



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

Thank you for supporting the CCTC throughout 2018. We look forward to providing you up-to-date clinical trials information that is seamless and fast. By increasing our provincial clinical trials enrollment, this has the potential to benefit patients and allow for more clinical trials to be considered in Canada.

If you have any concerns or improvements of the website, please let us know. Be sure to follow our twitter page [@COMET_Trials](#) for the latest updates regarding open trials.

Wishing you and your family a healthy and wonderful holiday season.

Sincerely,

Dr. Christine Brezden-Masley

Hello everyone,

Please feel free to share this newsletter with any colleagues that may be interested, as we are always happy to have new members join our network! Please contact me at cometrials@smh.ca for any questions or comments.

Kind Regards,

Daniel Lindsay

ARTICLE RECOMMENDATION

Transforming Clinical Trial Eligibility Criteria to Reflect Practical Clinical Application

Kim ES, Atlas J, Ison G, Ersek JL.

DOI: [10.14694/EDBK_155880](https://doi.org/10.14694/EDBK_155880) Published June 2016

ABSTRACT:

Historically, oncology clinical trials have focused on comparing a new drug's efficacy to the standard of care. However, as our understanding of molecular pathways in oncology has evolved, so has our ability to predict how patients will respond to a particular drug, and thus comparison with a standard therapy has become less important. Biomarkers and corresponding diagnostic testing are becoming more and more important to drug development but also limit the type of patient who may benefit from the therapy. Newer clinical trial designs have been developed to assess clinically meaningful endpoints in biomarker-enriched populations, and the number of modern, molecularly driven clinical trials are steadily increasing. At the same time, barriers to clinical trial enrollment have also grown. Many barriers contribute to nonenrollment in clinical trials, including patient, physician, institution, protocol, and regulatory barriers. At the protocol level, eligibility criteria have become a large roadblock to clinical trial accrual. Over time, eligibility criteria have become more and more restrictive. To accrue an adequate number of patients to molecularly driven trials, we should consider eligibility criteria carefully and attempt to reduce restrictive criteria. Reducing restrictive eligibility criteria will allow more patients to be eligible for clinical trial participation, will likely increase the speed of drug approvals, and will result in clinical trial results that more accurately reflect treatment of the population in the clinical setting.

TRIALS SNAPSHOT

Trial Type	Any Malignancy	Breast	GI	GU	GYNE	Head & Neck	Heme	Lung	Mel	Skin	Total
Imaging Study		1		2			1				4
Observational	1	4	1	1			1				8
Prevention			1				1				2
Radiation	1	2	3	5		1		5			17
Supportive Care	1	4									5
Surgical Therapy		1		1	1	1					4
Systemic Therapy	5	9	17	15	7	3	17	8	3	1	85
Therapeutic				2			2				4
TOTAL	8	21	22	26	8	5	22	13	3	1	129



TRIALS OF THE MONTH

Type	Acronym	Study Title	Description	Site(s)
Breast	LUCY	A Phase IIIb, Single-arm, Open-label Multicentre Study of Olaparib Monotherapy in the Treatment of HER2-ve Metastatic Breast Cancer Patients With Germline BRCA1/2 Mutations.	<ul style="list-style-type: none"> • HER2 Negative Metastatic • gBRCA1/2 or sBRCA1/2 mutations 	Odette Cancer Centre
GU	IMmotion010	A Study of Atezolizumab as Adjuvant Therapy in Participants With Renal Cell Carcinoma (RCC) at High Risk of Developing Metastasis Following Nephrectomy	<ul style="list-style-type: none"> • Renal Cell Carcinoma • Post-nephrectomy patients 	North York General Hospital
Heme	HBV	A Multi-centre Phase III Study to Evaluate Preemptive Tenofovir for Prevention of Hepatitis B Virus Reactivation in HBsAg Negative/Anti-HBc Positive Individuals Undergoing Rituximab-based Chemotherapy for Non-Hodgkin's Lymphoma	<ul style="list-style-type: none"> • Non-Hodgkin's Lymphoma or CLL/SLL • Prevention of HBV reactivation 	St. Michael's Hospital
Skin	Regeneron BCC	A Phase 2 Study of REGN2810, a Fully Human Monoclonal Antibody to Programmed Death-1, in Patients With Advanced Basal Cell Carcinoma Who Experienced Progression of Disease on Hedgehog Pathway Inhibitor Therapy, or Were Intolerant of Prior Hedgehog Pathway Inhibitor Therapy (R2810-ONC-1620)	<ul style="list-style-type: none"> • Advanced Basal Cell Carcinoma • Progressed on hedgehog inhibitor therapy 	London Health Sciences Centre
Lung	PET-BOOST	A Randomized Phase II Trial to Assess the Efficacy and Safety of Selective Metabolically Adaptive Radiation Dose Escalation in Locally Advanced Non-Small Cell Lung Cancer Receiving Definitive Chemoradiotherapy	<ul style="list-style-type: none"> • Non-small Cell Lung Cancer • Receiving Chemoradiotherapy 	Kingston General Hospital
GYNE	CX5	A Randomized Phase III Trial Comparing Radical Hysterectomy and Pelvic Node Dissection vs Simple Hysterectomy and Pelvic Node Dissection in Patients With Low-Risk Early Stage Cervical Cancer (SHAPE)	<ul style="list-style-type: none"> • Cervical Cancer • Surgical Therapy 	Royal Victoria Regional Health Centre
GI	RTOG 1112	Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma	<ul style="list-style-type: none"> • Liver Cancer • Radiation Therapy 	London Health Sciences Centre

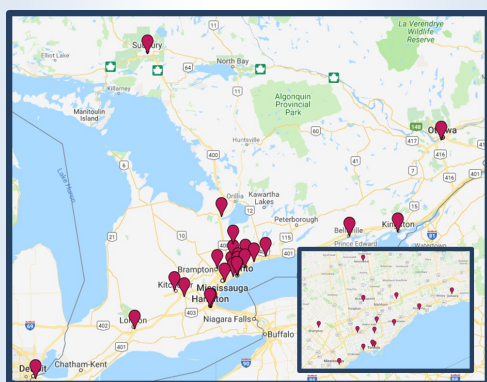


[Click here to NOMINATE your trial for Trials of the Month!](#)



MEMBERSHIP UPDATES

278 members
29 institutions
129 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	7	1
Humber River Regional Hospital	Toronto	5	2
Kingston General Hospital	Kingston	3	36
Juravinski Cancer Centre	Hamilton	6	-
Lakeridge Health Corporation	Oshawa	20	-
London Health Sciences Centre	London	10	54
Mackenzie Health Hospital	Richmond Hill	6	-
Markham Stouffville Hospital	Markham	4	-
Mount Sinai Hospital	Toronto	2	1
North York General Hospital	Toronto	14	4
Odette Cancer Centre/Sunnybrook	Toronto	64	54
Ontario Institute for Cancer Research	Toronto	4	-
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	23	14
Scarborough General Hospital	Toronto	3	-
Southlake Regional Health Centre	Newmarket	20	6
St. Joseph's Health Centre	Toronto	3	-
St. Joseph's Healthcare	Hamilton	4	-
St. Michael's Hospital	Toronto	13	7
Sudbury Regional Hospital	Sudbury	1	-
Thunder Bay Regional	Thunder Bay	2	-
Toronto General Hospital	Toronto	3	1
Trillium Health Partners	Mississauga	18	2
William Osler Health Systems	Brampton	3	-
Windsor Regional Hospital	Windsor	2	-