Annual Report 2023

Canadian Cancer Trials Group

Groupe canadien des essais sur le cancer

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2023 a year in review

Dr Janet Dancey, MD, FRCP(C) | Director, Canadian Cancer Trials Group

Welcome to the first CCTG Annual Report, where we have provided a snapshot of a tremendous year of activity, significant achievements and impact. These collective successes reflect the efforts of all CCTG members, investigators and trial staff who develop, conduct, and report on the results of our research.

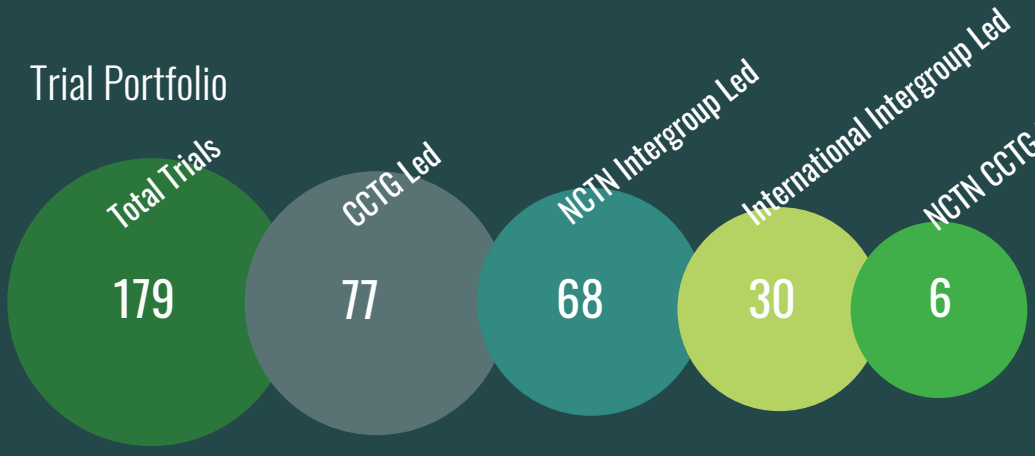
The Group is now at the midpoint of our Strategic Plan "Solving Cancer Together" and the scientific agenda continues to move forward. Our trials continue to improve outcomes for patients, and we are establishing innovative platforms in cell therapy, pre-operative trials, and data science. Our data science activities have focused on defining core data elements, identifying key trials for the data sharing platform, and on processes required for genomics and digital imaging data warehousing. Two cell therapy trials were awarded funding from the Canadian Institutes of Health Research and are currently in development. The planned expansion of the Tumour Tissue Data Repository (TTDR) continues to move forward, and work is underway to ensure that CCTG is well positioned to support next steps after the renovation.

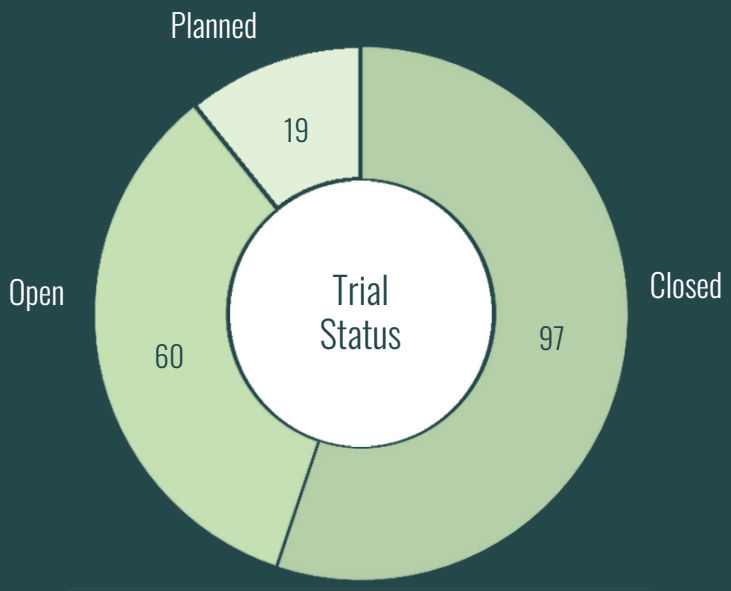
Our patient partners continue to share best practices in patient engagement and seek to understand and address questions of priority to those living with a cancer diagnosis. The EDIIA strategic initiative has progressed with a busy year of Working Groups, Virtual Round Tables, and a focused workshop on two upcoming trials. The feedback we have collected has given us some tangible steps to create a more inclusive and accessible trial ecosystem. In addition to maintaining our scientific and clinical trial operations, we have conducted a series of engagement sessions to understand the trial implementation challenges for our member sites. The session outcomes will lead to concrete actions addressing barriers to site participation and activation of CCTG led trials.

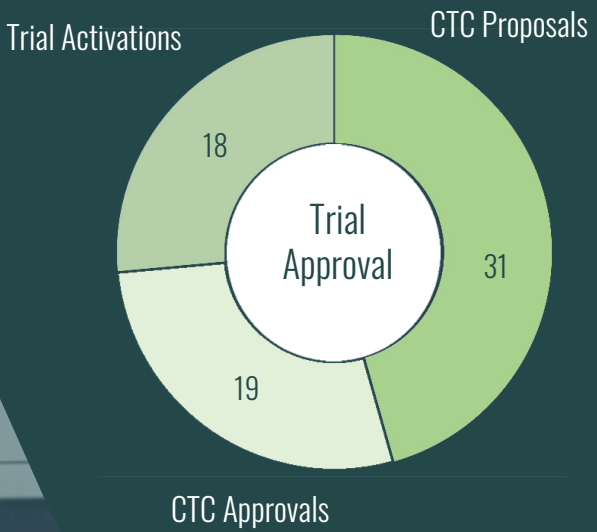
Our academic research group continues to be the most significant cancer research collaborative in Canada — internationally recognized for finding the treatments that give people with cancer longer, better quality lives by conducting clinical trials evaluating the full range of cancer treatments to determine their efficacy and safety.

CCTG BY THE NUMBERS - 2023

Trial Portfolio







CCTG NETWORK AT A GLANCE

87 Canadian centres working with **556 international centres** in **20 countries.**

Canadian Members
6969

Total Network
21157

International Members
14188

2244 Canadian Investigators
4725 Canadian Clinical Trial Personnel

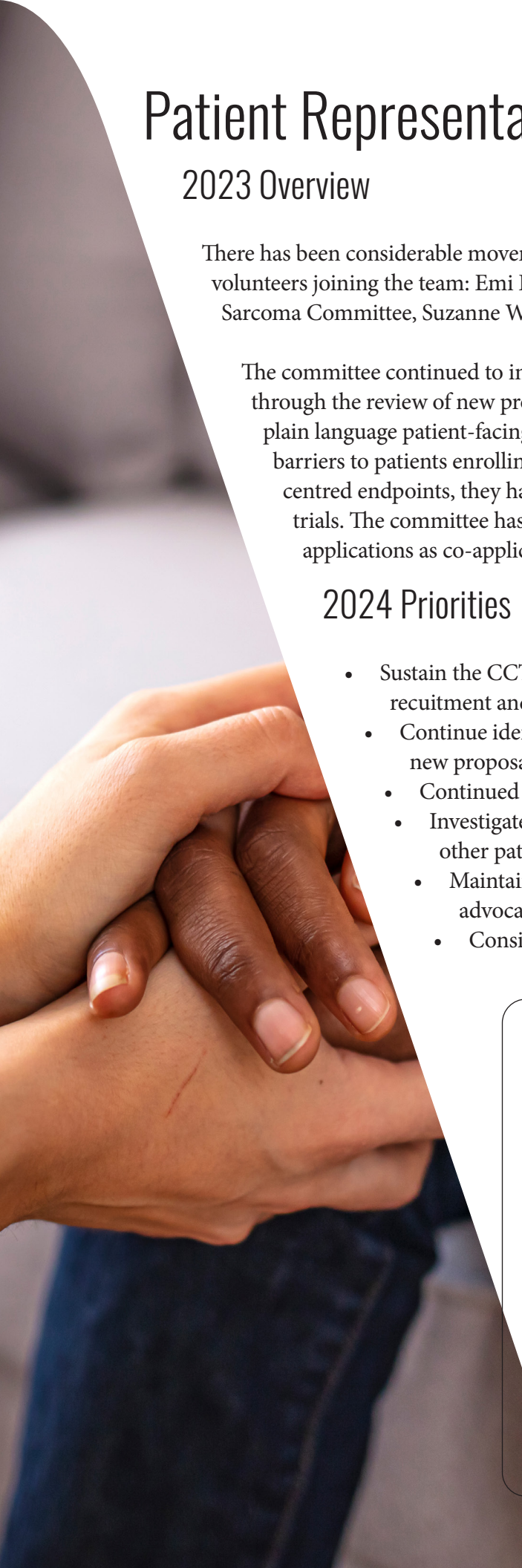
4356 International Investigators
9832 International Clinical Trial Personnel

74 trials opened in communities in Canada
and clinical research in over 30 different cancer types

3304 Patients Accrued Globally

3053 Patients Accrued in Canada

108,345
patient participants in
CCTG trials since
1980



Patient Representative Committee

2023 Overview

There has been considerable movement in the Patient Representative Committee with many new volunteers joining the team: Emi Bossio, Lung Cancer Committee, Jasmine Heuring, AYA & Sarcoma Committee, Suzanne Wood, and Haydn Bechthold supporting Gastrointestinal.

The committee continued to incorporate the patient perspective into all CCTG clinical trials through the review of new proposals, associated protocol and consentt, and importantly the plain language patient-facing materials. Through these efforts with a focus on identifying barriers to patients enrolling in trials and the inclusion of Quality of Life-related patient-centred endpoints, they have encouraged the receptivity of patients to participating in CCTG trials. The committee has also influenced funding opportunities by supporting trial grant applications as co-applicants and providing associated letters of support where needed.

2024 Priorities

- Sustain the CCTG Patients as Partners Model through committee member recuitment and training as well as investigator awareness initiatives
- Continue identifying and addressing barriers to accrual through the review of new proposals, protocol, consent, and plain language summaries
- Continued support of grant applications,
- Investigate plain-language summaries at trial closure, and identification of other patient priorities in research
- Maintain external partnerships, sharing of best practices with CCS, patient advocacy groups
- Consider EDIIA in committee refreshment and trial reviews

Yvonne Murray, M.Sc
Patient Engagement Lead

Yvonne Murray has worked with the CCTG Trial Management Group for over 20 years. During this time she has held various roles, most recently as a Team Leader. For over four years Yvonne has also been working with the Patient Representative Committee as the Central Office Representative. In early 2023 she was successfully recruited to the newly created CCTG Patient Engagement Lead position, a role that allows her to continue as a TMG Team Leader.

A message from the chair

Judy Needham
Patient Representative Committee Chair

On behalf of CCTG leadership, I would like to extend our sincere thanks to the incredible team of volunteers who make up the Patient Representative Committee. We are grateful that you chose to donate your time and talents to CCTG.

In 2023 you were a part of 21 new trial proposal reviews, as many grant applications and letters of support, and up to 15 protocol, consent, and patient facing material reviews for new trials; all of this work that is done quietly in your own space that no one sees.

We all share our fondest thoughts and memories of Sylvie Desmarais who's input was so valued. I would also like to extend a warm farewell and thank you to departing representatives; Marg Redlick, Lynn Bezanson, and Richard Wassersug for your incredible contributions during your committee term.

2023 Patient Representatives


Hayden Bechthold


Louise Bird


Emi Bossio


Lynn Bezanson


Carol Gordon


Jasmine Heuring


Hilary Horlock


David McMullen


Joan Petrie


Marg Redlick


Bill Richardson


Erwin Wanderer


Richard Wassersug


Catherine Wreford


Martina Wood

Investigational New Drug Program

2023 Overview

The IND Program is committed to access and to testing new anticancer therapeutics for Canadian patients. The aim is to ultimately identify new standards of care and improve outcomes for our patients. Strategies include a focus on our platform/master protocols, testing new agents, including the principles of personalized medicine and exploring exciting cell based therapies. This is done while also developing and optimising clinical trial methodology and ensuring the education of and collaboration with clinical trialists. A key objective continues to be incorporating patients into all aspects early clinical research design and decision making while also improving access; a specialized committee (PRECT) has been implemented to oversee these aspects.

2024 Priorities

- Continued expansion to allow the conduct of more phase II trials including opportunities to increase efficiency and reduce complexity where feasible.
- Improving patient understanding, access, consent and experience on early clinical trials, including the use of 'liquid' biopsies
- Mid cycle strategic review
- Investigator engagement, education and mentoring
- Continue development of our planned cell therapy trials

Program Executive

Dr. David Cescon
Chair

Dr Yvette Drew,
Incoming Chair

Dr. Quincy Chu
Past Chair

Dr. Lesley Seymour
IND Program Director

Joan Petrie
Patient Representative

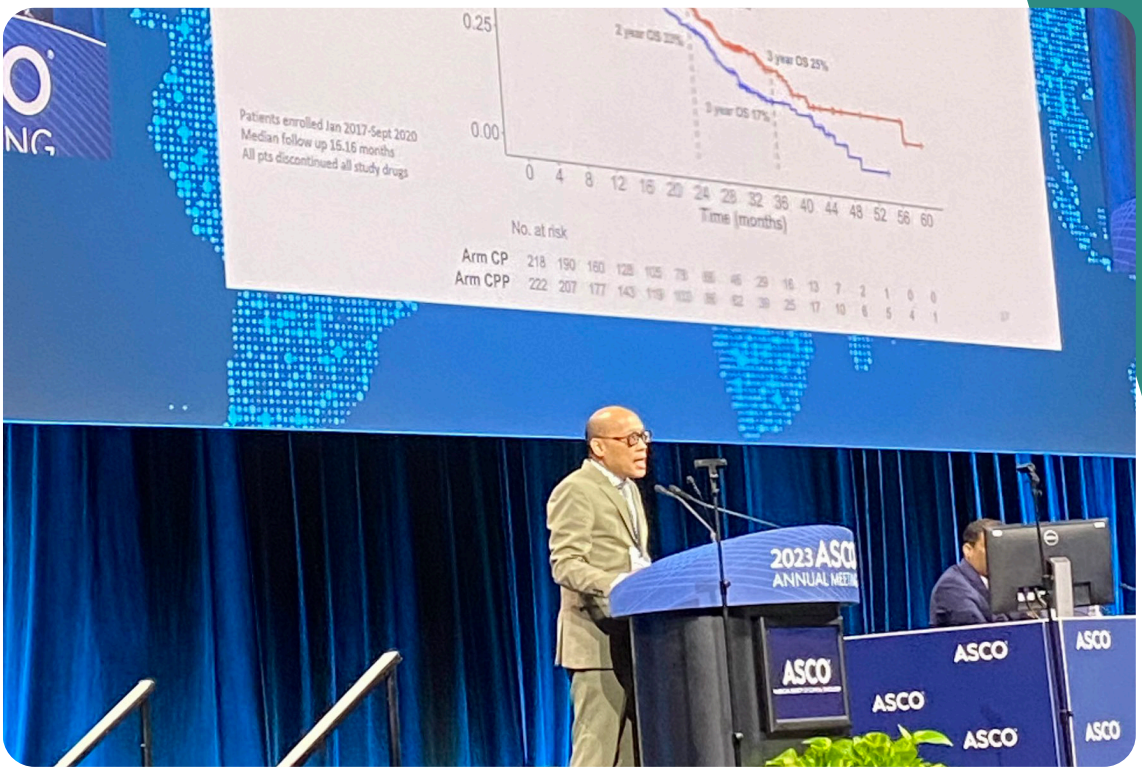
Dr. Dongsheng Tu
Senior Biostatistician

Dr. Wei Tu
Senior Biostatistician

Dr. Michael Kolinsky
Dr. Nathalie Levasseur
Dr. Jonathan Loree
Dr. Daniel John Renouf
Dr. Anna Tinker
Dr. Alexander Wyatt
Dr. Christina Addison

Dr. April Rose
Dr. Jonathan Spicer
Dr. John Hilton
Dr. Michael Ong
Dr. Courtney Coschi
Dr. Stephanie Lheureux
Dr. Anca Prica

Dr. Janet Dancey
Dr. Pierre-Olivier Gaudreau
Dr. Annette Hay
Dr. Mariam Jafri
Dr. Philippe Jamme
Ms. Laura Pearce
Dr. Amber Simpson



Trial Spotlight

IND227 a phase III randomized study of Pembrolizumab in patients with advanced malignant pleural mesothelioma

The IND227 phase III international study evaluated the use of the immunotherapy drug pembrolizumab combined with platinum-pemetrexed chemotherapy as a first-line treatment for patients with unresectable advanced or metastatic pleural mesothelioma. The positive results of the trial were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting and subsequently published in The Lancet.

The trial results showed that the addition of pembrolizumab to platinum-pemetrexed chemotherapy resulted in significantly improved overall survival, progression-free survival and objective response rates compared to platinum-pemetrexed chemotherapy alone, regardless of PD-L1 expression and represents a new treatment option for patients with advanced pleural mesothelioma.

This study was considered important as there have been few changes in the standard of care for patients with pleural mesothelioma. The research shows improvements in both progression free survival and overall survival, it is expected that the results of this study will have a tangible and meaningful effect on lung cancer patients.

Brain Disease Site Committee

2023 Overview

Over the past year, the Brain Disease Site Committee has continued to lead (CE7) and participate in (CEC6) international randomized trials with potential to change practice. The CE7 trial, comparing stereotactic radiosurgery with hippocampal-avoidant whole brain radiotherapy, continues to enroll across North America through the US National Clinical Trials Network (NCTN). CEC6 is a phase III intergroup radiotherapy study for anaplastic glioma or low-grade glioma and remains open to accrual.

The committee sought to renew their focus on the development of phase I and II trials of novel targeted agents and, in that context, was delighted with its success in securing a Canadian Cancer Society (CCS) Breakthrough Team Grant for CE9 (LUMOS2) to facilitate its collaboration with the Australian Cooperative Trials Group for Neuro-Oncology (COGNO). This is an umbrella study of novel, molecular-guided therapies in low and anaplastic glioma patients with recurrent disease. The committee has also created a Brain Working Group with the objective of generating new concepts and ideas, including focusing on trials with high recruitment potential in glioblastoma.

2024 Priorities

- Support completion of CE7 trial via NCTN
- Operationalize CE9 (LUMOS2) trial, including collaboration with Terry Fox Research Institute MOHCCN for parallel correlative bio-specimen collection and analyses
- Continue to develop new trial concepts though the Brain Tumour Working Group
- Identify IND program opportunities for enrollment of brain tumour patients.
- Explore opportunities for collaboration with international partners like the EORTC on international phase III trials with practice-changing potential
- Identify opportunities for leadership or collaboration on emerging NCTN trials

Trial Spotlight

CE9 a phase III intergroup study of radiotherapy with Concomitant and Adjuvant Temozolomide versus radiotherapy with adjuvant PCV chemotherapy in patients with 1p/19q co-deleted anaplastic glioma or low grade glioma

Brain cancers that are classified as grade 2 or 3 gliomas most often progress despite radical treatment and when they recur, the lack of effective therapies for these cancers leads to poor outcomes. Five-year survivors are rare and there is an urgent need for new, effective therapies for these patients — currently, there are no clinical trials in Canada testing promising treatments for recurrence.

With funding from CCS and Brain Canada, the committee is joining forces with Australian partners COGNO to open enrollment to Canadian patients to the CE9 (LUMOS2) international study. The researchers will identify novel tumour markers that can be targeted with new treatments that have the potential to dramatically improve patient outcomes.

Committee Executive

Dr. Marshall Pitz
Co-Chair

Dr. David Roberge
Co-Chair

Dr. Mary MacNeil
Dr. Mary Jane Lim-Fat
Dr. Nicole Mittmann
Dr. James Perry
Dr. Warren Mason
Dr. Gelareh Zadeh

Mr. Conor Dellar
Ms Karen Richardson
Ms. Brittany Popowich
Dr. Rebecca Harrison
Ms. Maureen Parkinson
Dr. Anne Leis

Catherine Wreford
Patient Representative

Chris O'Callaghan
Senior Investigator

Dr. Keyue Ding
Senior Biostatistician

Breast Disease Site Committee

2023 Overview

In 2023, the Breast Disease Site Committee focused on opening and enrolling patients to several US National Cancer Trials Network (NCTN) studies. MAC27 (COMPASSHER2) will look at how well trastuzumab emtansine and tucatinib work to prevent recurrence in patients with high-risk, HER2-positive disease. The MAC28 (DEBRA) trial will evaluate the de-escalation of breast radiation for stage 1 hormone-sensitive, HER2-negative, breast cancer. MAC29 (OptimICE-pCR), investigates a de-escalation of therapy in early-stage triple-negative breast cancer patients.

Ongoing enrollment to MA39 (Tailor RT), a CCTG-led NCTN trial of regional radiotherapy in biomarker low-risk, node-positive and larger node-negative breast cancer, is being championed. The CCTG-led MA40 (FINER) study, a trial with the experimental combination of fulvestrant and ipatasertib in advanced breast cancer, is nearing completion.

Addressing inclusivity and diversity within breast trials remains a focus, as does providing opportunities for early career investigator involvement. Translational science led by Canadian researchers remains a high priority for the committee.

2024 Priorities

- Focus on enrollment to NCTN trials
- Work with Alliance to co-lead a sub-study on the OptimICE trial in correlative biology
- Complete accrual on MA40 (FINER)
- Encourage rapid completion of MA39 (TailorRT)
- Develop strategies to overcome current barriers to accrual to CCTG studies
- Work with Unicancer on collaboration, development and participation in studies
- Participation in preoperative and neoadjuvant, window studies
- Develop strategies for enhanced inclusion of diverse populations onto CCTG breast trials

Committee Executive

Dr. Eileen Rakovitch
Co-Chair

Dr. Stephen Chia
Co-Chair

Dr. Valerie Theberge
Dr. Jean-Francois Boileau
Dr. Brooke Wilson
Dr. Philippe Bedard
Dr. Muriel Brackstone
Dr. Peter Watson

Ms. Martina Wood
Patient Representative

Dr. Wendy Parulekar
Senior Investigator

Dr. Lois Shepherd
Senior Investigator

Dr. Bingshu Chen
Biostatistician

Trial Spotlight

MAC27 (COMPASSHER2) a double-blind, phase III randomized trial of T-DM1 alone compared withT-DM1 with the addition of tucatinib for people with high risk HER2-positive breast cancer.

The purpose of this study is to determine if the addition of tucatinib to T-DM1 is better than T-DMI alone at preventing the return of cancer in patients with high-risk HER2-positive breast cancer and residual disease after neoadjuvant HER2-directed therapy.

The new drug is approved for HER2+ advanced or metastatic breast cancer but it is unclear how well it would work for early-stage high risk patients when combined with the standard treatment. Researchers want to see if the combination is better than standard treatment alone.

Gastrointestinal Disease Site Committee

2023 Overview

The Gastrointestinal Disease Site Committee had a positive year, completing accrual to three adjuvant colorectal trials: CO21 (CHALLENGE) assessing exercise as an intervention, CO27 (IROCAS) investigating triplet vs doublet chemotherapy for high-risk patients, and CO29 (DYNAMIC III) investigating ctDNA-directed escalation or de-escalation therapy.

They also centrally activated studies assessing peptide receptor radionuclide therapy retreatment in recurrent neuroendocrine disease, NE1 (NET RETREAT), and GA4 a novel anti-HER2 therapy in advanced gastric cancer. The committee continues to explore the role of ctDNA-directed therapy in an adjuvant colorectal population with CRC10 (CIRCULATE). A focus to improve recruitment for the PAC3 and PAC4 pancreatic cancer trials was successful with Canadian contribution reaching 15% and 11%, respectively.

They secured approval for the somatostatin de-escalation NE2 (STOPNET) trial in patients with neuroendocrine disease treated with PRRT an also, the two trials focused on the patient-priority of organ-preservation and optimization of quality of life in esophageal cancer ES3 (NEEDS]) and rectal cancer CO32 (NEO-RT). In 2024, the committee will lead both the NE1 and CO32 trials through the US National Cancer Trials Network (NCTN) and looks forward to getting the GA4, NE2 and ES3 trials up and running.

2024 Priorities

- Continue to improve accrual to PAC3 and PAC4
- Activate and recruit well to CO32, ES3, GA4, NE1 (NET RETREAT) and NE2 (STOPNET) trials
- Continue to develop concepts for novel and impactful trials across the spectrum of GI cancers

Trial Spotlight

NE1 comparing re treatment of 177Lu-DOTATATE PRRT versus Everolimus in patients with metastatic unresectable midgut Neuroendocrine tumors

NE1 (NET RETREAT) opened in June 2023 and is investigating the re treatment of PRRT compared to the current standard treatment in patients with metastatic midgut neuroendocrine tumours (NETs). 177Lutetium-DOTATATE, the drug being studied, has been shown to shrink tumours and seems promising to the researchers. However, it is not clear if receiving this drug again once disease begins to progress can offer better results than standard treatment.

This trial is a unique collaboration between CCTG and SWOG led by Dr. Simron Singh (CCTG Chair) and Dr. Aman Chauhan (SWOG co-Chair) representing an excellent example of real collaboration between cooperative groups in taking an important trial concept from genesis through implementation across North America via the NCTN mechanism.

Committee Executive

Dr. Sharlene Gill
Chair

Chris O'Callaghan
Senior Investigator

Mr. Hayden Bechthold
Patient Representative

Ms. Suzanne Wood
Patient Representative

Dr. Dongsheng Tu
Senior Biostatistician

Executive

Dr. Petr Kavan
Dr. Rebecca Ann Auer
Dr. Rachel Goodwin
Dr. Derek Jonker
Dr. Eric Chen
Dr. Howard Lim

Disease Oriented Group Chairs

Colon: Jon Loree, Rachel Goodwin
Rectal/Anal: Carl Brown, Vallerie Gordon
Esophagogastric: Elena Elimova, Gail Darling, Aamer Mahmud
Hepatobiliary: Vincent Tam, Paul Karanicolas
Neuroendocrine: Simron Singh, Tim Asmis
Pancreas: Daniel Renouf, George Zogopoulos

Genitourinary Disease Site Committee

2023 Overview

The Genitourinary Disease Site Committee has had a busy year with trial development and activation. PR24 (ASCENDE-SBRT), exploring stereotactic body radiotherapy (SBRT) for prostate cancer, was awarded a CIHR grants amd expected to be centrally activated in early 2024. The PR25 (oPTion-DDR) trial was also awarded a CIHR grant and will test docetaxel and carboplatin in patients with metastatic castration-resistant prostate cancer whose tumours have alterations in DNA repair. PR25 (oPTion-DDR) is being developed for activation in Fall 2024. This will be the first GU trial to include social determinants of health outcome measures and allow some elements of care within the trial to be performed at remote sites.

PR26 (Triple-Switch) was developed and approved by the Clinical Trials Committee (CTC). It is a CCTG-led NCTN trial using docetaxel in patients with metastatic castration-sensitive prostate cancer. BLC6 (MODERN) was also CTC approved. This innovative trial is using ctDNA as a measure of minimal residual disease (MRD) in bladder cancer to either escalate standard treatment in patients who still have ctDNA in their blood after surgery or de-escalate treatment in patients who have no measurable ctDNA after surgery.

Accrual to IND234, a pan-Canadian precision oncology trial that evaluates different targeted treatments, completed enrollment. This trial has allowed CCTG to successfully utilize a virtual molecular tumour board to match patients' genetic alterations to appropriate treatment options. Also, the GU DSC will support GCAR1, a CCTG led, CIHR funded solid-organ CAR-T phase I trial that will include some patients with renal cell carcinoma.

2024 Priorities

- PR24 (ASCENDE-SBRT) – support site activation and accrual
- PR25 (oPTion-DDR) – activate trial and start recruitment
- PR26 (Triple-Switch) – activate trial
- BLC6 (MODERN) – activate trial

Committee Executive

Dr. Sebastien Hotte
Chair

Dr. Wendy Parulekar
Senior Investigator

Dr. Tamim Niazi (Radiotherapy Co-Chair)
Dr. Wassim Kassouf (Surgical Co-Chair)
Dr. Michael Kolinsky
Dr. Scott North
Dr. Nawaid Usmani
Dr. Kim Chi
Dr. Neil Reaume (Economic Analysis)
Dr. Justin Lee (Quality of Life)

Dr. Mariam Jafri
Senior Investigator

Dr. Keyue Ding
Senior Biostatistician

Erwin Wanderer
Patient Representative

Richard Wassersug
Patient Representative

Trial Spotlight

PR24 androgen suppression combined with elective nodal irradiation and dose escalated prostate treatment: A non-inferiority, phase III randomized controlled trial of stereotactic body radiation therapy versus brachytherapy boost in patients with unfavourable risk localized prostate cancer

The CCTG PR24 (ASCENDE-SBRT) trial will determine whether stereotactic body radiotherapy (SBRT) can replace the current standard radiation treatment (brachytherapy boost) for men with unfavourable risk prostate cancer. SBRT is a non-invasive, high precision, less costly radiation technique that results in similar outcomes and tolerability to brachytherapy boost.

This new Canadian led NCTN trial will consider the benefits to the patients and the healthcare system of using this course of treatment. The SBRT treatment being investigated involves a higher dose per day, delivered with precision to target tumours and spare normal tissue from side effects of radiotherapy. If the trial shows that SBRT boost is non-inferior to brachytherapy boost for progression-free survival and is better tolerated, it would likely become the preferred treatment choice.

Gynecologic Disease Site Committee

2023 Overview

2023 saw big results for the Gynecologic Disease Site Committee, the CCTG-led CX5 (SHAPE) trial, presented at the 2023 ASCO Annual Meeting showed that a simple hysterectomy with pelvic node dissection is a safe treatment option for women with low-risk early-stage cervical cancer. The ENC1 study, a phase III randomized, placebo-controlled study of pembrolizumab in addition to paclitaxel and carboplatin for endometrial cancer, reported an impressive benefit of additional pembrolizumab. This study was presented at the Society of Gynecologic Oncology 2023 Annual Meeting and simultaneously published in the New England Journal of Medicine.

The team worked on new drug development studies, including IND240, an immunotherapy platform study in platinum-resistant high grade serous ovarian cancer, and IND243, a phase II study of rp-6306 in patients with advanced cancer. They also embarked on correlative analyses for the OV21 and OV25 (STICs and STONEs) trials.

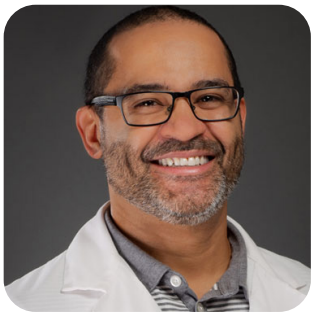
International collaborations with the Gynecologic Cancer Intergroup remain a priority as demonstrated by activation of the CCTG-led EN10 (RAINBO BLUE & TAPER) trial testing a de-escalated adjuvant treatment strategy directed by tumour molecular status, and EN11 (RAINBO-GREEN) study testing the role of adjuvant immunotherapy treatment in endometrial cancer based on molecular features. Both received CIHR funding to enable Canadian participation.

The CCTG led VU2 (STRIVE) study, exploring the stratification of vulvar squamous cell carcinoma by HPV and p53 status to guide excision, is in late stages of central activation, with plans to enroll at select sites in Canada and Australia in 2024. CX6 (GINECO), a French-led international validation study of sentinel node biopsy in early cervical cancer, continues to accrue well and will complete enrollment in 2024.

2024 Priorities

- Support enrollment to EN10 (RAINBO BLUE & TAPER)
- Support enrollment to EN11 (RAINBO-GREEN)
- Support enrollment to CX6 (GINECO)
- Activate VU2 (STRIVE)
- Complete a biomarker analysis of baseline samples on OV25 to inform leukemia risk with PARP therapy
- Develop novel concepts in gynecologic cancers including:
    - testing the impact of HPV ctDNA-guided adjuvant therapy in locally advanced cervical cancer
    - evaluating the impact of stereotactic body radiotherapy in oligometastatic endometrial cancer

Committee Executive



Dr. Stephen Welch
Co-Chair

Dr Mark Carey
Co-Chair

Dr. Josee-Lyne Ethier
Dr. Stephanie Lheureux
Dr. Rebecca Aspen
Dr. Corinne Doll
Dr. Iwa Kong (Quality of Life)
Dr. Janice Smith Kwon (Economic)
Dr. Josee Lyne Ethier (IND)
Dr. Helen MacKay (Correlative Sciences)

Carol Gordon
Patient Representative

Dr. Wendy Parulekar
Senior Investigator

Dr. Dongsheng Tu
Senior Biostatistician

Trial Spotlight

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.

The results of the CX5 (SHAPE) clinical trial, concluded that a simple hysterectomy is a safe treatment option for women with low-risk early-stage cervical cancer. The phase III international trial compared radical hysterectomy and pelvic node dissection with simple hysterectomy and pelvic node dissection and defined a new treatment option that has changed practice globally.

The results showed fewer surgical urological complications for the simple hysterectomy trial group who had an overall better quality of life with reduced toxicity. This study has implications in parts of the world where cervical cancer is endemic. Cervical cancer is the fourth most common cancer in women globally (according to the WHO), and unfortunately more common in less affluent countries.

Head & Neck Disease Site Committee

2023 Overview

The Head and Neck Disease Site Committee had a busy year with activations, final analysis, and preparation for upcoming trials. Both HN9 (LA-OSCC) and HN10 (EVADER) were prepared for final analysis which will include clinical outcomes, patient-reported outcomes (PROs), and results from correlative studies. In October, the HN11(Select) trial was activated, and patients are being enrolled by Dr. Antoine Eskander at the Odette Cancer Centre and Study Co-Chairs, Drs Ali Hosni Abdalaty and John De Almeida, at the Princess Margaret Cancer Centre.

CCTG-led HN13 (ON-TASC study), a phase III trial comparing stereotactic body radiation therapy to standard palliative radiation treatment which aims to optimize head and neck tumour and symptom control in patients unable to tolerate curative intent radiotherapy, was approved and successfully obtained CIHR funding.

2024 Priorities

- Accrue to HN11 (Select)
- Activate HN13 (ON-TASC)
- Initiate EDIIA activities for HN13
- Enhance collaboration with the IND Program
- Explore CCTG data science knowledge for HN9 (LA-OSCC), HN10 (EVADER) secondary analyses.

Trial Spotlight

HN11 SPECT-CT - guided elective contralateral neck treatment for patients with lateralized oropharyngeal cancer

The CCTG-led HN11 (Select) trial is exploring a personalized radiotherapy treatment for head and neck cancer. It is a randomized, controlled, phase III clinical trial for patients with lateralized oropharyngeal carcinoma comparing the effectiveness of standard radiotherapy to personalized radiotherapy guided by the lymphatic mapping technique SPECT-CT. The imaging of the drainage pattern of the primary tumour may help identify areas at risk for cancer recurrence which should be treated with radiotherapy to prevent this from happening.

The standard of care is to administer radiotherapy to both sides of the neck. However, cancerous lymph nodes on the opposite side of the neck occur in only 15% of patients. Routinely treating both sides of the neck may represent over-treatment increasing the risk of side effects. HN11 is a significant study because it looks to preserve areas from over-treatment with radiation and personalize treatment to provide a better outcome for the patient and improve quality of life.

Committee Executive

Dr. John Waldron
Co-Chair

Dr. John Hilton
Co-Chair

Dr. Scott Bratman (Co-Chair: incoming)
Dr. Houda Bahig
Dr. G. Jolie Ringash
Dr. Christopher Lee (QOL Liaison)
Dr. Ambika Parmar (Economics Committee Liaison)
Dr. Anna Spreafico (IND Liaison)

Dr. Wendy Parulekar
Senior Investigator

Mr. Bill Richardson
Patient Representative

Dr. Wei Tu
Senior Biostatistician

Hematology Disease Site Committee

2023 Overview

The Hematology Disease Site Committee is meeting CCTG priorities of supporting practice changing trials, evaluating promising novel therapies, and addressing rare hematological malignancies for Canadian patients. In 2023, the North American trial, HDC1, was a late-breaking abstract at the ASCO Annual Meeting. The trial represents a significant leap in advanced Hodgkin lymphoma treatment by harmonizing pediatric and adult care and further reducing chemotherapy exposure while increasing survival.

Two large CIHR grants were awarded in 2023; one for MY13, a de-escalation study for multiple myeloma, to reduce the burden of therapy among responding patients, and the other for a cellular therapy trial in myeloma. The team is expecting the first MY13 patient to be enrolled soon and getting this trial up and running across Canada is a priority.

This past year saw the engagement of many new investigators across the country, drawn by the highest number of enrolling trials the committee in several years. IND244, for the treatment of primary CNS lymphoma, is cementing their relationship with the IND Program and opening opportunities for innovative therapies in this rare but devastating disease.

2024 Priorities

- Coordinating HD12 (RADAR), an international Hodgkin trial for the US and Canadian sites.
- Opening myeloMATCH a NCTN led AML/MDS platform trial
- Opening CCTG led AL6 trial (myeloMATCH) and designing new trials for the myeloMATCH platform.
- Developing international partnerships through HD11 that will pave the way for future international collaborations.
- Engaging new investigators in all stages of trial development and conduct across the country.
- Continuing development of the planned cell therapy trials with the IND Program.

Trial Spotlight

MY13 a phase III trial of fixed-duration daratumumab versus continuous daratumumab among transplant ineligible older adults with newly-diagnosed multiple myeloma.

The CCTG led MY13 trial is a non-inferiority randomized controlled trial that will investigate if patients need to stay on continuous daratumumab or if they can discontinue safely and be monitored.

There is little scientific evidence around the effective timing of injectable treatments for multiple myeloma. These patients receive treatment with three medicines - two tablets and an injection - all continued indefinitely until they stop working, or the side effects become unmanageable. MY13 will help researchers understand if limiting the timing of the injectable treatments to 18 months is as good as the usual continuous treatment. They also hope to learn if the controlled timing reduces side effects like infections and improves quality of life.

Committee Executive

Dr. Anthony Reiman
Co-Chair

Dr. Sarit Assouline
Co-Chair

Dr. Annette Hay
Senior Investigator

Dr. Lois Shepherd
Senior Investigator

Dr. Bingshu Chen
Senior Biostatistician

David McMullen
Patient Representative

Marg Redlick
Patient Representative

Dr. Tanya Skamene
Dr. Michael Crump
Dr. John Kuruvilla
Dr. Anca Prica
Dr. Mary Lynn Savoie
Dr. Laurie Sehn
Dr. Christopher Venner

Lung Disease Site Committee

2023 Overview

The Lung Disease Site Committee has been focused this year on the analysis of two clinical trials and the development of two new studies.

Stage 1 of the BR36 trial a biomarker-directed, multi-centre phase II/III study of ctDNA response adaptive immuno-chemotherapy in non-small cell lung cancer, was completed and was published in Nature Medicine demonstrating the benefit of using ctDNA as a predictive guide for therapy. The second stage of the BR36 trial was activated in December. IND227, a phase II/III randomized study of pembrolizumab in patients with advanced malignant pleural mesothelioma, demonstrated an improvement in overall survival when immunotherapy was added to standard chemotherapy. Trial results were presented as an oral abstract at the ASCO 2023 Annual Meeting and published in the Lancet.

IND242, a neoadjuvant platform trial in patients with surgically resectable non-small cell lung cancer and its first sub study, IND242A a phase II pre-operative trial in patients with surgically resectable non-small cell lung cancer, were activated in the spring. This platform study aims to identify promising neoadjuvant treatments for patients with non-small cell lung cancer for later validation in randomized clinical trials. New sub studies for the platform will be added in the future to test additional new treatments.

The lung committee is developing a second trial, BR38, which consolidates the use of radiotherapy to block (CURB2) oligo progression in patients with metastatic non-small-cell lung cancer. This international trial will test if radiation to a small number of sites that are progressing can work better than changing to new drug treatment.

2024 Priorities

- Activation of BR38
- New sub studies for IND242
- BR31 potential final analysis
- Continue development of new concepts

Committee Executive

Dr. Penelope Bradbury
Co-Chair

Dr. Alexander Sun
Co-Chair

Dr. Normand Blais
Dr. Glenwood Goss
Dr. Scott Laurie
Dr. Frances Shepherd
Dr. Joseph Pater
Dr. Quincy Chu (IND Liaison)
Dr. Biniam Kidane (QoL Liaison)
Dr. Devin Schellenberg (Radiology Liaison)
Dr. Ming-Sound Tsao (CS/TB Liaison)
Dr. Barbara Lynn Melosky
Dr. Jonathan Spicer
Dr. David Dawe
Dr. Alexander Louie

Emi Bossio
Patient Representative

Dr. Keyue Ding
Senior Biostatistician

Dr. Janet Dancey
Senior Investigator

Dr. Pierre-Olivier Gaudreau
Senior Investigator

Trial Spotlight

A biomarker directed, open label, multi-centre phase II study of molecular response adaptive immuno-chemotherapy in patients with non-small cell lung cancer

The goal of the first stage of the BR36 trial was to identify, through collection of serial liquid biopsies, the optimal time points for molecular ctDNA response and to validate concordance of molecular and radiological response — using ctDNA to identify patients who could benefit from a switch in their therapeutic regimen.

Results showed that immunotherapy responses could be detected early, within an average of eight weeks after treatment started. In addition, results showed that ctDNA response may reflect survival more accurately, especially for patients with stable disease on radiological imaging. These results, published in Nature Medicine, suggest that ctDNA could be used as an early marker of immunotherapy response and may help guide future therapy decisions.

The second stage of the trial, activated in December 2023, will evaluate the potential clinical benefit of tailoring treatment to ctDNA response. Overall, this study will provide critical information to aid in personalizing treatment strategies based on ctDNA responses to immunotherapy.

Melanoma Disease Site Committee

2023 Objectives

The Melanoma Disease Site Committee have been busy with trial activation and successful grant applications to fund correlative science studies and initiate new clinical trials. The ME13L sub-study obtained CIHR and Terry Fox MOHCCN funding and will profile samples from the ME13 (STOP-GAP) trial to characterize predictive biomarkers.

The ME17 study obtained funding from CIHR, CCS, and the Weston Foundation and is close to activation. This phase II trial will evaluate fecal microbiota transplantation in combination with standard of care immune checkpoint blockade (SOC ICB) therapy, compared to SOC ICB alone in patients with advanced melanoma in the first line.

2024 Priorities

- Expand participating sites and work to promote current trials
- Launch the ME13L sub-study
- Develop trials to better manage toxicity, other IND agents
- Continue discussions with international partners on the next melanoma neoadjuvant study
- Evaluate participation in new international trials assessing de-escalation of lymph node dissection post neoadjuvant IO, and adjuvant tebentafusp for high-risk uveal and neoadjuvant study in cSCC
- Standardize genomics reports across MOHCCN projects, including ME13L

Committee Executive

Dr. Ian Watson
Co-Chair

Dr. Marcus Butler
Co-Chair

Dr. Carman Giacomantonio
Dr. Wilson Miller
Dr. Rahima Jamal
Dr. Michael Ong
Dr. Baskoro (Adi) Kartolo
Dr. Vanessa Bernstein

Ms. Louise Bird
Patient Representative

Dr. Bingshu Chen
Senior Biostatistician

Dr. Janet Dancey
Senior Investigator

Trial Spotlight

ME13L is a bio marker sub-study of the CCTG ME13 duration of anti PD-1 therapy in metastatic melanoma STOP-GAP trial.

This sub- study of the ME13 trial will profile human bodily material (HBM) before, during and post-treatment with immune-checkpoint inhibitors to characterize predictive bio markers of response, progression -free and overall survival, and immune -related toxicity. The investigators anticipate multi-dimensional molecular profiling of melanomas, and circulating immune cells can identify a subset of markers to best predict clinical outcomes.

By combining innovative single -cell profiling, ctDNA, and multi-omic analytical approaches coupled with the unique CCTG ME13 (STOP-GAP) trial design, the ME13L sub -study has an unprecedented opportunity to develop biomarker-based approaches to inform on optimal duration of anti-PD-1 therapy to facilitate clinical decision-making and improve patient outcomes.

Sarcoma Disease Site Committee

2023 Objectives

This year, the Sarcoma Disease Site Committee has been focused on attendance at international meetings with Dr. Shantanu Banerji, CCTG's Sarcoma Co-Chair, presenting IND228 at the Connective Tissue Oncology Society Annual meeting. Dr. Banerji and Dr. Mariam Jafri represented CCTG at the NCTN sarcoma leadership meeting at ASCO. Also, Dr. Gladdy completed a study comparing the effect of radiotherapy on abdominal recurrence-free survival in patients with primary retroperitoneal sarcoma which was published in Annals of Surgery (STREXIT and STRASS).

The Committee supported the development of the upcoming GCAR1 trial, a phase I feasibility and safety study of a chimeric antigen receptor (CAR) t-cell therapy for participants with relapsed or refractory GPNMB-expressing solid tumours.

They also focused on mentoring early career investigators, including Dr. Alannah Smrke who completed the CCTG New Investigator Cancer Trials Practicum focused on sarcoma. The Committee also successfully recruited an adolescent and young adult (AYA) patient representative, Jasmine Heuring, who is a cancer advocate and healthcare analyst diagnosed with Ewing's Sarcoma at the age of 26.

The Committee continues working actively to engage with the Canadian basic science community.

2024 Priorities

- Establish regular quarterly meetings to discuss ideas and connect as a sarcoma community (clinicians and researchers) at the West Coast Sarcoma Conference
- Ongoing mentorship of clinical and laboratory scientists
- Bring two biological-driven proposals forward through the IND Program
- Support US National Cancer Trials Network studies
- Engagement with the new AYA Patient Representative in trial design

Committee Executive

Dr. Rebecca Gladdy
Co-Chair

Dr. Shantanu Banerji
Co-Chair

Dr. Abha Gupta
Dr. Philip Wong
Dr. Jan-Willem Henning
Dr. Torsten Nielsen
Dr. Christine Simmons
Dr. Albiruni Razak (IND liaison)

Ms. Jasmine Heuring
Patient Representative

Dr. Mariam Jafri
Senior Investigator

Dr. Janet Dancey
Senior Investigator

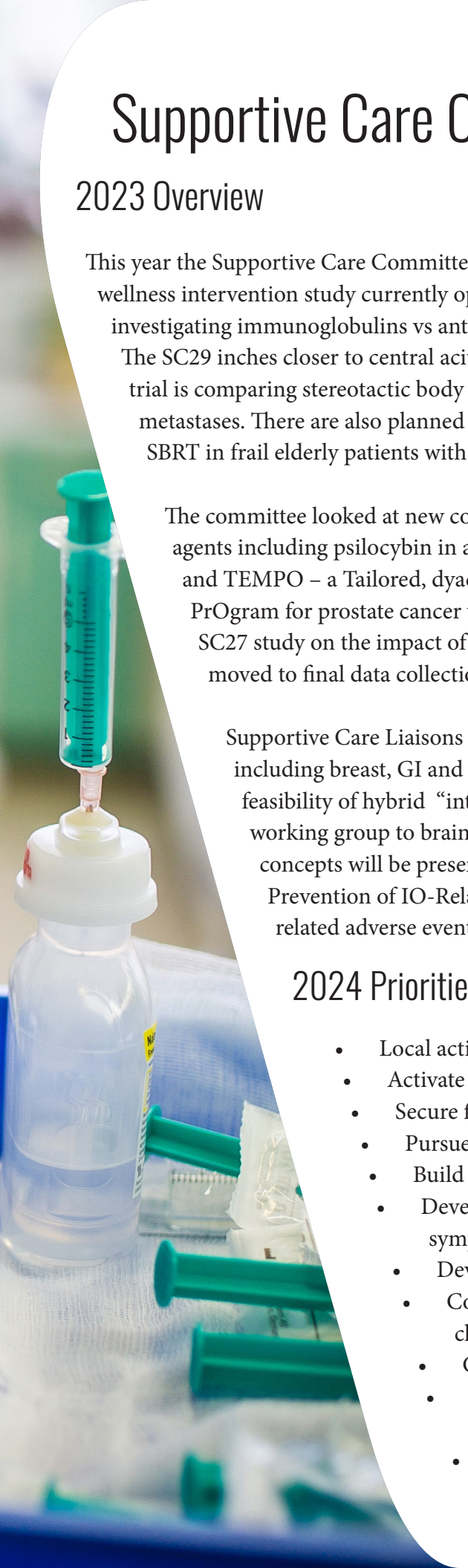
Dr. Dongsheng Tu
Senior Biostatistician

Trial Spotlight

SR7 is a randomized phase III study of neoadjuvant chemotherapy followed by surgery versus surgery alone for patients with high-risk retroperitoneal sarcoma

SR7 (STRASS 2) is an international study led by European researchers with collaborators in the UK, Australia, Canada, New Zealand, and the US. It is the first trial investigating potential benefits of chemotherapy before surgery to improve disease control and survival in patients with retroperitoneal sarcoma.

Retroperitoneal sarcoma is a very rare tumour that is unfortunately challenging to diagnosis and treat. The standard of care consists of surgery with a 60-70% overall survival at 5 years following surgery. The role of systemic therapy before or after surgery remains unproven and its use varies widely among different institutions.



Supportive Care Committee

2023 Overview

This year the Supportive Care Committee centrally activate the CCTG led SC28 (SEAMLESS) trial, a wellness intervention study currently open to accrual. They also focused on SC30 central activation, a study investigating immunoglobulins vs antibiotics to reduce infections in hematological malignancies. The SC29 inches closer to central acitvation with a proposal submitted to CIHR in September 2023, This trial is comparing stereotactic body radiotherapy (SBRT) to conventional radio therapy to palliate bone metastases. There are also planned discussions in geriatric oncology to supplement HN13, comparing SBRT in frail elderly patients with head & neck cancer.

The committee looked at new concepts: Complimentary and Alternative Medicine (CAM)-related agents including psilocybin in a psilocybin assisted therapy which will be resubmitted to CIHR; and TEMPO – a Tailored, dyadic, wEb-based, psychosocial and physical activity self-Management PrOgram for prostate cancer which was CIHR Funded (July 2023) and resubmitted to the CTC. The SC27 study on the impact of the COVID-19 pandemic on cancer patients during treatment has moved to final data collection, analysis and publication.

Supportive Care Liaisons have been assigned to selected CCTG disease site committees including breast, GI and GU, with a potential hematology liaison. They are also assessing the feasibility of hybrid "intergroup" model. The committee is establishing an immunotherapy working group to brainstorm proposals for study concepts led by Dr. Tina Hsu. New study concepts will be presented at Spring Meeting 2024 and include: Vedolizumab for the Prevention of IO-Related Colitis, and JAK inhibitors for salvage therapy of severe immune-related adverse events.

2024 Priorities

- Local activations and accrue to SC28
- Activate and accrue to SC29
- Secure funding for SC30
- Pursue grant for psilocybin symptom science proposal
- Build consensus for TEMPO
- Develop phase II concept for prevention/management of immune-related symptoms
- Develop proposal for secondary analysis of existing CCTG data
- Consider symptom science platform to evaluate predictors of toxicity for checkpoint inhibition
- Continue discussion of possible opportunities in geriatric oncology
- 2024 Spring Meeting - discuss structure to support CCTG digital clinical trial strategies
- Continue discussions for a future collaboration with IND and CSTB

Committee Executive

Dr. Michael McKenzie
Co-Chair

Dr. Margot Burnell
Co-Chair

Ms. Hilary Horlock
Patient Representative

Dr. Tina Hsu
Dr. Martin Chasen
Dr. Arjun Sahgal
Dr. Lynda G. Balneaves
Dr. Linda Carlson
Dr. Camilla Zimmermann
Dr. Doris Howell (QOL)
Mr. Carlo De Angelis (Pharma)

Dr. Harriet Richardson
Senior Investigator

Dr. Wei Tu
Senior Biostatistician

Trial Spotlight

SC28 trial is a pragmatic multi-site randomized waitlist-controlled trial of a smartphone app-based mindfulness intervention for cancer survivors

The CCTG SC28 (SEAMLESS) study is investigating an app based mindfulness meditation to see if it helps to improve stress and well-being. The SC28 study chair Dr. Linda Ellen Carlson believes that people who have had cancer may have multiple unmet psychosocial needs after the completion of their primary treatment.

The mindfulness program (Mindfulness Based Cancer Survivorship Journey) is delivered through a mobile (Am Mindfulness) smartphone app that aims to reduce ongoing psychosocial symptoms such as stress, anxiety, depression, fatigue, and fear of cancer recurrence or progression that are often experienced by survivors. There is a recognized need for more accessible approaches to delivering psychosocial care after the completion of primary treatment to ensure the growing population of survivors experience a better quality of life and improved health outcomes.

Committee of Economic Analysis

2023 Overview

The Committee for Economic Analysis (CEA) continues to lead trial specific health economic analyses, and advance methodological approaches to collecting and analyzing data. This is achieved through collaboration between Canadian Cancer Trials Group investigators - including Patient Representatives, Disease Site, and Quality of Life Committees – in addition to external partners.

In 2023, the economic analysis of the SC24 clinical trial was completed - highlighted below. Publications included methodological work on power and sample size calculations for incremental net benefit in cost effectiveness analyses, and a review of linkage of clinical trial and administrative data as a potential means to augment economic analyses. The Committee created 3 working groups. The first is focused on model-based economic analyses, the second on data linkage, and the third on financial toxicity.

2024 Priorities

- Appoint economic analysis liaisons for the Brain and GU disease site committees
- Complete the IND227 health economic analysis
- Further develop the working groups
- Administrative linkages - analyze the LIFE study (LY12) long term innovative follow up extension)
- Model based – consider model based economic analyses for completed trials
- Financial toxicity – complete an environmental scan of tools within trials
- Identify a post-doctoral fellow for a combined CCTG/ARCC fellowship
- Revise document to aid prioritizing CEA efforts

Trial Spotlight

An economic analysis of SC24 in Canada quantified the incremental cost-effectiveness of stereotactic body radiation therapy (SBRT) compared to chemoradiotherapy (CRT) in individuals with spinal metastases.

SBRT has upfront costs compared to CRT. However within the Canadian health care system, SBRT with 2 fractions is likely to be cost-effective relative to CRT. In patients randomized to initially receive SBRT, the total cost for the base case of SBRT was $2,869CAD compared with $2,343CAD for CRT. This produced an incremental cost of $526CAD for SBRT over CRT.
Cost-effectiveness was assessed using a Markov model and took into account observed survival, treatments costs, retreatment, and quality of life over the lifetime of the patient.

Committee Executive

Dr. Kelvin Chan
Co-Chair

Dr. Matthew Cheung
Co-Chair

Carol Gordon
Patient Representative

Dr. Annette Hay
Senior Investigator

Dr. Bingshu Chen
Senior Biostatistician

Dr. Wei Tu
Senior Biostatistician

Dr. Tim Hanna (Radiation Oncology)
Dr. Natasha Leighl (Lung)
Dr. Neil Reaume (GU)
Dr. Pierre Villeneuve (Hem/Supportive Care)
Mr. Carlo De Angelis (Pharmacy)
Dr. Nicole Look Hong (Melanoma)
Dr. Anca Prica (Hem/Quality of Life)
Dr. Alexander Louie (Lung)
Dr. Ambika Parmar (Head/Neck/Lung)
Dr. Danielle Rodin (Breast)
Dr. Marc Kerba (Supportive Care)
Dr. Winson Cheung (Quality of Life)
Dr. Janice Smith Kwon (Gynecology)
Dr. Stuart J Peacock
Dr. Ana Johnson
Dr. Lee Mozessohn (Hem)
Dr. Ying Wang

Quality of Life Committee

2023 Overview

The Quality-of-Life (QOL) Committee has continued the work toward completing the value frameworks study to better understand cancer treatment decisions. This study is led by Dr. Colleen Cuthbert with support from Dr. Winson Cheung who are both at the University of Calgary. Project funding was successfully obtained from the Canadian Centre for Applied Research in Cancer Control (ARCC). This project represents a collaboration between the QOL Committee and the Cost-Effectiveness Analysis (CEA) Committee led led by Drs. Kelvin Chan and Matthew Cheung.

As clinical trials are developed, engaging with the QOL liaisons in each of the disease site committees to support inclusion of QOL components is critical. They continue to explore an increasing number of collaborations between endpoints committees (QOL and CEA), including a systematic review of financial toxicity instruments or tools and a potential study on time toxicity. The Committee is also aiming to integrate EDIIA considerations into their QOL work.

2024 Priorities

- Analyze, complete, and publish findings from value frameworks study
- Foster additional collaborations between QOL and CEA
- Act as a resource for disease site committees during trial design to ensure early QOL integration.
- Further enhance patient engagement and develop shared objectives

Committee Executive

Dr. Joelle Helou
Co Chair

Dr. Winson Cheung
Co Chair

Ms. Louise Bird
Patient Representative

Dr. Joseph Pater
Senior Investigator

Dr. Julie Lemieux (Breast)
Dr. Michael Brundage
Dr. Hira Mian (Hem)
Dr. Kelvin K-W Chan
Dr. Matthew Cheung
Dr. Doris Howell (Supportive Care)
Dr. Michael McKenzie (Supportive Care)
Dr. Christopher Lee (LUNG/MEL Liaison)
Dr. Anca Prica (HEM)

Dr. Jolie Ringash (Rad Onc)
Mr. David Boren
Dr. Biniam Kidane (Lung)
Dr. Iwa Kong (Gynae Liaison)
Dr. Christine Simmons
Dr. Anne Leis (Brain)

Dr. Dongsheng Tu
Senior Biostatistician

Equity, Diversity, Inclusivity, Indigenization, and Accessibility

CCTG recognizes that equity, respect for diversity, and promotion of inclusivity are essential to our continued research success. CCTG's Equity, Diversity, Inclusivity, Indigenization, and Accessibility (EDIIA) strategic initiative has been an important focus for our trial teams, committees, and investigators as we address issues, barriers and ensure opportunities for our patient partners, network, and partners. CCTG will foster a research network and culture that values a breadth of perspectives and lived experiences.

CCTG's EDIIA action plan has been progressing with the creation of three Working Groups: Design, Methodology and Data Management, Operations, and Network Participation. Over 50 CCTG members from across the network have participated in these Working Groups which have Activities throughout 2023 included a mandate to develop and present recommendations to CCTG leadership to ensure EDIIA core values and principles are integrated into our leadership, membership, staffing, and research practices.

Several "Lunch and Learn" sessions to promote and increase awareness of EDIIA-related topics, updates to our SOPs and policies to reflect EDIIA language, and an EDIIA guide was created to assist with future updates.

2024 EDIIA workshop & round tables

A series of EDIIA virtual round tables were planned for 2024 which include renowned panelists with expertise in equity and diversity in cancer care and clinical trials. These curated discussions are open to anyone with interest in strategies for enhancing clinical trial diversity and making clinical trials more accessible to all populations.

Anna Johnson

EDIIA Lead

Anna Johnson is the CCTG's Equity, Diversity, Inclusivity, Indigenization, and Accessibility (EDIIA) Lead. She joined CCTG in 2022 to support the advancement of the group's EDIIA Action Plan which focuses on integrating EDIIA into our network, research, and scientific priorities. Over the past year, she has worked on building relationships with representatives of equity-deserving groups and communities previously underrepresented in clinical trials to understand barriers they face when accessing cancer care and clinical trials. These relationships are imperative to better understand how to improve clinical trial enrollment of equity-deserving populations and the research priorities that are important to these populations.

Solving Cancer Together

We are "Solving Cancer Together", making scientific progress and identifying new treatments that improve outcomes for patients. We will continue to support new and ongoing trials and our scientific activities. Actions taken by our patients representatives, network leaders and members, international collaborators, industry partners, central office team, and our funders will create change.

Network Engagement

- Virtual Road Show - recommendations addressing local challenges & supports needs
- Trial supports and funds
- Scientific Review process and policy created
- Network Leadership supports
- Terms of Reference for Support Committees - reviewed and updated

Communication & Knowledge Transfer

- Communication within and across committees
- Communication of CCTG activities and impact
- Evaluate current approach to communication and needs of key stakeholders
- Communications Plan with identification of priority areas to focus on over the next year
- Update KT strategy to standardize the flow of knowledge transfer of research outcomes for partners, stakeholders

Sustainable Funding

- Establish plan for Midterm review 2024
- NCTN Program Grant Renewal 2024
- Develop and submit grants for CIHR Spring / Fall Competitions
- Government affairs – CCS workshop, messaging to House of Commons Committee
- Advancement and philanthropy – Finalize MOU,
- Support CCS naming activities,
- Practicum funding
- Review and refresh the Case for Support

Research Platforms

Cell Therapy
Preoperative Clinical Trials
Data Science

Cell Therapy

Two cell therapy trials were awarded a combined $5,852,251 from the Canadian Institutes of Health Research and are currently in development: The GCAR-1 trial: a phase I feasibility and safety study of GCAR1, a chimeric antigen receptor (car) t-cell therapy for participants with relapsed or refractory GPNMB-expressing solid tumors. The anticipated start will be mid-2024. The TACtful trial: A first in human phase I single arm multi-centre trial of anti-BMCA-specific T-cell antigen coupler infusion, generated from cryopreserved G-CSF mobilized peripheral blood, in patients with relapsed and refractory multiple myeloma. The anticipated central activation will be in 2025 with the aim of ensuring manufacturing readiness at the end of 2024.

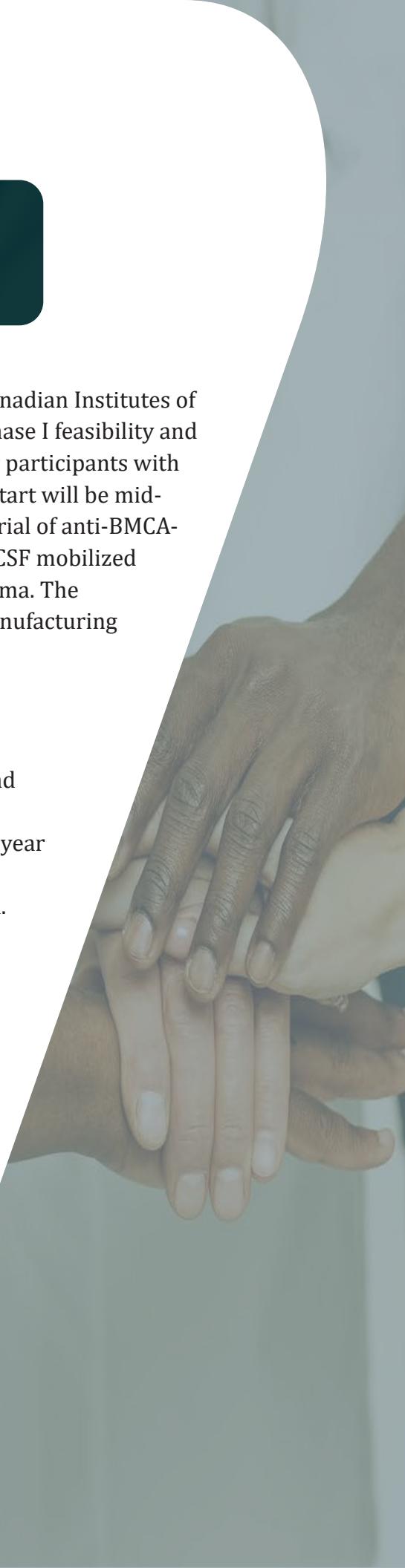
Preoperative Clinical Trials

Expansion of the Tumour Tissue Data Repository (TTDR)
Funding obtained through the CFI Innovation Fund in 2019 to enhance and expand the TTDR's capacity to support all CCTG activities, including pre-operative trials, cell therapies, and future directions in data science. This year CCTG was focused on establishing plans for the renovation in addition to relocation of TTDR equipment and freezers to prepare for the renovation. Policies and processes have been reviewed, including databases and structures, to ensure CCTG is well positioned to support next steps post renovation.

TTDR expansion supports trials such as IND242, a neoadjuvant platform trial in patients with surgically resectable non-small cell lung cancer (NSLC) developed during this reporting report. The first arm, IND242A: a phase II pre-operative trial for patients with surgically resectable NSCLC, was activated.

Data Science

The data science activities for the Group were focused on defining core data elements, identifying key trials for the data sharing platform, and on processes required for genomics and digital imaging data warehousing. In addition, a Post Doctoral Fellow was recruited to support the data science efforts.

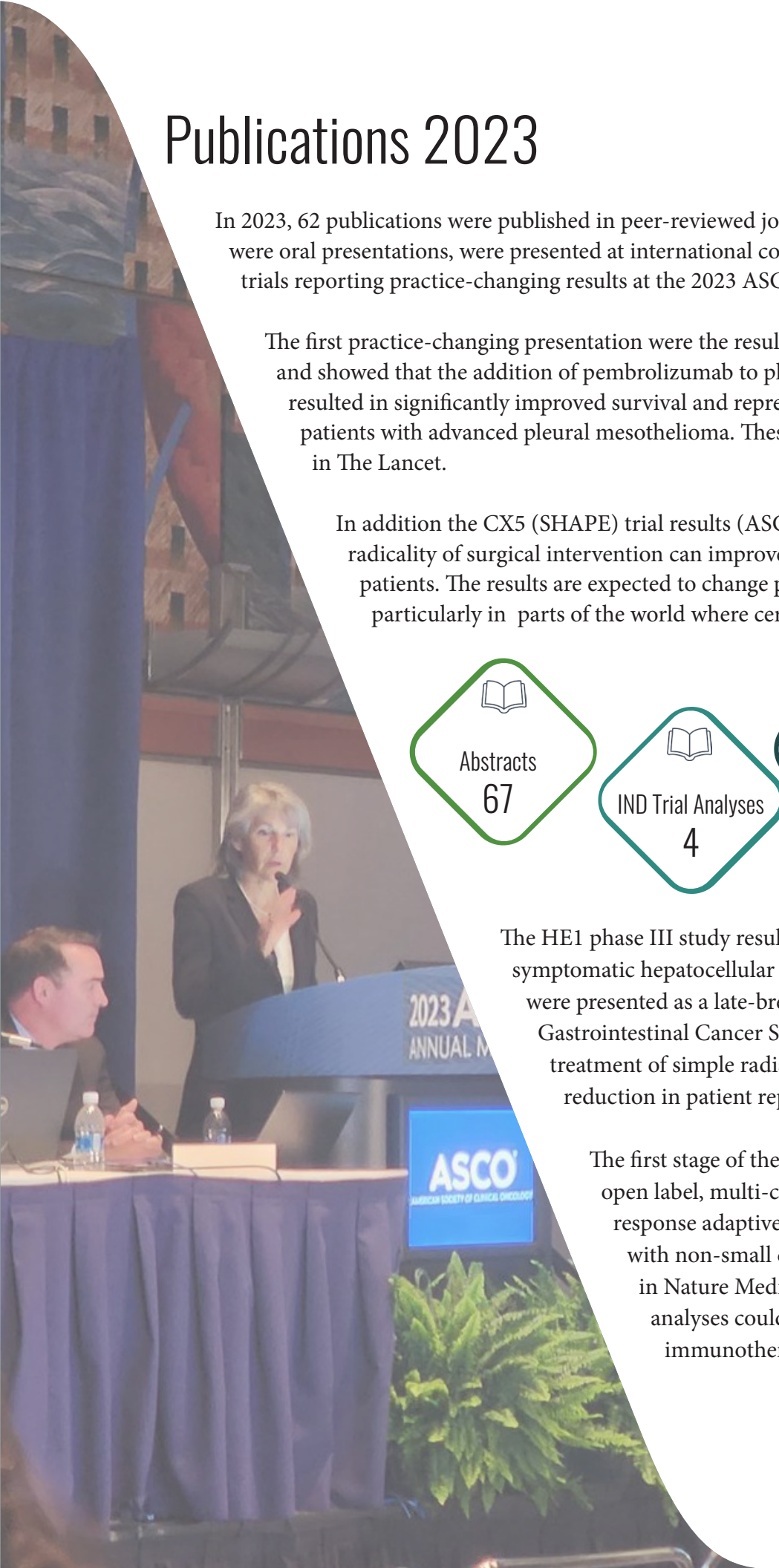


Publications 2023

In 2023, 62 publications were published in peer-reviewed journals and 74 abstracts, 27 of which were oral presentations, were presented at international conferences, including 2 CCTG-led trials reporting practice-changing results at the 2023 ASCO Annual Meeting.

The first practice-changing presentation were the results for the IND227 study (2023 ASCO) and showed that the addition of pembrolizumab to platinum-pemetrexed chemotherapy resulted in significantly improved survival and represents a new treatment option for patients with advanced pleural mesothelioma. These results were subsequently published in The Lancet.

In addition the CX5 (SHAPE) trial results (ASCO 2023) demonstrated that reduced radicality of surgical intervention can improve quality of life for cervical cancer patients. The results are expected to change practice in Canada and globally, particularly in parts of the world where cervical cancer is endemic.



Abstracts
67

IND Trial Analyses
4

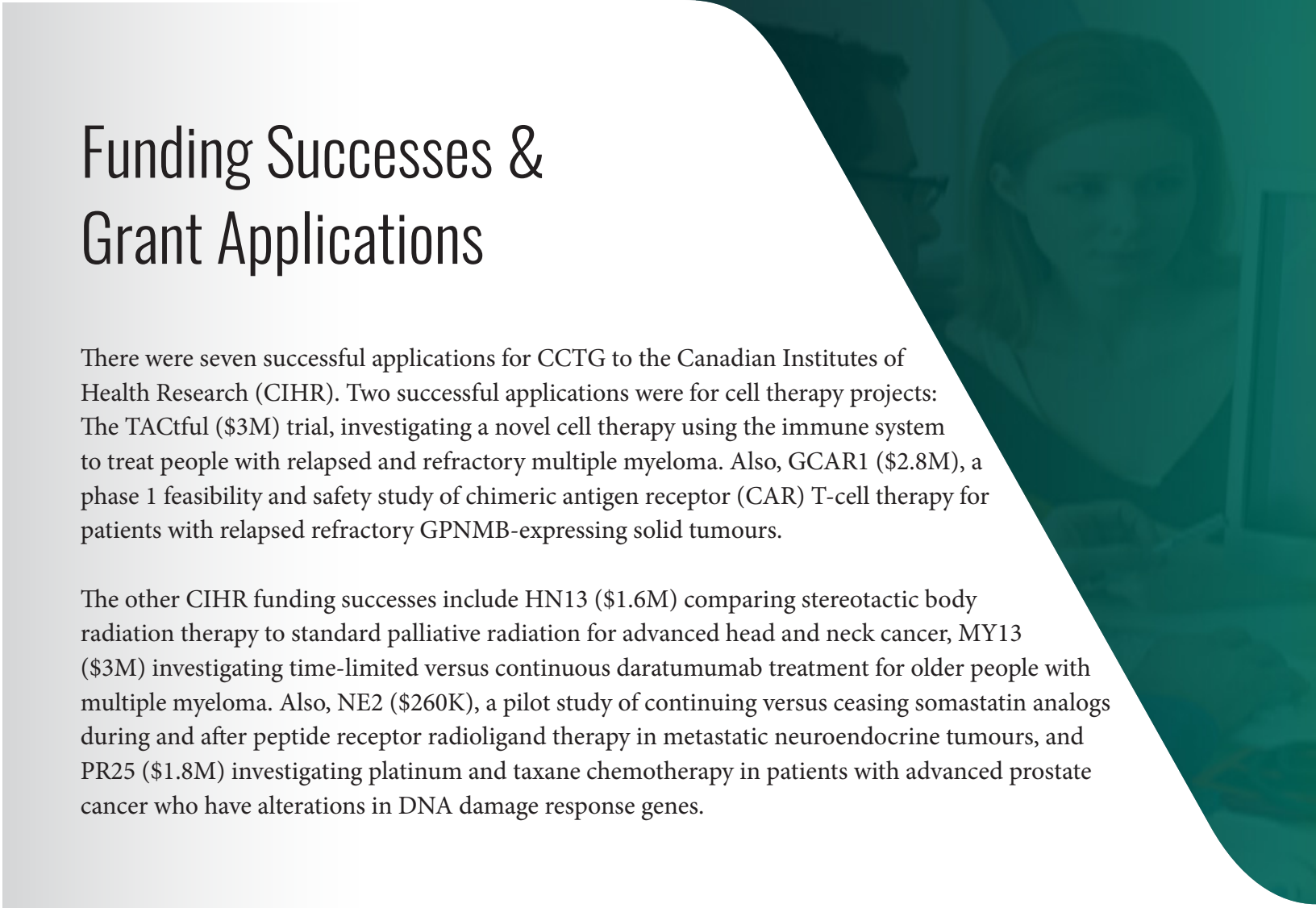
Publications
62

Phase III Analyses
5

The HE1 phase III study results of palliative radiotherapy for symptomatic hepatocellular carcinoma and liver metastase were presented as a late-breaking abstract at the 2023 ASCO Gastrointestinal Cancer Symposium. The study found that one treatment of simple radiation therapy to the liver resulted in a reduction in patient reported pain improving quality of life.

The first stage of the BR36 trial, a bio-marker-directed, open label, multi-centre phase II study of molecular response adaptive immuno-chemotherapy in patients with non-small cell lung cancer, was published in Nature Medicine, suggesting that ctDNA analyses could be used as an early marker of immunotherapy response.

Funding Successes & Grant Applications



There were seven successful applications for CCTG to the Canadian Institutes of Health Research (CIHR). Two successful applications were for cell therapy projects: The TACtful ($3M) trial, investigating a novel cell therapy using the immune system to treat people with relapsed and refractory multiple myeloma. Also, GCAR1 ($2.8M), a phase 1 feasibility and safety study of chimeric antigen receptor (CAR) T-cell therapy for patients with relapsed refractory GPNMB-expressing solid tumours.

The other CIHR funding successes include HN13 ($1.6M) comparing stereotactic body radiation therapy to standard palliative radiation for advanced head and neck cancer, MY13 ($3M) investigating time-limited versus continuous daratumumab treatment for older people with multiple myeloma. Also, NE2 ($260K), a pilot study of continuing versus ceasing somastatin analogs during and after peptide receptor radioligand therapy in metastatic neuroendocrine tumours, and PR25 ($1.8M) investigating platinum and taxane chemotherapy in patients with advanced prostate cancer who have alterations in DNA damage response genes.

21 grants submitted, 11 funded, totaling nearly $18M

205 Contracts
14 Clinical Trial Agreements
15 Data & Correlative Agreements

Dr. Hira Mian, MY13 Chair, was awarded $450,000 from Myeloma Canada to support the following quality of life activities, including dedicated patient trial information, site costs for data collection and submission, as well as knowledge translation and results presentation at international meeting and peer reviewed journal.

Dr. Alex Wyatt was awarded $1M from the Prostate Cancer Foundation in the US to support biomarker discovery and qualification as part of PR21.

Canadian Cancer Trials Group Founding Director Appointed to the Order of Canada

Dr. Joseph Pater was appointed as an Officer of the Order of Canada in recognition of a lifetime dedication to cancer research and a commitment to improving the lives of Canadians with cancer.

For over 40 years, Dr. Pater has advanced clinical trial research in Canada. Sometimes called the "father" of cancer clinical trials research in Canada, he accepted appointments in the Departments of Medicine and Oncology at Queen's University when medical oncology was still in its infancy. In 1980, a formal collaborative cancer clinical trials network was established by the Canadian Cancer Society with Dr. Pater as the inaugural Director. His leadership transformed CCTG from a small program to the largest academic cooperative oncology group in Canada.

Dr. Elizabeth Eisenhauer, past Director of CCTG's Investigational New Drug Program and Officer of the Order of Canada, says "Dr. Pater has been the driving force in creating a vibrant cancer clinical trials community in Canada and thousands of patients are living cancer-free today because of his work. Canada and the world owe him so much gratitude and I was very fortunate to have been mentored by him at the beginning of my career."

David McMullen receives 2023 CCRA Award

Exceptional Leadership in Patient Involvement in Cancer Research

In the Fall the Canadian Cancer Research Alliance (CCRA) presented CCTG Patient Representative, David McMullen the award for Exceptional Leadership in Patient Involvement in Cancer Research. The award recognizes his extensive work developing and conducting support programs for patients with multiple myeloma and his continued involvement in promoting patient engagement in cancer clinical trials.

"I meet countless numbers of cancer patients who are greatly concerned about the symptom control, side effects, and quality of life aspects of their disease and treatments. It is my role as a Patient Representative to ensure that needs of patients are heard in the development of clinical trials," says David who was diagnosed with Multiple Myeloma in 2012. In addition to his work with CCTG he has also been a patient representative in other research and health care organizations, and at numerous national and international conferences.

CCTG in the Community

Kingston Pride Parade

Relay for Life

Relay for Life

Pansy's for Pancreatic Cancer

Every Child Matters

Anti Bullying Day

Ride For Dad

CCS donations @ Spring Meeting

Movember

Christmas food drive

Canadian Cancer Trials Group

Groupe canadien des essais sur le cancer

The Canadian Cancer Trials Group is proud to be a national program of the Canadian Cancer Society (CCS). CCTG is also the only non-American partner of the US National Clinical Trials Network and collaborates with research cooperative groups around the world. The CCTG Operations and Statistical Centre, based at Queen's University, is recognized as a Canada Foundation for Innovation Major Sciences Initiative facility.

www.cctg.ca

Canadian Cancer Society | Société canadienne du cancer

Queen's University

NCI National Clinical Trials Network

a National Cancer Institute program