning.

## TRIALS SNAPSHOT

Trial Type	Any Malignancy	Breast	CNS	GI	GU	GYN	Head & Neck	Heme	Lung	Mel	Skin	Total
Imaging Study		1			2			1				4
Observational	1	3				1		1				6
Prevention				1				1				2
Radiation		2		3	4		1		5			15
Supportive Care	1	5										6
Surgical Therapy		1	1		1	1	1					5
Systemic Therapy	1	8		14	21	5	2	10	9	5	3	78
Therapeutic		1			4	1		3				9
<b>TOTAL</b>	<b>3</b>	<b>21</b>	<b>1</b>	<b>18</b>	<b>32</b>	<b>8</b>	<b>4</b>	<b>15</b>	<b>14</b>	<b>5</b>	<b>3</b>	<b>125</b>



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### TRIALS OF THE MONTH

Type	Acronym	Study Title	Description	Site(s)
Breast	<a href="#"><u>OLYMPIA (MA.36)</u></a>	A randomised, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy	<ul style="list-style-type: none"> <li>• Adjuvant (Stage I, II, or III)</li> <li>• Systemic Therapy</li> <li>• HER2 Negative</li> </ul>	Odette Cancer Centre
GU	<a href="#"><u>HOPE renal 218</u></a>	A Randomized, Double-blind, Phase 2 Trial to Assess Safety and Efficacy of Lenvatinib at Two Different Starting Doses (18 mg vs. 14 mg QD) in Combination With Everolimus (5 mg QD) in Renal Cell Carcinoma Following One Prior VEGF-Targeted Treatment	<ul style="list-style-type: none"> <li>• Systemic Therapy</li> <li>• Renal Cell Carcinoma</li> </ul>	Odette Cancer Centre
Heme	<a href="#"><u>ACE LYM 308</u></a>	A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study of Bendamustine and Rituximab (BR) alone Versus in Combination with Acalabrutinib (ACP-196) in Subjects with Previously Untreated Mantle Cell Lymphoma	<ul style="list-style-type: none"> <li>• Systemic Therapy</li> <li>• Mantle Cell Lymphoma</li> </ul>	Odette Cancer Centre
GYN	<a href="#"><u>Ariel 4</u></a>	ARIEL4 (Assessment of Rucaparib In Ovarian CancEr Trial): A Phase 3 Multicenter, Randomized Study of Rucaparib Versus Chemotherapy in Patients With Relapsed, BRCA Mutant, High Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	<ul style="list-style-type: none"> <li>• Systemic Therapy</li> <li>• Relapsed ovarian, fallopian tube, or primary peritoneal cancer</li> </ul>	London Health Sciences Centre
Lung	<a href="#"><u>MEDI4736</u></a>	A Randomized Trial of Durvalumab and Tremelimumab ± Platinum-Based Chemotherapy in Patients With High-Risk Metastatic (Stage IV) Squamous or Non-Squamous Non-Small Cell Lung Cancer (NSCLC)	<ul style="list-style-type: none"> <li>• Systemic Therapy</li> <li>• Stage IV NSCLC</li> </ul>	Humber River Regional Hospital Kingston General Hospital
Mel	<a href="#"><u>ME13</u></a>	A Randomized Phase III Trial of the Duration of Anti-PD-1 Therapy in Metastatic Melanoma (STOP-GAP)	<ul style="list-style-type: none"> <li>• Systemic Therapy</li> <li>• Metastatic Melanoma</li> </ul>	Kingston General Hospital London Health Sciences Centre Odette Cancer Centre Royal Victoria Regional Health Centre
GI	<a href="#"><u>FRACTION-Gastric</u></a>	A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants With Advanced Gastric Cancer	<ul style="list-style-type: none"> <li>• Systemic Therapy</li> <li>• Advanced Gastric Cancer</li> </ul>	Odette Cancer Centre



[Click here to NOMINATE your trial for Trials of the Month!](#)



## MEMBERSHIP UPDATES

**278 members**

**31 institutions**

**125 accruing trials**



## ACKNOWLEDGEMENTS

The CCTC has been funded by unrestricted educational grants from the following supporters:



## 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	4
Grand River Hospital	Waterloo	9	1
Humber River Regional Hospital	Toronto	5	3
Kingston General Hospital	Kingston	4	20
Juravinski Cancer Centre	Hamilton	7	-
Lakeridge Health Corporation	Oshawa	21	-
London Health Sciences Centre	London	9	60
Mackenzie Health Hospital	Richmond Hill	6	-
Markham Stouffville Hospital	Markham	4	1
Mount Sinai Hospital	Toronto	2	2
North York General Hospital	Toronto	14	7
Odette Cancer Centre/Sunnybrook	Toronto	59	53
Ontario Institute for Cancer Research	Toronto	4	-
Ottawa Hospital	Ottawa	2	-
Princess Margaret Cancer Centre	Toronto	23	1
Quinte Health Care	Belleville	1	-
Rouge Valley Health System	Ajax	3	-
Royal Victoria Regional Health Centre	Barrie	23	17
Scarborough General Hospital	Toronto	3	-
Southlake Regional Health Centre	Newmarket	19	7
St. Joseph's Health Centre	Toronto	4	-
St. Joseph's Healthcare	Hamilton	4	-
St. Michael's Hospital	Toronto	15	4
Sudbury Regional Hospital	Sudbury	1	-
Thunder Bay Regional	Thunder Bay	2	-
Toronto General Hospital	Toronto	3	1
Toronto East General Hospital	Toronto	6	-
Trillium Health Partners	Mississauga	17	-
William Osler Health Systems	Brampton	4	-
Windsor Regional Hospital	Windsor	1	-
Wingham and District Hospital	Wingham	1	-