



**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](https://twitter.com/COMET_Trials) for the latest updates regarding open trials.

Sincerely,

Dr. Christine Brezden-Masley

Hello CCTC members,

Please feel free to share this newsletter with any colleagues that may be interested! We always love when new members join our network.

If any new trials are open at your site or if you would like to be featured in our *Trials of the Month*, please do not hesitate to contact me at comettrials@smh.ca for assistance or for any other questions you may have.

Kind Regards,

Alexandria Abbruzzino

ARTICLE RECOMMENDATION

Statistical advances in clinical trials and clinical research.

Shan G, Banks S, Miller JB, Ritter A, Bernick C, Lombardo J, Cummings JL.

DOI: [10.1016/j.trci.2018.04.006](https://doi.org/10.1016/j.trci.2018.04.006) Published Jun. 14 2018

ABSTRACT:

Introduction: New treatments for neurodegenerative disease are urgently needed, and clinical trial methods are an essential component of new drug development. Although a parallel-group study design for neurological disorder clinical trials is commonly used to test the effectiveness of a new treatment as compared to placebo, it does not efficiently use information from the on-going study to increase the success rate of a trial or to stop a trial earlier when the new treatment is indeed ineffective.

Methods: We review some recent advances in designs for clinical trials, including futility designs and adaptive designs.

Results: Futility designs and noninferiority designs are used to test the nonsuperiority and the noninferiority of a new treatment, respectively. We provide some guidance on using these two designs and analyzing data from these studies properly. Adaptive designs are increasingly used in clinical trials to improve the flexibility and efficiency of trials with the potential to reduce resources, time, and costs. We review some typical adaptive designs and new statistical methods to handle the statistical challenges from adaptive designs.

Discussion: Statistical advances in clinical trial designs may be helpful to shorten study length and benefit more patients being treated with a better treatment during the discovery of new therapies for neurological disorders. Advancing statistical underpinnings of neuroscience research is a critical aspect of the core activities supported by the Center of Biomedical Research Excellence award supporting the Center for Neurodegeneration and Translational Neuroscience.

TRIALS SNAPSHOT

Trial Type	Any Malignancy	Breast	GI	GU	GYNE	Head & Neck	Heme	Lung	Mel	Skin	Total
Imaging Study		1		1			1				3
Observational	1	4	1	1			2				9
Prevention			1				1				2
Radiation	1	2	3	5		1		5			17
Supportive Care		4									4
Surgical Therapy		1		1	1	1					4
Systemic Therapy	6	12	17	15	5	3	16	6	5	1	86
Therapeutic							2				2
TOTAL	8	24	22	23	6	5	22	11	5	1	127



TRIALS OF THE MONTH

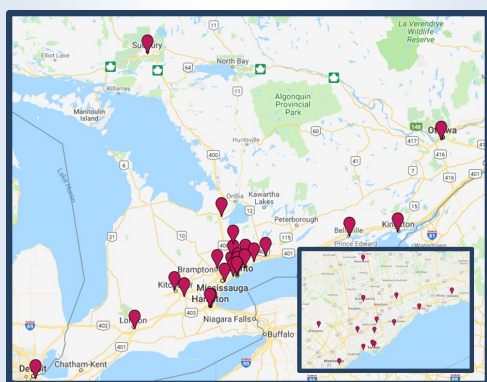
Type	Acronym	Study Title	Description	Site(s)
Breast	<u>NRG BR002</u>	A Phase IIR/III Trial of Standard of Care Therapy With or Without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer	<ul style="list-style-type: none"> • HER2 primary tumor or metastasis • Stereotactic Radiosurgery 	London Health Sciences Centre
GU	<u>TOPCOP</u>	Toward Personalizing Care for Older Men With mCRPC – Understanding and Predicting Treatment Toxicities	<ul style="list-style-type: none"> • Observational study • Prostate Cancer 	Kingston General Hospital
Heme	<u>SC24</u>	A Randomized Phase II/III Study Comparing Stereotactic Body Radiotherapy(SBRT) Versus Conventional Palliative Radiotherapy (CRT) for Patients With Spinal Metastases	<ul style="list-style-type: none"> • Any histologically confirmed malignancy <ul style="list-style-type: none"> • Bone Disease 	London Health Sciences Centre
MEL	<u>COMBI-APlus</u>	Open-label, Phase IIIb Study of Dabrafenib+Trametinib in the Adjuvant Treatment of Stage III BRAF V600+ Melanoma After Complete Resection to Evaluate the Impact on Pyrexia Related Outcomes	<ul style="list-style-type: none"> • Malignant Melanoma <ul style="list-style-type: none"> • Stage III • Adjuvant Treatment 	Odette Cancer Centre
Lung	<u>PROACTIVE</u>	A Randomized Phase III Study of Palliative Radiation of Advanced Central Tumors With Intentional Avoidance of the Esophagus	<ul style="list-style-type: none"> • Non-small Cell Lung Cancer • Palliative Radiotherapy 	London Health Sciences Centre
GYNE	<u>NEC</u>	A Phase II, Open Label Study of the Poly(ADP-ribose) Polymerase Inhibitor Niraparib (MK 4827) in Recurrent Endometrial Cancer	<ul style="list-style-type: none"> • Systemic therapy • Advanced/Recurrent endometrial cancer 	Kingston General Hospital
GI	<u>TAS-120</u>	Phase 1/2 Study of TAS-120 in Patients With Advanced Solid Tumors Harboring FGF/FGFR Aberrations	<ul style="list-style-type: none"> • FGF/FGFR aberrations • Cholangiocarcinoma • Metastatic (treatment resistant) 	Odette Cancer Centre





MEMBERSHIP UPDATES

280 members
30 institutions
127 accruing trials



INSTITUTIONS

Institution	Location	Trials	Members
Cambridge Memorial Hospital	Cambridge	4	3
Grand River Hospital	Waterloo	1	7
Humber River Regional Hospital	Toronto	2	5
Kingston General Hospital	Kingston	33	3
Juravinski Cancer Centre	Hamilton	-	6
Lakeridge Health Corporation	Oshawa	-	20
London Health Sciences Centre	London	51	10
Mackenzie Health Hospital	Richmond Hill	-	6
Markham Stouffville Hospital	Markham	-	4
Mount Sinai Hospital	Toronto	1	2
North York General Hospital	Toronto	4	14
Odette Cancer Centre/Sunnybrook	Toronto	53	64
Ontario Institute for Cancer Research	Toronto	-	4
Ontario Hospital	Toronto	-	1
Ottawa Hospital	Ottawa	-	2
Princess Margaret Cancer Centre	Toronto	1	25
Quinte Health Care	Belleville	-	1
Rouge Valley Health System	Ajax	-	3
Royal Victoria Regional Health Centre	Barrie	13	23
Scarborough General Hospital	Toronto	-	3
Southlake Regional Health Centre	Newmarket	6	20
St. Joseph's Healthcare	Hamilton	-	4
St. Joseph's Health Centre	Toronto	-	3
St. Michael's Hospital	Toronto	9	13
Sudbury Regional Hospital	Sudbury	-	1
Thunder Bay Regional	Thunder Bay	-	2
Toronto General Hospital	Toronto	1	3
Trillium Health Partners	Mississauga	4	18
William Osler Health Systems	Brampton	-	3
Windsor Regional Hospital	Windsor	-	2

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CONTACT US

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

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