



**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 cancer care colleagues that may be interested! We would love for new members to 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

Recommendations for Methodology of Virtual Reality Clinical Trials in Health Care by an International Working Group: Iterative Study.

Birckhead B, Khalil C, Liu X, Conovitz S,, Rizzo A, Danovitch I, Bullock K, Spiegel B.
DOI: [10.2196/11973](https://doi.org/10.2196/11973). Published Jan. 31 2019

ABSTRACT:

BACKGROUND: Therapeutic virtual reality (VR) has emerged as an efficacious treatment modality for a wide range of health conditions. However, despite encouraging outcomes from early stage research, a consensus for the best way to develop and evaluate VR treatments within a scientific framework is needed.

OBJECTIVE: We aimed to develop a methodological framework with input from an international working group in order to guide the design, implementation, analysis, interpretation, and communication of trials that develop and test VR treatments.

METHODS: A group of 21 international experts was recruited based on their contributions to the VR literature. The resulting Virtual Reality Clinical Outcomes Research Experts held iterative meetings to seek consensus on best practices for the development and testing of VR treatments.

RESULTS: The interactions were transcribed, and key themes were identified to develop a scientific framework in order to support best practices in methodology of clinical VR trials. Using the Food and Drug Administration Phase I-III pharmacotherapy model as guidance, a framework emerged to support three phases of VR clinical study designs-VR1, VR2, and VR3. VR1 studies focus on content development by working with patients and providers through the principles of human-centered design. VR2 trials conduct early testing with a focus on feasibility, acceptability, tolerability, and initial clinical efficacy. VR3 trials are randomized, controlled studies that evaluate efficacy against a control condition. Best practice recommendations for each trial were provided.

CONCLUSIONS: Patients, providers, payers, and regulators should consider this best practice framework when assessing the validity of VR treatments.

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	8	11	15	16	5	3	19	3	5	1	86
Therapeutic							2				2
TOTAL	10	23	20	24	6	5	25	8	5	1	127



TRIALS OF THE MONTH

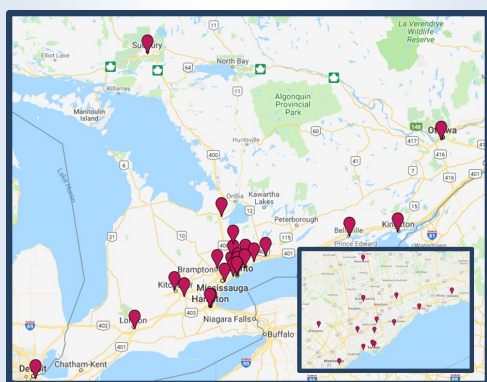
Type	Acronym	Study Title	Description	Site(s)
Breast	WO40181	A Phase II, Multicenter, Randomized Study To Compare The Efficacy Of Venetoclax Plus Fulvestrant Versus Fulvestrant In Women With Estrogen Receptor-Positive, Her2-Negative Locally Advanced Or Metastatic Breast Cancer Who Experienced Disease Recurrence Or Progression During Or After CDK4/6 Inhibitor Therapy	<ul style="list-style-type: none"> ER+, HER2- metastatic or locally advanced 	Southlake Regional Health Centre
GU	BAYOU	A Phase II, Randomized, Multi-Center, Double-Blind, Comparative Global Study to Determine the Efficacy and Safety of Durvalumab in Combination With Olaparib for First-Line Treatment in Platinum-Ineligible Patients With Unresectable Stage IV Urothelial Cancer	<ul style="list-style-type: none"> Systemic Therapy Bladder Cancer 	Southlake Regional Health Centre
Heme	PNH Registry	Paroxysmal Nocturnal Hemoglobinuria (PNH) Registry	<ul style="list-style-type: none"> Observational Diagnosis of PNH or a detected PNH clone 	Odette Cancer Centre
MEL	KEYNOTE-716	Adjuvant Therapy With Pembrolizumab Versus Placebo in Resected High-risk Stage II Melanoma: A Randomized, Double-blind Phase 3 Study	<ul style="list-style-type: none"> Stage IIB or IIC cutaneous melanoma Systemic Therapy 	Odette Cancer Centre
Lung	Ad/MG1-MAGEA3-001 (Sandpiper)	A Phase 1/2 Trial of MG1 Maraba Expressing MAGE-A3 (MG1-MAGEA3), With Adenovirus Vaccine Expressing MAGE-A3 (Ad-MAGEA3), in Combination With Pembrolizumab in Patients With Previously Treated Metastatic Non-Small Cell Lung Cancer (NSCLC)	<ul style="list-style-type: none"> Non-small Cell Lung Cancer Systemic Therapy 	Kingston General Hospital
Any	EVOLVE	A Phase IV, Real World Observational Study on the Use of Akynzeo (netupitant/palonosetron) for the Prevention of Nausea and Vomiting in Oncology Patients Receiving Highly Emetogenic Chemotherapy (HEC) Over Multiple Cycles	<ul style="list-style-type: none"> Systemic therapy Patients Receiving Highly Emetogenic Chemotherapy 	Royal Victoria Regional Health Centre St. Michael's Hospital
GI	COMPASS	Comprehensive Molecular Characterization of Advanced Pancreatic Ductal Adenocarcinoma (PDAC) for Better Treatment Selection: A Prospective Study	<ul style="list-style-type: none"> Pancreatic Cancer Adjuvant (Stage III) 	Kingston General Hospital





MEMBERSHIP UPDATES

283 members
30 institutions
127 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	Trials	Members
Cambridge Memorial Hospital	Cambridge	3	3
Grand River Hospital	Waterloo	1	7
Humber River Regional Hospital	Toronto	2	5
Kingston General Hospital	Kingston	33	3
Juravinski Cancer Centre	Hamilton	1	7
Lakeridge Health Corporation	Oshawa	-	20
London Health Sciences Centre	London	50	10
Mackenzie Health Hospital	Richmond Hill	-	6
Markham Stouffville Hospital	Markham	-	4
Mount Sinai Hospital	Toronto	1	2
North York General Hospital	Toronto	3	14
Odette Cancer Centre/Sunnybrook	Toronto	53	62
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	12	23
Scarborough General Hospital	Toronto	-	3
Southlake Regional Health Centre	Newmarket	7	21
St. Joseph's Healthcare	Hamilton	-	4
St. Joseph's Health Centre	Toronto	-	3
St. Michael's Hospital	Toronto	11	15
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