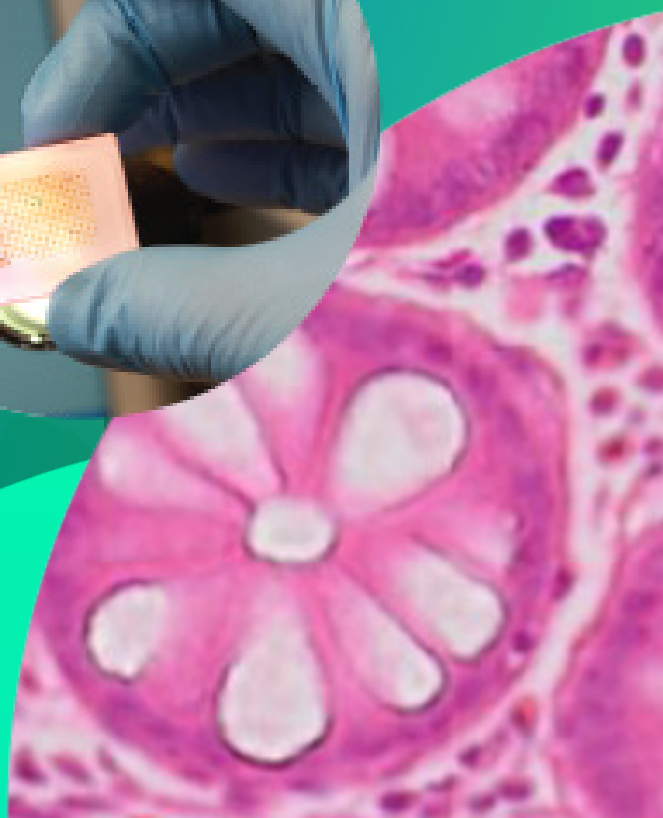
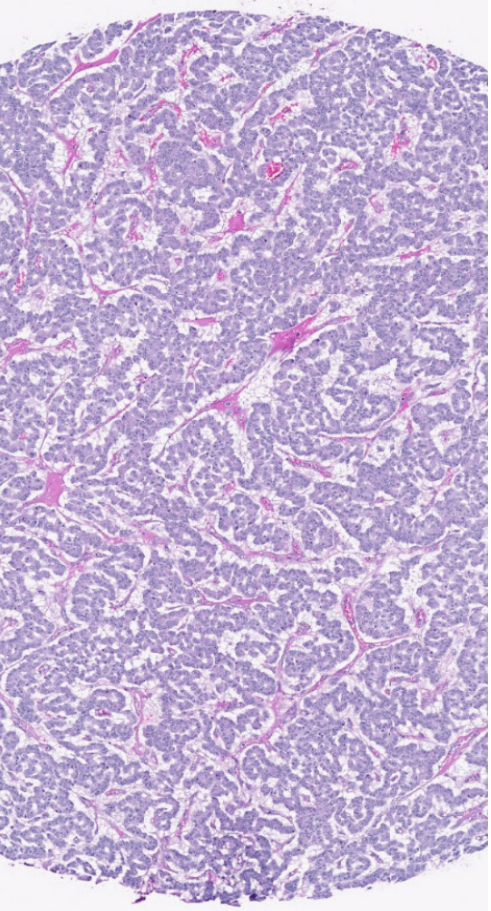
Canadian Cancer Trials Group

Groupe canadien des essais sur le cancer

Annual Report 2025





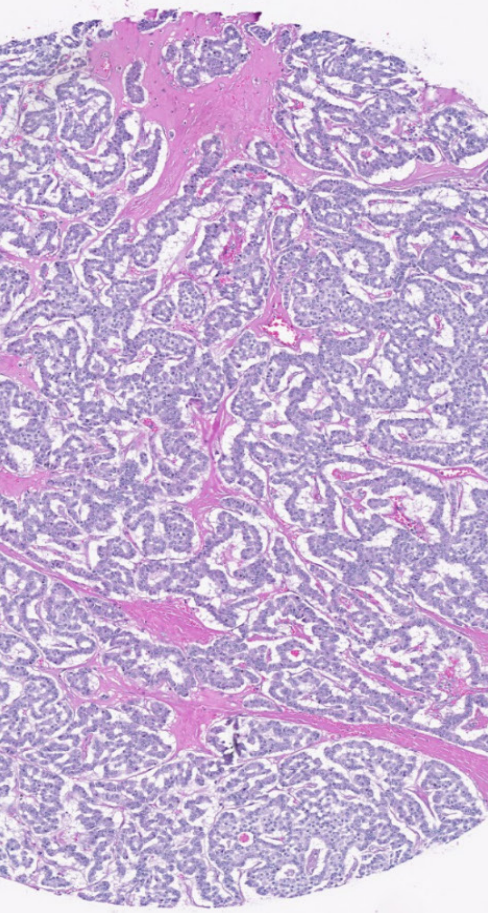


Table of Contents

CCTG Year in Review

2025 Highlights & Achievements

Dr Janet Dancey, CCTG Chair

In 2025, the Canadian Cancer Trials Group (CCTG) demonstrated scientific excellence and national and international recognition for its leadership in academically driven cancer clinical trials. These achievements reflect the commitment of investigators, site teams, clinical research associates, patient partners, and CCTG staff.

The year began with important CIHR Project Grant successes. SC.30 (RATIONAL) was awarded nearly $1.2 million to study treatment strategies for patients with hematologic malignancies and low antibody levels. PAC.5 received $742,000 to evaluate lanreotide for prevention of postoperative pancreatic fistula, and SR.8 (HARMONY) received nearly $1.5 million to address an unmet need in high-risk soft-tissue sarcoma. CCTG's U.S. National Clinical Trials Network renewal application successfully completed scientific review.

Trial activity remained strong, with 166 trials in the portfolio, 56 open to accrual, and seven new trials activated across disease sites. In total, 1,359 patients were accrued. ME.17, one of the largest randomized trials investigating fecal microbiota transplantation with immune checkpoint blockade for advanced melanoma, exemplified CCTG's ability to lead complex, multicentre studies.

CCTG continued to build capacity, welcoming 116 new investigators and 246 new clinical research associates. The CRA Lunch and Learn program delivered five sessions, engaging 918 CRAs in practical education on trial activation and conduct. The New Investigator Cancer Trials program continued to train emerging researchers, and two new education initiatives—the VISION Program and Investigational New Drug Early Clinical Trial Education Program—will launch in 2026.

CCTG trials generated substantial scientific output, including 78 abstracts and 50 publications, among them seven primary trial reports. Highlights included MA.40 FINER, presented at the ASCO Annual Meeting, which demonstrated the importance of targeting the AKT pathway in advanced ER-positive, HER2-negative breast cancer; the CO.28 correlative study, presented at GI ASCO, supporting the potential of tumour-free circulating tumour DNA as a decision tool for organ preservation in node-negative rectal cancer; and CO.29 DYNAMIC-III, presented at ESMO, may inform future studies and individualized risk–benefit discussions in colon cancer.

The international recognition of CO.21 CHALLENGE underscored the global impact of academically led research. This world-first trial showed that a structured exercise program significantly improves survival for patients with stage III colon cancer by reducing recurrence and new primary cancers. Spanning 17 years, CHALLENGE helped establish exercise as a life-extending supportive care intervention and has influenced guidelines worldwide.

Health equity and patient partnership remained central to CCTG's mission. Caroline Hamm and Dr. Julie My Van Nguyen joined as Health Equity Leads, supporting the Health Equity Committee and the PR.25 and HN.13 trials. CCTG also welcomed four new patient representatives: Catherine Caule, Lesley Beaton, Darren Frew, and Tracey Kitz.

The year was also marked by recognition of CCTG leaders. Dr. Lesley Seymour was named a Fellow of the Canadian Academy of Health Sciences; Dr. Tim Whelan was appointed an Officer of the Order of Canada; and Dr. Natasha Leighl received the 2025 ESMO Women for Oncology Award. Together, these accomplishments reflect CCTG's ongoing leadership in improving cancer outcomes in Canada and internationally.

CCTG BY THE NUMBERS 2024

Since 1980 a total of **113,290** patients were accrued into trials including **82,627** patients from Canada, **20,260** from the United States, and **10,403** patients from other countries.

Accrual 2025

3,304 Patients Accrued Globally

3,053 Patients Accrued in Canada

Trials 2025

This year **56 trials** were open in communities across Canada with clinical research in over **30 different cancer types**

72 CCTG led clinical trials

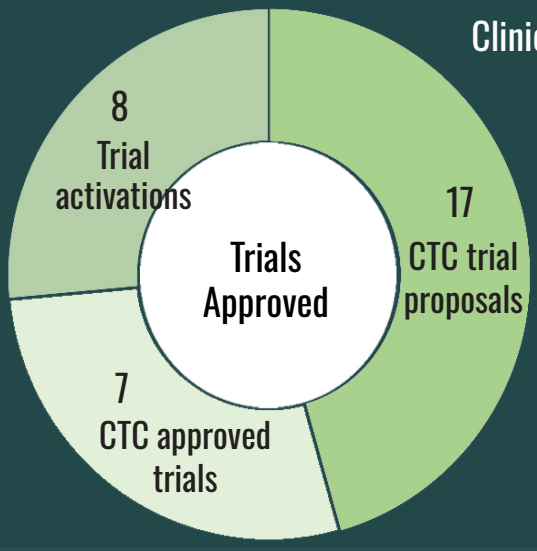
60 NCTN Intergroup led trials

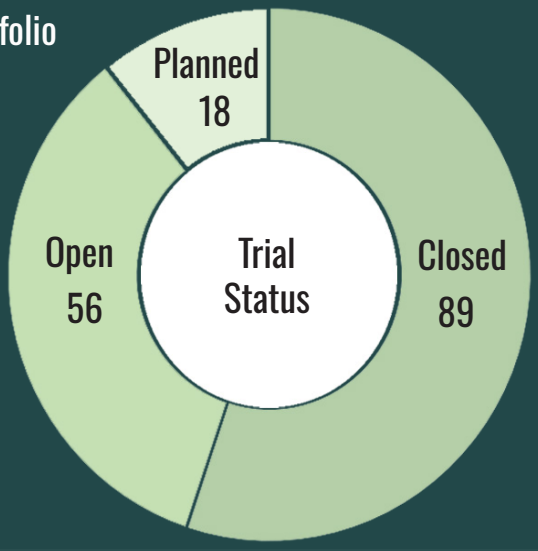
11 NCTN CCTG led trials

22 International Intergroup Led

166 total number of clinical trials

Clinical Trial Portfolio





CCTG NETWORK AT A GLANCE

The CCTG network includes 86 Canadian centres working with 680 international centres in 20 countries.

Canadian Members
7,502

Total Network
23,090

International Members
15,588

2,375
Canadian Investigators

4,744
International Investigators

5,127
Canadian Clinical Trial Personnel

10,844
International Clinical Trial Personnel

Publications

Publications this year reflected the impact of our practice-changing clinical research, showcasing CCTG's role as both a research leader and valued collaborator working alongside our international and intergroup partners.

Abstracts
71

Publications
71

IND Trial Analyses
8

Phase III Analyses
10

Patient Representative Committee

2025 Overview

This was milestone year for the Patient Representative Committee (PRC), with the successful transition of leadership to Michelle Audoin as the committee chair. Recruitment and onboarding continued with four new members joining the committee in 2025. New representatives will be supporting the Hematology Disease Site Committee and the Gastrointestinal Disease Site Committee. Patient Representative placements also occurred on the Quality of Life, Economic Analysis, Correlative Sciences & Tumour Biology and Health Equity Committees.

Investigator awareness initiatives continued with another successful Investigator Workshop at CCTG's Annual Spring Meeting and a patient engagement session for the New Investigator Practicum. The impactful Patient Priorities Report, developed in 2024, was shared with CCTG leadership and featured as an oral presentation at the Canadian Cancer Research Conference (CCRC).

At the close of the year a PRC survey was undertaken to measure Patient Representative satisfaction and engagement. Patient Representatives continue to review all new trials and support all grant applications, ensuring trials are patient friendly and contributing to ongoing trial success.

2026 Priorities

- Support of EDIIA initiatives through PRC collaboration with the Health Equity Committee
- Continued engagement in the development of the SC32S patient survey study and the PR25 & HN13 health equity trials
- Strengthening patient engagement through implementation of additional training regarding Clinical Trial Committee (CTC) processes, refreshing tools for PRC input as well as PRC resources
- Investigator awareness through patient engagement sessions at the New Investigator Clinical Trials Course and the IND Education Series.
- Implementation of patient representative review of the participant information study results letters across trials
- Review 2025 Patient Rep Survey results and application of the learnings
- Ongoing review of 100% of CCTG new proposals, protocols, consents and patient facing material
- Ongoing support of 100% of CCTG grant applications

This year the PRC has welcomed Senior Investigator Dr. John Queenan to the team, he has over a decade of experience in patient and family engaged research. His focus is on the psychosocial dimensions of illness, the development and validation of disease case definitions in electronic health records, and the application of statistical and machine-learning methods to chronic disease surveillance. Dr. Queenan is deeply involved in equity-driven research, contributing to improved patient experiences, care pathways, and the representation of underserved populations in health research.

Patient Representatives

Michelle Audoin
Chair

"This has been a year of many firsts for me as Chair, which included interviewing and onboarding new representatives, chairing the Spring Meeting committee meetings, becoming a member of the Health Equity committee, and setting strategic priorities at the Leadership Retreat.

CCTG values the diverse perspectives PRC members bring to our collective work, be it through identifying meaningful questions of research, ensuring inclusive trial design and recruitment strategies, or creating patient-facing materials. The greatest privilege for me is working with an engaged and passionate team of patient representatives, and I'm delighted to continue working with this amazing group of individuals."

Ruth Ackerman

Dawn Barker

Hayden Bechthold

Lesley Beaton

Louise Bird

Emi Bossio

Catherine Caule

Deb Clark

Lindsay Clarke

Jasmine Heuring

Carol Hill

Janice Hodgson

Hilary Horlock

Tracy Kitz

Sally Nystrom

Bill Richardson

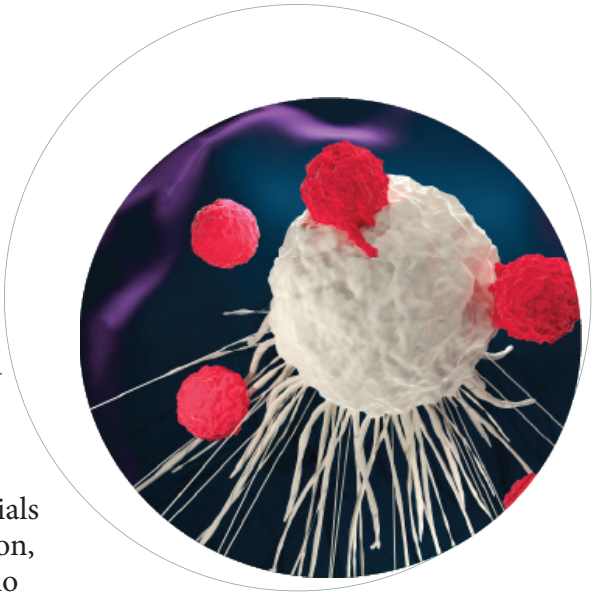
Catherine Wreford

Darren Frew

Executive: Yvonne Murray, Nancy Dusharm, Lisa Callahan, John Queenan

Investigational New Drug Program

2025 Overview



In 2025, the Investigational New Drug (IND) Program continued its efforts to access new anticancer drugs for testing in trials with innovative designs, including personalized medicine strategies, and actively engaged with industry to explore additional opportunities. A key focus was the development of cell-based therapies. The IND Program pursued added-value strategies like data collection for participants who are genomically screened but not enrolled onto trials and advanced methodological initiatives in RECIST, image collection, and radiomics. They also progressed collaborations with the Ontario Institute of Cancer Research, and internationally with the Early Clinical Trial (ECT) Consortium. In addition, IND promoted a true patient focus in trial design and conduct by prioritizing populations often excluded from ECTs and ensuring diversity, inclusivity, and equity were considered for all trial participants.

Investigator engagement and education were also priorities. The IND Drug Development Fellowship was reinstated for physicians who have completed their oncology or hematology specialty training and who are interested in clinical research and drug development. Additionally, the IND Program developed the IND Early Clinical Trial Education Program that will leverage existing training materials available across the country and engage individuals at institutions interested in shared leadership and training offerings.

The IND.227 updated analysis, confirming the benefits of adding pembrolizumab to standard chemotherapy in malignant pleural mesothelioma, was presented at the 2025 World Conference on Lung Cancer. Additional analyses are planned, including outcomes by biomarkers and exploratory analyses incorporating additional patients enrolled to the phase II component of the trial originally excluded from the overall survival analysis and central pathology re-review.

Finally, the primary analysis for IND.228, a multi-centre, non-blinded, open-label phase II basket trial of durvalumab and tremelimumab in patients with advanced rare cancer, was published and showed that durvalumab + tremelimumab treatment resulted in meaningful responses in salivary carcinoma and clear cell carcinoma of the ovary and deserves further exploration in front-line studies.

2026 Priorities

- Open and accrue to new and ongoing IND trials, including two cell therapy-based trials; focus on immunotherapy and personalized approaches
- Continue to enhance national and international partnerships and opportunities
- Continue to ensure CCTG equity strategies are implemented for all IND trials
- Test and pilot the incorporation of PROs in selected IND trials and ensure cost effectiveness
- Continue with initiatives to increase efficiency and quality in IND trial conduct
- Engage with industry, support the Drug Development Fellow, and implement the IND Early Clinical Trial Education Program

Trial Glossary

- IND.227 A Phase II/III Randomized Study of Pembrolizumab in Patients with Advanced Malignant Pleural Mesothelioma
- IND.228 A Phase II Study of Durvalumab and Tremelimumab in Patients with Advanced Rare Tumours

Trial Spotlight

IND.246: A Phase I Study of GCAR1, a Chimeric Antigen Receptor (CAR) T-Cell Therapy for Participants with Selected Relapsed/Refractory GPNMB-Expressing Solid Tumours

CAR T-cell therapy is a promising treatment with multiple agents now approved for use in blood cancers. To date, however, no CAR T-cell therapy has been approved for solid cancers. Scientists at the University of Calgary Riddell Centre for Cancer Immunotherapy (RCCI) have created GCAR1, a novel CAR T-cell therapy that shows activity in mouse models in certain rare and other solid cancers. GCAR1 specifically targets the GPNMB protein found on the surface of these cancer cells.

IND.246 is a phase I, dose-escalation study evaluating safety and efficacy and determining recommended phase II dose of GCAR1 in participants with GPNMB-expressing alveolar soft part sarcoma (rare cancer predominantly in adolescents and young adults), renal cell carcinoma, and triple negative breast cancer that has progressed following standard of care treatments. The patient's own T cells are collected, genetically modified to recognize the GPNMB target (creating GCAR1), and infused into the patient to treat the cancer. Blood and tissue samples collected on the study will inform us how GCAR1 is working. IND.246 is a collaboration with RCCI and other Canadian institutions supported by grants from CIHR and BioCanRx. This first cell therapy trial being conducted by CCTG is expected to be centrally activated Q2 2026.

Committee Executive

Dr. Yvette Drew
Chair

Dr. Eric Xueyu Chen
Incoming Chair

Dr. David Cescon
Past Chair

Dr. Lesley Seymour
IND Program Director

Laura Pearce
Senior Investigator

Dr. Dongsheng Tu
Senior Biostatistician

Dr. Wei Tu
Senior Biostatistician

Carol Hill
Patient Representative

Michael Ong
Moira Rushton
April Rose
Jonathan Spicer
Adrian Sacher
Erica Tsang

Stephanie Lheureux
Amber Simpson
Daniel Breadner
Kevin Hay
Quincy Chu
Alexander Wyatt

Annette Hay
Janet Dancey
Mariam Jafri
Pierre-Olivier Gaudreau
Pamela Brown-Walker
Nathalie Levasseur

Christina Addison
Terry Ng (Quality of Life Liason)
Claire Howe (CRA Representative)
Stephanie DeLuca (Pharma Representative)
Maxwell Sherry (Study Coordinator)
Sofia Genta (Practicum)

Brain Disease Site Committee

2025 Overview

In 2025, the Brain Disease Site Committee activated and began enrolling patients to the international CE.9 LUMOS2 trial led by the Australian Cooperative Trials Group for Neuro-Oncology (COGNO). This umbrella study evaluates personalized treatment options using multiple novel and molecularly targeted therapies. The treatment options are selected based on the tumour DNA analysis of patients with recurrent low-grade and anaplastic gliomas. Accrual to one treatment arm has been completed, and a new arm was added in 2025 with additional arms planned for 2026.

The planned interim futility analysis on neurocognitive progression-free survival and overall survival for the CCTG-led CE.7 trial, was completed with the recommendation that the trial continue to its target sample size. The committee also successfully collaborated with the European Organisation for Research and Treatment of Cancer (EORTC) on the CE.10 VIGOR trial. Researchers are investigating whether vorasidenib should be used as a maintenance option after chemoradiotherapy treatment in patients with IDH-mutated astrocyctomas. VIGOR was opened by the EORTC late in 2025 and will be activated in Canada in early 2026.

Finally, both CEC.6 and CEC.7 have met their accrual targets and are awaiting final analysis. The CEC.6 study compares radiotherapy with concomitant and adjuvant temozolomide versus radiotherapy with adjuvant PCV chemotherapy in patients with in anaplastic or low-grade gliomas. The CEC.7 trial is asking if time to surgical bed failure is increased with fractionated SRS compared to single fraction SRS in patients with resected brain metastasis.

2026 Priorities

- Expand participation and enrolment to CE.9 LUMOS2; develop and open additional arms
- Open CE.10 VIGOR
- Promote accrual to CE.7 post interim analysis
- Focus on developing phase I and II trials of novel targeted agents with the CCTG Investigational New Drug Program
- Mandate and pursue translational/correlative studies in trials to better understand mechanisms of drug resistance and failure with a view ultimately to develop personalized medicine for patients with primary brain tumours
- Continue to foster career development of young investigators and encourage trainees to consider careers in neuro-oncology

Committee Executive

Dr. Marshall Pitz
Co-Chair

Dr. David Roberge
Co-Chair

Chris O'Callaghan
Senior Investigator

Dr. Keyue Ding
Senior Biostatistician

Catherine Wreford
Patient Representative

James Perry
Gelareh Zadeh
Warren Mason
Mary MacNeil

Rebecca Harrison (IND Liaison)
Michael Yan (Economic Analysis Liaison)
Xin Wang (Practicum)

Trial Spotlight

CE.7 is a phase III trial of stereotactic radiosurgery compared with hippocampal-avoidant whole brain radiotherapy (HA-WBRT) plus memantine for 5 or more brain metastases

The CE.7 trial compares stereotactic radiosurgery (SRS) to whole brain radiotherapy (WBRT) in patients with 5 to 15 brain metastases. Researchers want to understand the effects of receiving SRS versus receiving WBRT plus a drug called memantine used to protect memory in brain metastases.

The primary objectives are overall survival and neurocognitive progression-free survival in patients who receive SRS compared to patients who receive WBRT. The 2025 interim futility analysis, conducted by the Data Safety Monitoring Committee, on the co-primary endpoints indicated that the trial should continue to its full sample size of 206 patients—at the time of the analysis 165 patients were enrolled.

While SRS offers targeted treatment with fewer cognitive issues, it may be as effective as WBRT, making the study crucial for determining the best balance of tumor control and quality of life. CE.7 is a multi-centre international trial led by CCTG and conducted through the US National Clinical Trials Network.

Trial Glossary

- CE.7 | A phase III Trial of Stereotactic Radiosurgery Compared with Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) Plus Memantine for 5 or More Brain Metastases
- CE.9 LUMOS2 | Low and Anaplastic Grade Glioma Umbrella Study of Molecular Guided Therapies
- CE.10 VIGOR | Vorasidenib as Maintenance Treatment after First-line Chemoradiotherapy in IDH-mutant Grade 2 or 3 Astrocytoma
- CEC.6 (Alliance N0577) | 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
- CEC.7 (Alliance A071801) | Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery Compared with Fractionated SRS for Resected Metastatic Brain Disease

Breast Disease Site Committee

2025 Overview

This year, the Breast Disease Site Committee had four trials open to accrual, the three US intergroup led trials, MAC.28, MAC.29, and MAC.30, continue to accrue well. The international CCTG-led MA.39 TAILOR-RT randomized, controlled, non-inferiority trial is expected to reach its accrual goal in 2026. The trial seeks to reduce over treatment of breast cancer by using molecular biomarkers to identify patients that may not require regional nodal radiotherapy (RT). This is an important patient-centred study evaluating quality of life, hypothesized to be improved by the avoidance of RT.

The MA.38 trial results exploring the use of continuous versus standard palbociclib treatment in metastatic breast cancer were published this year. The study had a rich biomarker component looking at the molecular profiling of breast tissue and associated liquid biopsies which was an important secondary outcome. Also, thirteen other secondary analyses were published using data from CCTG-led and other group-led trials reflecting the Committee's commitment to mining its rich clinical, radiological, and genomic database. A highlight was the meta-analysis conducted by the Early Breast Cancer Trialists' Collaborative Group and published in The Lancet using data from the CCTG-led MA.17 and MA.17R trials. The analysis investigated the impact of extended endocrine treatment for early breast cancer and found that adding 5 years of aromatase inhibitor treatment reduced subsequent distant recurrence rates by about a quarter, despite substantial non-adherence.

The MA.42 NoLeeta (Unicancer-led) trial was approved by the Clinical Trials Committee and is planned for activation in 2026. This phase III trial intends to determine whether intermediate-risk breast cancer patients receiving a combination CDK4/6 inhibitor therapy plus endocrine therapy, can omit chemotherapy in the adjuvant setting without compromising outcomes.

2026 Priorities

- Continue accrual to all trials, including those led by our National Clinical Trials Network (NCTN) partners
- Seek opportunities to lead phase II/III trials
- Continue to bring ideas forward to the NCTN through the US National Cancer Institute (NCI) Breast Steering Committee
- Build the trial portfolio through collaborations with the NCTN, Australia/New Zealand, France and others
- Continue to exploit the rich clinical, radiological and genomic database from CCTG-led trials
- Look for opportunities to extend the trial portfolio to remote or under serviced areas in Canada

Trial Glossary

- MA.17 | A Phase III Randomized Double Blind Study of Letrozole versus Placebo in Women with Primary Breast Cancer Completing Five or More Years of Adjuvant Tamoxifen
- MA.17R | A Double Blind Randomization to Letrozole or Placebo for Women Previously Diagnosed with Primary Breast Cancer Completing Five Years of Adjuvant Aromatase Inhibitor Either as Initial Therapy or After Tamoxifen
- MA.38 | Continuous versus Standard Palbociclib Treatment and Molecular Profiling of Solid Tissues and Liquid Biopsies in Advanced Breast Cancer.
- MA.39 TAILOR-RT | A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer

Committee Executive

Dr. Eileen Rakovitch
Co-Chair

Dr. Stephen Chia
Co-Chair

Dr. Wendy Parulekar
Senior Investigator

Dr. Lois Shepherd
Senior Investigator

Dr. Bingshu Chen
Biostatistician

Ruth Ackerman
Patient Representative

Dawn Barker
Patient Representative

Muriel Brackstone
Jean-Francois Boileau
Valerie Theberge
Danielle Rodin (Economic Analysis Liaison)
Julie Lemieux (Quality of Life Liaison)
Arif Awan (IND Liaison)
Marya Hussain (Practicum)

Trial Spotlight

MA.40 FINER – A Double-Blind Placebo Controlled Randomized Phase III Trial of Fulvestrant and Ipatasertib as Treatment for Advanced HER-2 Negative and Estrogen Receptor Positive (ER+) Breast Cancer Following Progression on First Line CDK 4/6 Inhibitor and Aromatase Inhibitor

MA.40 was a CCTG-led trial investigating fulvestrant and ipatasertib for advanced HER-2 negative and estrogen receptor positive (ER+) breast cancer. This is the first CCTG-led breast cancer trial using real time circulating tumour DNA analysis as a biomarker. The primary results were presented at the 2025 American Society of Clinical Oncology Annual Meeting by study chair Dr. Stephan Chia. The results found that cancer spread was delayed with the addition of ipatasertib to fulvestrant in patients with ER+/HER2- advanced breast cancer, especially those with specific mutations in their breast cancer.

The administration of drugs that target tumour vulnerabilities is an important treatment strategy and is increasingly used in clinical care. However, clinical trials are needed to identify drugs or combinations of drugs that target different tumour pathways, safely delay tumour spread, maintain QoL and ultimately, increase survival. The MA.40 FINER trial was a successful international collaboration between CCTG, Breast Cancer Trials (Australia/New Zealand) and Hoffman-La Roche Foundation Medicine.

- MA.42 NoLEEta (Unicancer) | No Chemotherapy in Intermediate-risk HR + HER2- Early Breast Cancer Treated with Ribociclib in the Adjuvant Setting, a Non-Inferiority Phase III Trial
- MAC.28 DEBRA (NRG BR007) | A Phase III Clinical Trial Evaluating De-escalation of Breast Radiation for Conservative Treatment of Stage 1, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score ≤18 Breast Cancer
- MAC.29 OptimICE-pCR (Alliance A012103) | De-escalation of Therapy in Early-Stage TNBC Patients who Achieve pCR after Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy
- MAC.30 OFSET (NRG BR009) | A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score ≤25

Gastrointestinal Disease Site Committee

2025 Overview

The Gastrointestinal (GI) Disease Site Committee oversees a diverse trial portfolio and longstanding collaborations with international partners including the Australasian Gastro-Intestinal Trials Group (AGITG) and the Unicancer federation of French comprehensive cancer centres. In 2025, the GI Committee had nine trials open to accrual, including two that were recently activated. The first is HE.2 SLIDE-HCC comparing progression-free survival between STRIDE (durvalumab + tremelimumab) with lenvatinib versus STRIDE alone in patients with intermediate and advanced hepatocellular carcinoma. The other is the CO.33 BATTMAN trial which compares the effect of the combination of botensilimab and balstilimab and best supportive care (BSC) on overall survival (OS) in patients with refractory, metastatic colorectal cancer.

The CO.21 CHALLENGE trial results were presented at ASCO 2025 with simultaneous publication in the New England Journal of Medicine (NEJM). This trial has established a new, global standard of care based on the finding that a structured exercise program significantly improved disease-free (DFS) and OS for colon cancer patients. Other important results from three international trials were also published in 2025, including the CO.29 DYNAMIC-III study demonstrating that a simple blood test detecting circulating tumour DNA (ctDNA) may help physicians make more personalized treatment decisions for people with colon cancer. Also NEC.3, a trial of pazopanib versus placebo in patients with advanced extrapancreatic neuroendocrine tumours, suggests that VEGF is a valid target for therapy, but efficacy benefit needs to be weighed against the increased toxicity. Finally, GA.3 INTEGRATE IIa, evaluated regorafenib for the treatment of patients with advanced gastro-esophageal cancer and showed a statistically significant improvement in overall survival.

2026 Priorities

- Continue to evaluate utility of ctDNA to reduce the burden of adjuvant treatment and improve outcomes in resected colon cancer
- Test and expand novel immunotherapy combinations (CO.33, HE.2)
- Explore surgical avoidance and reduced treatment morbidity in early-stage rectal and esophageal squamous cell cancer (CO.32, ES.3)
- Define the optimal approach for radioligand therapeutics in advanced neuroendocrine cancers (NE.1, NE.2)
- Test novel targeted mechanisms in pre-treated advanced esophagogastric cancers (GA.4)
- Continue to expand robust correlative science efforts

Trial Glossary

- CO.29 DYNAMIC III (AGITG)| Circulating Tumor DNA Analysis Informing Adjuvant Chemotherapy in Stage III Colon Cancer: A Multicentre Phase II/III Randomised Controlled Study
- CO.32 NEO-RT | A Phase 3 Randomized Trial Of Neoadjuvant Chemotherapy, Excision And Observation versus Chemoradiotherapy For Early Rectal Cancer
- CO.33 BATTMAN | Botensilimab + Balstilimab vs Best Supportive Care as Therapy in Chemo-refractory, Unresectable, Colorectal Adenocarcinoma
- ES.3 NEEDS | NEoadjuvant chemoradiotherapy for Esophageal squamous cell carcinoma versus Definitive chemoradiotherapy with salvage Surgery as needed
- GA.3 INTEGRATE IIa (AGITG) | A Randomised Phase III Double-Blind Placebo-Controlled Study of Regorafenib in Refractory Advanced Gastro-Oesophageal Cancer

Committee Executive

Dr. Sharlene Gill
Chair

Dr. Chris O'Callaghan
Senior Investigator

Dr. Dongsheng Tu
Senior Biostatistician

Hayden Bechthold
Patient Representative

Lesley Beaton
Patient Representative

Petr Kavan
Derek Jonker
Hagen Kennecke
Rebecca Ann Auer
Eric Chen

Howard Lim
Rachel Goodwin
Patricia Tang (IND Liaison)
Winson Cheung (Quality of Life Liaison)
Kelvin Chan (Economic Analysis Liaison)
Joao Paulo Solar Vasconcelos (Practicum)

Trial Spotlight

CO.21 is a Phase III Study of the Impact of a Physical Activity Program on Disease-Free Survival in Patients with High-Risk Stage II or Stage III Colon Cancer: A Randomized Controlled Trial

In a world-first, CCTG's CO.21 CHALLENGE trial demonstrated that a structured exercise program significantly improves overall survival for colon cancer patients by reducing the risk of disease recurrence and new primary cancers. CO.21 was a phase III randomized trial assessing the impact of a physical activity program on DFS in patients with stage III or high-risk stage II colon cancer. Between 2009 and 2024, the international trial enrolled 889 patients who had completed surgery and adjuvant chemotherapy. Patients were randomly assigned to either participate in a 3-year structured exercise program or to receive health education materials promoting physical activity and healthy nutrition. All patients received standard cancer surveillance and follow-up care.

The results revealed a significant improvement in OS and DFS among participants assigned to the structured exercise program compared to those who only received health education materials. Patients in the structured exercise program had a 37% lower risk of death and a 28% lower risk of recurrence or developing other cancers. These results were presented at the American Society of Clinical Oncology 2025 Annual Meeting and published in NEJM. The trial publication was selected by the editors as one of the top NEJM 15 articles of 2025. In addition, the ESMO Clinical Practice Guidelines now incorporate these results with structured exercise recommended as a new standard of care for early-stage colon cancer.

- GA.4 |A Randomized Phase II Study of Paclitaxel and Ramucirumab +/- Zanidatamab in HER2 Positive Advanced Gastroesophageal Adenocarcinoma
- HE.2 SLIDE-HCC| A Phase II Study of STRIDE (durvalumab + tremelimumab) with Lenvatinib versus STRIDE Alone in Patients with Unresectable Hepatocellular Carcinoma
- NE.1 NET RETREAT |: A Phase II Study of 177Lutetium- DOTATATE Retreatment vs. Everolimus or Sunitinib or Cabozantinib in Metastatic/unresectable Gastroenteropancreatic Tumours
- NE.2 STOPNET (AGITG) | A Randomized Study of Cessation of Somatostatin Analogues after Peptide Receptor Radionuclide Therapy in Mid, Hind-Gut and Pancreatic Neuroendocrine Tumours
- NEC.3 (Alliance A021202) | Prospective Randomized Phase II Trial of Pazopanib Versus Placebo in Patients with Progressive Carcinoid Tumors

Genitourinary Disease Site Committee

2025 Overview

In 2025, the Genitourinary (GU) Disease Site Committee had four trials open to accrual. The first is PR.24 ASCENDE-SBRT an international CCTG-led US National Clinical Trials Network (NCTN) trial comparing stereotactic body radiotherapy to conventional external beam RT with brachytherapy boost for men with unfavourable, localized prostate cancer. Another CCTG-led trial, PR.25 oPTion-DDR, aims to determine if patients with alterations in DNA damage response genes have an additional survival benefit with carboplatin in combination with docetaxel. The BLC.6 MODERN trial is investigating whether a blood test measuring ctDNA can help researchers make better decisions about who should get immunotherapy after surgery for bladder cancer and which immunotherapy treatment is best. Finally, PR.26 TRIPLE-SWITCH, a CCTG-led NCTN international trial, is testing whether the addition of docetaxel chemotherapy to standard of care androgen deprivation therapy (ADT) + androgen receptor pathway inhibitors (ARPI) improves overall survival of patients with metastatic castration sensitive prostate cancer.

Notably, PR.25 is one of CCTG's equity pilot trials to increase trial accessibility to patients who are historically underrepresented in clinical trials. Initiatives include ensuring the trial protocol contains elements such as virtual visits, equity training in the trial start-up webinar, inclusion of a Social Determinants of Health Questionnaire, participant reimbursement for trial-related expenses, the creation of a Diversity Action Plan, and the translation of patient-facing materials into additional languages.

Finally, findings from IND.234, a prostate cancer biomarker enrichment and treatment protocol, were presented at the 2025 ASCO Annual Meeting demonstrating that biomarker-selected platform designs are an efficient way to screen potential new therapeutics, are well suited to multicentre cooperative group settings, and are strongly supported by patient advocates.

.

2026 Priorities

- Actively engage with network investigators to promote accrual to PR.25, PR.26, and BLC.6
- Publish PR.21 primary analysis and protocol-embedded correlative analyses
- Publish IND.234
- Continue to engage with patient partners and advocacy groups to support prostate cancer-specific health equity activities
- Continue to develop radiotherapy trial concepts

Trial Glossary

- BLC.6 MODERN (Alliance A032103) | An Integrated Phase II/III and Phase III Trial of MRD-Based Optimization of Adjuvant Therapy in Urothelial Cancer
- PR.24 ASCENDE-SBRT | 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
- PR.25 OPTION-DDR | A Randomized Phase III Trial Investigating Platinum and Taxane Chemotherapy in Metastatic Castration Resistant Prostate Cancer Patients with Alterations in DNA Damage Response Genes
- PR.26 TRIPLE-SWITCH | A Randomized Phase III Clinical Trial for the Addition of Docetaxel to Androgen Receptor Pathway Inhibitors in Patients with Metastatic Castration Sensitive Prostate Cancer and Suboptimal PSA Response
- IND.234 | Prostate Cancer Biomarker Enrichment & Treatment Selection (PC_BETS) Study Master Screening Protocol

Trial Spotlight

PR.21 is a Randomized Phase II Study of 177Lu-PSMA-617 vs Docetaxel in Patients with Metastatic Castration-Resistant Prostate Cancer and PSMA-Positive Disease

PR.21 a CCTG-led, multicentre, open-label, trial comparing docetaxel to 177Lu-PSMA-617 (LU-P) in men diagnosed with metastatic castration-resistant prostate cancer (mCRPC) and PSMA-positive disease. The primary objective was to evaluate radiographic progression-free survival (rPFS) of PSMA-positive mCRPC patients treated with LU-P radioligand therapy versus docetaxel. Secondary endpoints included overall survival (OS), PSA response rate (RR), objective response rate (ORR), and patient-reported outcomes (PROs).

The trial was closed to accrual in January 2024. Results were the subject of an oral presentation at the 2025 European Society of Medical Oncology Congress. The study enrolled 199 patients and found that the population with chemo-naive mCRPC, there was no significant rPFS difference between LU-P and docetaxel. PSA RR, ORR and frequency of treatment-related grade 3/4 adverse events favoured LU-P; OS favoured the arm assigned to docetaxel at randomization. Correlative studies, including baseline PSMA PET SUV and serial ctDNA sampling, are planned.

Committee Executive

Dr. Sebastien Hotte
Chair

Dr. Wendy Parulekar
Senior Investigator

Dr. Mariam Jafri
Senior Investigator

Dr. Keyue Ding
Senior Biostatistician

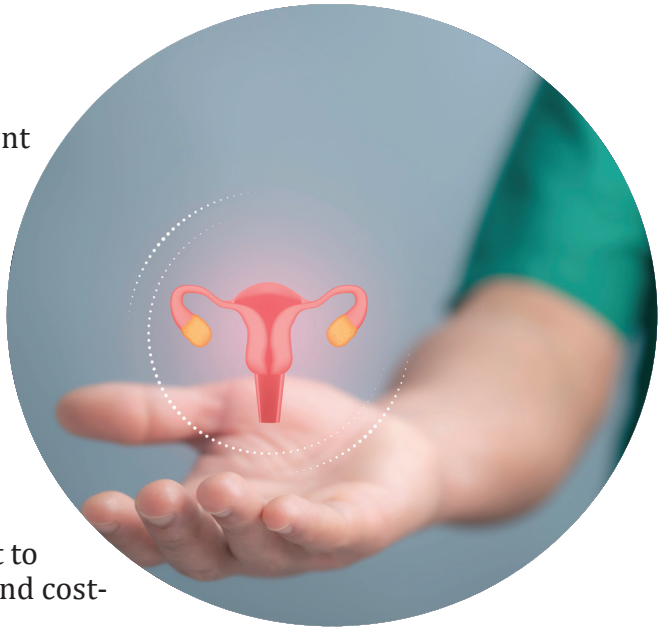
Lindsay Clarke
Patient Representative

Bill Richarson
Patient Representative

Bernhard Eigl
Kim Chi
Tamim Niazi
Wassim Kassouf
Scott Morgan
Michael Kolinsky (IND Liaison)
Jeffrey Graham (Economic Analysis Liaison)
Neil Reaume (Economic Analysis Liaison)
Daniel Khalaf (Quality of Life Liaison)
Joelle Helou (Quality of Life Liaison)
Steven Tisseverasinghe (Practicum)

Gynecology Disease Site Committee

2025 Overview



This year, the Gynecology Disease Site Committee advanced its strategic agenda to improve cancer outcomes, optimize treatment selection through advanced molecular testing, and evaluate patient-reported outcomes related to anticancer therapies.

The CCTG-led EN.10 RAINB0-Blue and EN.11 RAINBO-Green trials opened to accrual, they are part of an international clinical and translational research initiative supported by the Gynecologic Cancer Intergroup. The third RAINBO trial, EN.12 RAINBO-Orange, was approved by the CCTG Clinical Trials Committee and a grant to support its conduct was submitted to the Canadian Institutes of Health Research. The RAINBO series comprises four trials, each directed at one of four endometrial cancer molecular subgroups comparing personalized treatment to standard treatment in terms of efficacy, toxicity, quality of life, and cost-utility for endometrial cancer patients.

There were three publications reporting results of secondary analyses using data from the practice-changing CCTG-led CX.5 trial, which showed that a simple hysterectomy with pelvic node dissection is a safe treatment option for women with low-risk early-stage cervical cancer. Findings showed that simple hysterectomy was associated with lower rates of sexual dysfunction than radical hysterectomy, with a lower proportion of women having sustained sexual-vaginal dysfunction. These results further support the quality of life benefits of surgical de-escalation for low-risk cervical cancer.

Finally, the preplanned long-term analysis of the randomized EN.7 PORTEC-3 trial with a post-hoc analysis including molecular classification of the tumours was completed and published in The Lancet. The results showed that 10-year overall survival and recurrence-free survival were improved for patients with HREC treated with adjuvant chemoradiotherapy versus radiotherapy alone, with most clinically relevant benefit suggested for p53 abnormal cancers.

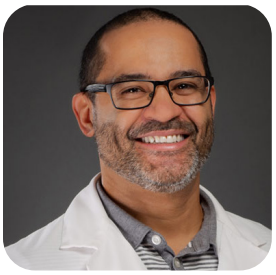
2026 Priorities

- Continue to enroll patients to ongoing trials, including EN.10, EN.11, VU.2
- Activate EN.12
- Analyze and publish OV.25 primary results
- Complete and publish ongoing correlative analyses from closed CCTG-led trials
- Mentor and train early/mid-career investigators within the CCTG network
- Generate innovative trial concepts designed to improve cancer outcomes in gynecological malignancies

Trial Glossary

- CX.5 SHAPE | 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
- EN.7 PORTEC-3 (DCGOG) | Randomized Phase III Trial Comparing Concurrent Chemoradiation and Adjuvant Chemo-therapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma
- EN.10 RAINBO-Blue – A Phase II Study of Tailored Adjuvant Therapy in POLE-mutated and p53-wildtype/NSMP Early Stage Endometrial Cancer

Committee Executive



Dr. Stephen Welch
Co-Chair

Dr Mark Carey
Co-Chair

Dr. Wendy Parulekar
Senior Investigator

Dr. Dongsheng Tu
Senior Biostatistician

Deb Clark
Patient Representative

Marie Plante
Stephanie Lheureux
Laura Hopkins
Corinne Doll
Josee-Lyne Ethier (IND liaison)
Iwa Kong (Quality of Life Liaison)
Janice Smith Kwon (CEA liaison)

Trial Spotlight

VU.2 STRIVE STRatIfication of Vulvar squamous cell carcinoma by HPV and p53 status to guide Excision

VU.2 is a prospective, international, multicentre, phase II platform study currently enrolling participants with VSCC stratified by HPV status. This pivotal study is a move away from current 'one size fits all' treatment approaches through the testing of a vulvar cancer patients' tissue to determine the best treatment options. Researchers want to evaluate if the molecular features in tissues removed in the first surgery can direct the need for additional surgery versus a close follow-up for patients with vulvar squamous cell cancer.

The primary objective is to estimate the 3-year local recurrence rates in patients with HPV-Associated (HPV-A) and HPV-Independent (HPV-I) VSCC surgically managed based on dVIN/p53 status and tumour margin clearance. Secondary objectives include the estimation of recurrence-free survival, disease-specific survival, overall survival, economic impact of surgical management, and descriptions of patient-reported outcomes. Molecular testing may also identify people who do not need a second surgery, sparing them the negative impact on surgery related symptoms, self-image, quality of life and sexual function.

- EN.11 RAINBO-Green (DGOG) – Refining Adjuvant treatment IN endometrial cancer Based On molecular features, TransPORTEC platform trials - The MMRd-Green trial
- EN.12 RAINBO NSMP-Orange (UCLCTU) – Refining Adjuvant treatment IN endometrial cancer Based On molecular features (RAINBO) No Specific Molecular Profile (NSMP)
- OV.25 – A Randomized Phase II Double-Blind Placebo-Controlled Trial of Acetylsalicylic Acid (ASA) in Prevention of Ovarian Cancer in Women with BRCA 1/2 Mutations (STICs and STONEs)

Head & Neck Disease Site Committee

2025 Overview

The Head & Neck Committee have been working on two CCTG-led trials that are currently open to accrual. First is HN.11 SPECT-CT, conducted as part of the US National Clinical Trials Network, a phase III trial to determine if a personalized lymphatic mapping-guided approach using SPECT-CT is better than the standard radiotherapy in patients with lateralized oropharyngeal cancer. Researchers want to know if using SPECT-CT to image the neck will help to identify lymphatic drainage patterns to prevent over-treatment with radiation. The other trial is HN.13 comparing palliative stereotactic body radiotherapy (SBRT) to standard palliative radiotherapy (RT) in participants with advanced mucosal, squamous cell head and neck cancer.

The Committee also supported the SKC.1 trial investigating whether adding an immunotherapy drug prior surgical treatment for advanced skin cancer in the head and neck area, can improve patient outcomes. In addition, the primary analysis for HN.9, which was closed to accrual in 2022, was underway in 2025 and is expected to be completed and presented in 2026.

In 2025, the committee continued to focus on early career investigators welcoming Dr. Carlton Johnny, a participant in CCTG's New Investigator Cancer Trials Practicum, and Dr. Wensha Zhang, a Canadian Network for Statistical Training in Trials (CANSTAT) fellow.

2026 Priorities

- Conduct quality of life/swallowing function analyses using data from the HN.6 legacy trial and the recently analyzed HN.10 study
- Finalize and publish HN.10 primary analysis
- Conduct statistics and methodology analyses, including concordance between CTCAE and PRO-CTCAE correlative analyses, for HN.10 and HN.9 (including microbiome)
- Promote and support enrollment to HN.11, HN.13, SKC.1

Trial Glossary

- HN.6 | A Phase III Study of Standard Fractionation Radiotherapy with Concurrent High-Dose Cisplatin Versus Accelerated Fractionation Radiotherapy with Panitumumab in Patients with Locally Advanced Stage III and IV Squamous Cell Carcinoma of the Head and Neck
- HN.9 | Randomized Phase II Study of Cisplatin plus Radiotherapy versus Durvalumab plus Radiotherapy followed by Adjuvant Durvalumab versus Durvalumab plus Radiotherapy followed by Adjuvant Tremelimumab and Durvalumab in Intermediate Risk HPV-Positive Locoregionally Advanced Oropharyngeal Squamous Cell Cancer (LA-OSCC)
- HN.10 EVADER | A Phase II Single Arm Trial of Elective Volume Adjusted De-Escalation Radiotherapy in Patients with Low-risk HPV-related Oropharyngeal Squamous Cell Carcinoma
- HN.11 SPECT-CT | Guided Elective Contralateral Neck Treatment for Patients with Lateralized Oropharyngeal Cancer. A Phase III Randomized Controlled Trial
- HN.13 | A Phase III Randomized Controlled Trial Comparing Palliative Stereotactic Body Radiotherapy vs. Palliative Standard Radiotherapy in Patients with Advanced Head and Neck Cancer
- SKC.1 (NRG HN014) | Randomized Phase III Trial of Neoadjuvant Immunotherapy with Response-Adapted Treatment Versus Standard-Of-Care Treatment for Resectable Stage III/IV Cutaneous Squamous Cell Carcinoma

Trial Spotlight

HN.13 is a phase III Randomized Controlled Trial Comparing Palliative Stereotactic Body Radiotherapy vs. Palliative Standard Radiotherapy in Patients with Advanced Head and Neck Cancer

The CCTG-led, HN.13 trial is comparing palliative SBRT to standard palliative RT in participants with advanced mucosal, squamous cell head and neck cancer unable to tolerate curative radiation therapy. The primary objective is to compare overall survival between the two arms and see if SBRT offers better cancer and symptom control than RT. While SBRT is a promising technique, rigorous multicentre evaluation is required prior to adoption in the clinical setting.

The patient-centred HN.13 study aims to enroll 196 patients and addresses an unmet need in an elderly population. It is also one of CCTG's equity pilot trials where several initiatives are being piloted to increase trial accessibility to patients who are historically underrepresented in clinical trials. Initiatives involve making changes to the trial protocol to include virtual visits, providing equity training in the trial start-up webinar, including a Social Determinants of Health Questionnaire, providing participant reimbursement for trial-related expenses, creating a Diversity Action Plan, and translating patient-facing materials into additional languages.

Committee Executive

Dr. Scott Bratman
Co-Chair

Dr. John Hilton
Co-Chair

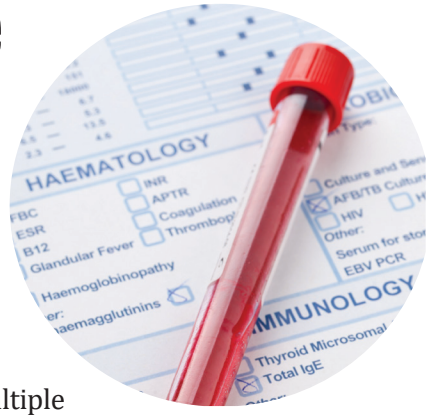
Dr. Wendy Parulekar
Senior Investigator

Dr. Wei Tu
Senior Biostatistician

Mr. Bill Richardson
Patient Representative

Anna Spreafico (IND liaison)
Winson Cheung (Quality of Life Liaison)
Nhu-Tram Nguyen (Quality of Life Liaison)
Ambika Parmar (Economic Analysis Liaison)
Carlton Johnny (Practicum)

Hematology Disease Site Committee



2025 Overview

The Hematology Committee portfolio included ten trials open to accrual in 2025, ranging from smaller studies in rare diseases incorporating biological endpoints to large, pragmatic, patient-centered trials with integrated quality of life measures. This active portfolio spans both national and international collaborations with other cooperative groups.

Reflecting this diversity, there were trials across a range of disease areas, including multiple myeloma (MYC.2, MY.13), non-Hodgkin lymphoma (LY.17, LY.18), Hodgkin lymphoma (HD.11, HD.12), and chronic lymphocytic leukemia (CLC.3). The work also included studies in acute leukemia (AL.6, ALC.7, ALC.8), as part of the US National Cancer Institute–led myeloMATCH initiative. In addition, close partnerships with the Investigational New Drug Program and Supportive Care Committee provided opportunities for wider accrual in primary CNS lymphoma (IND.244) and acute leukemia (SC.26).

Primary publications included LY.17, a randomized trial with four arms comparing rituximab-gemcitabine-dexamethasone-cisplatin (R-GDP) with ibrutinib-R-GDP, Selinexor-R-GDP, and R-DICEP. The ibrutinib and R-DICEP experiences were published. The shifting landscape and approval across Canada for CAR T cell therapy in this patient population has reduced the population of patients eligible for this trial and the selinexor arm closed before reaching its target sample size.

Three secondary analyses were presented at the American Society of Hematology Annual Meeting. First was the development of an individualized prediction model for early-stage Hodgkin lymphoma incorporating HD.6 data (Rodday, NEJM Evidence, 2025). Also HDC.1, where authors found that circulating tumour DNA analyses of molecular tumour burden are superior to PET-assessed responses and recommended future prospective studies incorporate ctDNA analyses to improve precision therapy (Paczkowska, Blood, 2025). Finally, with ALC.4, the authors provided a comprehensive landscape of genomic alterations in adult B-ALL and identified a new group characterized by deregulation of CEBPA/CEBPB, providing insights into the efficacy of blinatumomab in different molecular subgroups (Zhong, Blood, 2025).

2026 Priorities

- Promote accrual to open trials and expeditiously activate planned trials
- Continue to build international trial collaborations, including exploring MY.13 expansion in the US, Europe, Australia and Asia, and activating the MD.1 trial CCTG is leading across North America
- Prioritize efforts to support activities in correlative science
- Complete analyses and publish results of LY.17, LY.18, and HD.11 CCTG-led trials

Trial Glossary

- AL.6 myeloMATCH | A Measurable Residual Disease Focused, Phase II Study of Venetoclax Plus Chemotherapy for Newly Diagnosed Younger Patients with Intermediate Risk Acute Myeloid Leukemia
- ALC.4 (ECOG E1910) | A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-Negative B Lineage Acute Lymphoblastic Leukemia in Adults.
- ALC.7 myeloMATCH – Master Screening and Reassessment Protocol for Tier Advancement in the NCI myeloMATCH Clinical Trials
- ALC.8 (SWOG MM1YA-S01) | A Randomized Phase II Study Comparing Cytarabine + Daunorubicin VS Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome + Venetoclax in Patients who are Considered High-Risk Acute Myeloid Leukemia
- CLC.3 EVOLVE (SWOG S1925) | Randomized Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus DeLayed Therapy with VEnetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
- HD.6 | A Phase III Study of Radiotherapy or ABVD Plus Radiotherapy versus ABVD Alone in the Treatment of Early Stage Hodgkin's Disease
- HD.11 | A Multi-stage Randomized Phase II Study of Novel Combination Therapy in the Treatment of Relapsed and Refractory Aggressive B-Cell Lymphoma
- HD.12 RADAR | A Randomized Phase III Trial with a PET Response Adapted Design Comparing ABVD +/- ISRT with A2VD +/- ISRT in Patients with Previously Untreated Stage IA/IIA Hodgkin Lymphoma

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

John Kuruvilla
Michael Crump
Florencia Comelles
Kristjan Paulson

Mary Lynn Savoie
Christopher Venner
Diego Villa Restrepo
Laurie Sehn

Tanya Skamene (IND Liaison)
Pierre Villeneuve (Economic Analysis Liaison)
Anca Prica (Quality of Life Liaison)
Tomohiro Aoki (Practicum)
Curtis Marcoux (Practicum)

Trial Spotlight

MY.13 is a phase III Non-Inferiority Randomized Controlled Trial of Fixed Duration versus Continuous Daratumumab Among Transplant Ineligible Older Adults with Newly Diagnosed Multiple Myeloma

The MY.13 clinical trial is investigating time-limited versus continuous Daratumumab treatment for older people with multiple myeloma. The study is designed for older adults who are not eligible for autologous stem cell transplantation. The protocol emphasizes decentralized trial conduct making it accessible to individuals living in remote and rural regions. Prospective assessment of quality of life, frailty, and health economics are important components.

In 2025, the protocol was amended to incorporate quadruplet therapy, mass spectrometry, and biobanking. A successful investigator and Clinical Research Associate meeting was held at the 2025 CCTG Annual Spring Meeting of Participants. The wider team advanced discussions with potential international partners in the US, Europe, Asia, and Australia. At the end of 2025, 70 patients had enrolled from Canada. With 570 participants required, expansion of accrual is a key priority for the Hematology Committee in 2026 and beyond.

- HDC.1 (SWOG S1826) | A Phase III Randomized Study of Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) plus AVD in Patients (age >/= 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma
- IND.244 | A Phase 2 Study of Ibrutinib Combination Therapy in Transplant Ineligible Individuals with Newly Diagnosed Primary Central Nervous System Lymphoma
- LY.17 | A Multi-stage Randomized Phase II Study of Novel Combination Therapy in the Treatment of Relapsed and Refractory Aggressive B-Cell Lymphoma
- LY.18 | A Phase I Master Protocol of Novel Combination Therapy for Patients with Relapsed or Refractory Aggressive B-Cell Lymphoma
- MD.1 CALMS myeloMATCH |Combination Therapy with Luspatercept in Lower Risk MDS: A Non-Comparative, Parallel, Multi-Arm Phase 2 Study
- MY.13 | A Phase III Non-Inferiority Randomized Controlled Trial of Fixed Duration versus Continuous Daratumumab Among Transplant Ineligible Older Adults with Newly Diagnosed Multiple Myeloma
- MYC.2 DRAMMATIC (SWOG S1803) | A Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration
- SC.26 EASE - Emotion and Symptom-focused Engagement: A Multi-Site Randomized Controlled Trial of an Intervention for Individuals with Acute Leukemia

Melanoma & Skin Cancer Disease Site Committee

2025 Overview

In 2025, the Melanoma & Skin Cancer Committee continued to advance its priorities and conduct trials of experimental therapeutics; reduce morbidity of melanoma and its treatment; and demonstrate the value of incorporating patient-reported outcomes including cost effectiveness analyses.

Five trials were open to accrual this year. The CCTG-led ME.13 STOP-GAP trial, is evaluating whether intermittent PD-1 inhibitor therapy is non-inferior to continuous PD-1 inhibitor therapy in improving melanoma patients' overall survival. The associated ME.13L biomarker sub study is also underway. The innovative CCTG-led ME.17 trial also opened and will assess whether patients with advanced melanoma have improved outcomes with microbiota transplant prior to standard immunotherapy. Finally, the intergroup SKC.1 trial is investigating whether adding cemiplimab to standard treatment in patients with squamous cell skin cancer can improve event-free survival.

The international ME.15 MeLMART II study closed to accrual with over 300 Canadian patients enrolled. This international phase III trial, led by Melanoma and Skin Cancer of Australia, randomized over 3000 patients with stage II cutaneous melanoma to 1 cm versus 2 cm excision margins. Researchers want to determine whether limited margins improve participants' quality of life while preserving disease-free survival—patient follow-up continues.

The Committee plans to activate ME.18 MSLT-3, led by the Melanoma Institute of Australia. This international trial will evaluate whether patients with stage III melanoma who experience major response to immunotherapy can safely avoid surgery to remove the lymph nodes—reducing complications and improving outcomes.

2026 Priorities

- Develop strategic partnerships with dermatology, surgical oncology, and pathology networks to support ME.18
- Develop centralized molecular profiling platforms (e.g. Terry Fox Research Institute Marathon of Hope Cancer Centres Network) for translational research collaborations
- Develop translational research capacity, including ctDNA analysis in clinical trial designs
- Develop trials in the neoadjuvant setting for melanoma and other skin cancers
- Develop IND early-phase trials in metastatic setting for melanoma, rare cancers, and other skin cancers

Committee Executive

Dr. Ian Watson
Co-Chair

Dr. Marcus Butler
Co-Chair

Dr. Janet Dancey
Senior Investigator

Dr. Bingshu Chen
Senior Biostatistician

Sally Nystrom
Patient Representative

Vanessa Bernstein	Nicole LookHong	(Economic Analysis Liaison)
Rahima Jamal	Michael Ong	(IND Liaison)
Wilson Miller	Christopher Lee	(Quality of Life Liaison)
Carman Giacomantonio	Vincent Poon	(Practicum)

Trial Spotlight

SKC.1 (NRG HN014) is a Randomized Phase III Trial of Neoadjuvant Immunotherapy with Response-Adapted Treatment Versus Standard-Of-Care Treatment for Resectable Stage III/IV Cutaneous Squamous Cell Carcinoma

Globally, there are >1.8 million cases of cutaneous squamous cell carcinoma (CSCC) diagnosed and nearly 65,000 deaths annually. These cancers are often located near the head, neck and face where the destructive effects of treatment, including surgery and radiation, can result in severe functional impairment, disfiguration, and reduction in quality of life. Despite aggressive surgery and adjuvant radiation, patients with locally advanced-stage CSCC often face a guarded prognosis. In unresectable CSCC, immunotherapy has shown impressive response rates and improvement in survival. Phase II data has shown a benefit in treating locally advanced CSCC with immunotherapy upfront prior to surgery with high pathologic response rates and benefits to patients.

SKC.1 aims to determine whether neoadjuvant immunotherapy combined with response-adapted oncologic surgery improves investigator-assessed event-free survival compared to standard of care surgery in resectable stage III/IV CSCC. The trial was activated by CCTG in April 2024 and aims to enrol a total of 420 patients.

Trial Glossary

- ME.13 STOP-GAP | A Randomized Phase III Trial of the Duration of Anti-PD-1 Therapy in Metastatic Melanoma
- ME.13L STOP-GAP| A Biomarker Sub-study of the CCTG ME.13 Duration of Anti PD-1 Therapy in Metastatic Melanoma Trial
- ME. 15 MELMART-II | A Phase III, Multi-centre, Multi-national Randomized Control Trial Investigating 1cm vs 2cm Wide Excision Margins for Primary Cutaneous Melanoma
- ME.17 | A Phase II Randomized Trial of LND101 for Fecal Microbiota Transplantation in Combination with Immune Checkpoint Blockade in Patients with Advanced Melanoma
- ME.18 (MIA MSLT-3) | A Phase III, International, Multicentre, Randomized Controlled Trial of Selective Index Node Resection versus Therapeutic Lymph Node Dissection after Neoadjuvant Immunotherapy for Stage IIIB-D Melanoma.

Sarcoma Disease Site Committee

2025 Overview

In 2025, the Sarcoma Disease Site Committee was actively accruing to two intergroup trials, the SR.7 STRASS 2 trial comparing the effects of chemotherapy before surgery vs surgery alone in patients with high-risk retroperitoneal sarcoma. While the standard treatment is surgery alone without chemotherapy, researchers think that neoadjuvant chemotherapy may improve the treatment. The other trial is the SRC.8 study, investigating whether a combination of immunotherapy and chemotherapy is more effective than chemotherapy alone for adults with advanced sarcoma.

The Committee is also working to nationally activate SR.8 HARMONY, which was approved by the Clinical Trials Committee in 2024 and awarded Canadian Institutes of Health Research funding in 2025. The phase III study addresses a significant unmet need in the treatment of high-risk soft-tissue sarcoma by evaluating radiotherapy treatments and immunotherapy. Researchers want to understand whether the addition of cemiplimab, an anti-PD-1 immunotherapy drug, can reduce the risk of recurrence as well as assess whether a shorter preoperative radiation schedule (hypofractionated RT) offers comparable local control to the standard, longer radiation therapy regimen.

This committee is an engaged and enthusiastic group including early and mid-career investigators, surgeons, medical and radiation oncologists, and translational scientists.

2026 Priorities

- Continue to support SR.7 STRASS 2 and SRC.8
- Develop SR.8 HARMONY, including securing drug funding and delivery and agreements with the UK and Australia/New Zealand with an aim to open the trial in late 2026
- Support IND.246 GCAR-1 planned for activation in early 2026

Trial Glossary

- IND.246 – A Phase I Study of GCAR1, a Chimeric Antigen Receptor (CAR) T-CELL Therapy for Participants with Selected Relapsed/Refractory GPNMB-Expressing Solid Tumours
- SR.2 - A Phase III Study of Pre-Operative External Beam Radiotherapy Compared to Post-Operative External Beam Radiotherapy in the Local Management of Curable Extremity Soft Tissue Sarcoma
- SR.7 STRASS 2 (EORTC 1809-STBSG) – A Randomized Phase III Study of Neoadjuvant Chemotherapy Followed by Surgery versus Surgery Alone for Patients with High Risk RetroPeritoneal Sarcoma
- SR.8 HARMONY – Hypofractionated Alternative Radiation with MOdulation of Neoadjuvant/peri-operative immunotherapY in Sarcoma
- SRC.8 (ECOG-ACRIN EA7222)– A Randomized Phase III Trial of Doxorubicin + Pembrolizumab versus Doxorubicin Alone for the Treatment of Undifferentiated Pleomorphic Sarcoma (UPS) and Related Poorly Differentiated Sarcomas

Trial Spotlight

SRC.8 (ECOG-ACRIN EA7222) is a Randomized Phase III Trial of Doxorubicin + Pembrolizumab versus Doxorubicin Alone for the Treatment of Undifferentiated Pleomorphic Sarcoma and Related Poorly Differentiated Sarcomas

SRC.8 was opened to accrual in Canada in 2024 to test if immunotherapy can improve outcomes for patients with undifferentiated pleomorphic sarcoma (UPS). The primary objective of the trial is to assess patients with metastatic or unresectable sarcoma, to determine if the combination of doxorubicin and pembrolizumab will improve progression-free survival (PFS), specifically in undifferentiated pleomorphic or poorly differentiated sarcoma subtypes.

The trial will aim to evaluate the potential benefits of the immunotherapy drugs with a known side effects. Secondary objectives include overall survival, evaluating the safety and tolerability in each treatment arm, and quantifying the overall response rate and durability of response in each arm. Researchers intend to enroll a total of 180 patients who will be randomly assigned to receive either chemotherapy (current standard of care) or immunotherapy plus chemotherapy.

Committee Executive

Dr. Rebecca Gladdy
Co-Chair

Dr. Shantanu Banerji
Co-Chair

Dr. Mariam Jafri
Senior Investigator

Dr. Dongsheng Tu
Senior Biostatician

Jasmine Heuring
Patient Representative

Abha Gupta
Albiruni Razak
Philip Wong
Janet Dancey
Shantanu Banerji
Michael Monument
Christine Simmons
Torsten Nielsen
Jonathan Noujaim (IND Liaison)

Thoracic Oncology Committee

2025 Overview

In 2025, the Thoracic Oncology Committee had three trials open to accrual, two of which are led by CCTG. The first is BR.36, evaluating the efficacy of circulating tumour DNA response-adaptive immuno-chemotherapy in participants with metastatic non-small cell lung cancer (NSCLC). The second trial is BR.38 CURB2, exploring whether the addition of stereotactic body radiotherapy to standard immunotherapy treatment can improve outcomes for patients with metastatic NSCLC and limited disease oligoprogression. Finally, the intregroup led BRC.8 MAVERICK trial is comparing cognitive failure-free survival between MRI surveillance alone and MRI surveillance with prophylactic cranial irradiation for small cell lung cancer patients.

The final BR.31 analyses of overall survival (OS) and minimal residual disease (MRD) in resected NSCLC was presented at the ESMO Annual Congress. The results showed that adjuvant durvalumab vs placebo did not improve OS in EGFR-/ALK- patients regardless of PD-L1 status and that MRD+ status was prognostic for poor OS irrespective of PD-L1 status, and predictive of an OS benefit for treatment with durvalumab. In the biomarker exploratory analyses, BAP1 loss was associated with improved OS, while MTAP loss correlated with poorer OS. Neither one of these two biomarkers was predictive of an OS benefit for treatment with durvalumab.

The IND.227 updated results were presented during the IASLC World Conference on Lung Cancer and confirmed the benefit of adding pembrolizumab to standard chemotherapy in advanced pleural mesothelioma. Furthermore, when patients from the interim analyses were added, OS observed with pembrolizumab alone was reasonable and was felt to warrant additional study.

The committee continued development of the CCTG-led BR.39 LUNA-2 trial, which will assess the safety and efficacy of fecal microbial transplantation before treatment with chemotherapy and immunotherapy in patients with metastatic NSCLC. The trial is expected to open at the end of 2026.

2026 Priorities

- Develop strategic partnerships with dermatology, surgical oncology, and pathology networks to support ME.18
- Develop centralized molecular profiling platforms (e.g. Terry Fox Research Institute Marathon of Hope Cancer Centres Network) for translational research collaborations
- Develop translational research capacity, including ctDNA analysis in clinical trial designs
- Develop trials in the neoadjuvant setting for melanoma and other skin cancers
- Develop IND early-phase trials in metastatic setting for melanoma, rare cancers, and other skin cancers

Trial Glossary

- BR.31 | A Phase III Prospective Double-Blind Placebo Controlled Randomized Study of Adjuvant MEDI4736 in Completely Resected Non-Small
- Cell Lung Cancer
- BR.36 | A Biomarker-Directed, Multi-Centre Phase II/III Study of CTDNA Response Adaptive Immuno-Chemotherapy in Non-Small Cell Lung Cancer
- BR.39 LUNA-2 | A Phase II Randomized Trial of LND101 for Fecal Microbiota Transplantation in Combination with Immune Checkpoint Blockade and Chemotherapy in Patients with Advanced Non-Small Cell Lung Cancer
- BRC.5 (CALGB 140503) | A Phase III Randomized Trial of Lobectomy Versus Sublobular Resection For Small, (≤2cm) Peripheral Non-Small Cell Lung Cancer
- BRC.8 MAVERICK (SWOG S1827) | MRI Brain Surveillance Alone versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer
- IND.227 | A Phase II/III Randomized Study of Pembrolizumab in Patients with Advanced Malignant Pleural Mesothelioma
- IND.242: Neoadjuvant Platform Trial in Patients with Surgically Resectable Non-Small Cell Lung Cancer

Trial Spotlight

BR.38 CURB2 Consolidative Use of Radiotherapy to Block Oligoprogression in Patients with Metastatic Non-Small-Cell Lung Cancer-A Randomized Phase III Trial

BR.38 CURB2 is a CCTG-led trial conducted in collaboration with the US National Clinical Trials Network. Co-primary objectives will evaluate if the addition of early SBRT/ablative radiotherapy to extra-cranial oligoprogressive disease and continuation of first-line chemo-immunotherapy can prolong progression-free survival and overall survival compared to second-line SOC systemic therapy in patients with metastatic oligoprogressive NSCLC. Secondary objectives will evaluate change of quality of life, patient-reported outcomes, treatment-related toxicities, cost-effectiveness of SBRT, and time to initiate new systemic therapy by treatment groups.

While immunotherapy-based treatments can be very effective for patients with metastatic NSCLC, it may become less effective over time. The challenge is oligoprogression, where only a few areas of cancer are progressing while the rest remain stable. In the context of oligoprogression, SBRT offers a way to control the isolated areas of cancer growth by delivering high-dose, highly precise radiation directly to cancerous tumours while minimizing exposure to surrounding healthy tissue and allowing patients to continue their current immunotherapy. This targeted approach aims to control tumour growth, delay the need to change treatments, and extend the duration of treatment benefit and improve OS for patients. A total of 320 patients will be enrolled.

Committee Executive

Dr. Penelope Bradbury
Co-Chair

Dr. Alexander Sun
Co-Chair

Dr. Pierre-Olivier Gaudreau
Senior Investigator

Dr. Keyue Ding
Senior Biostatistician

Emi Bossio
Patient Representative

Normand Blais
Glenwood Goss
Rosalyn Anne Juergens
Janet Dancey
Scott Laurie
Barbara Lynn Melosky

David Dawe (SCLC Working Group Chair)
Devin Schellenberg (Radiation Oncology Working Group Chair)
Jonathan Spicer (Mesothelioma/Thymoma Working Group Chair)
Ming-Sound Tsao (CSTB Working Group Chair)
Ambika Parmar (Economic Analysis Liaison)
Biniam Kidane (Quality of Life Liaison)

Quincy Chu (IND Liaison)
Michela Febbraro (Practicum)
Sharon Kelly (CRA Representative)
Pearl Cai (Pharmacy Representative)
Ryan Kelly (Study Coordinator Representative)

Supportive Care Committee

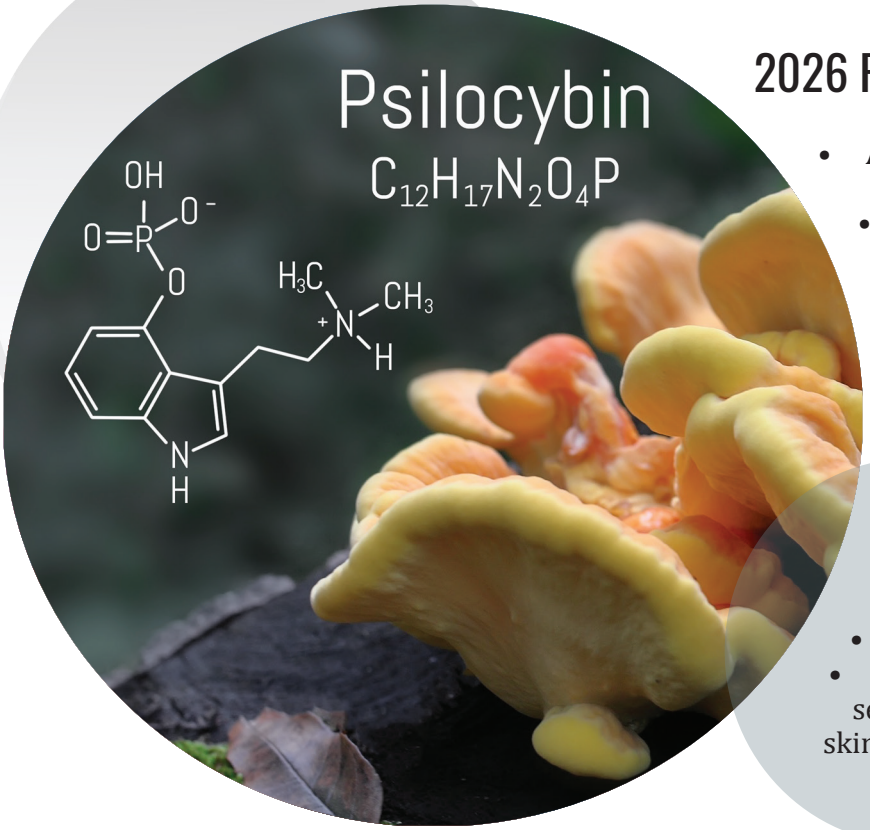
2025 Overview

In 2025, the Supportive Care Committee had three trials open to accrual and led by CCTG. The first is SC.26 investigating the use of the Emotion and Symptom-focused Engagement (EASE) intervention aimed at alleviating the physical pain and psychological distress associated with the sudden onset, and intensive treatment of acute leukemia. The next trial, SC.28 is evaluating the effectiveness of a smartphone-based mindfulness intervention to assess its impact on cancer patient stress—anxiety, depression, fatigue, physical function, and overall quality of life are important secondary outcomes. Finally, SC.29 is comparing stereotactic body radiotherapy (RT) to conventional palliative RT in patients with solid tumours and painful non-spine bone metastases, for 3-month complete pain response, administered to the dominant site of pain.

The Committee supported the successful application to the Canadian Cancer Society (CCS) Breakthrough Team Grant competition. The CAN-PACT team, led by Dr. Linda Carlson at the University of Calgary, was awarded $5.5M to evaluate the efficacy of high-dose psilocybin-assisted therapy for advanced cancer patients. A study is in development, and this future phase III trial is planned to be available across the CCTG network.

An additional three supportive care studies are planned for activation next year. The SC.30 RATIONAL-PT study will look at the role of antibiotic therapy or immunoglobulin on infections in hematology. The SC.31 study is going to evaluate the cost and impact of adapting TEMPO – a tailored, dyadic, web-based physical activity and self-management program for men with prostate cancer and their caregivers. The SC.32S survey study will assess the feasibility and acceptability of collecting sociodemographic data in CCTG trials.

A recent publication reporting the primary results of the study ICC.1 NCI COVID-19 in Cancer Patients: A Longitudinal Natural History Study was published in Journal of the American Medical Association (JAMA) Oncology. The findings showed that COVID-19 had a significant impact on patients with cancer, including hospitalization, treatment disruptions, and death.



2026 Priorities

- Apply a symptom science framework to the development of selected proposals
- Evaluate interventions to manage unique symptom complexes related to immunotherapy
- Advance a digital technology initiative in collaboration with CCTG's QOL and Patient Representative Committee
- Conduct CO.21 CHALLENGE fatigue sub-study analysis
- Refresh the Executive Committee
- Promote accrual to SC.26 (with the Australasian Leukemia and Lymphoma Group), SC.28, and SC.29
- Activate SC.30, SC.31, SC.32S
- Develop IND early-phase trials in metastatic setting for melanoma, rare cancers, and other skin cancers

Committee Executive

Dr. Michael McKenzie
Co-Chair

Dr. Margot Burnell
Co-Chair

Dr. Harriet Richardson
Senior Investigator

Dr. Wei Tu
Senior Biostatician

Hilary Horlock
Patient Representative

Danielle Kain
Tina Hsu
Arjun Sahgal
Linda Carlson

Lynda Balneaves
Doris Howell (QOL Liaison)
Fiona Hellicar (Pharmacy Rep)
Wei Liu (Practicum)

Trial Spotlight

SC.32S – Feasibility and Acceptability of Collecting Sociodemographic Data in CCTG Trials

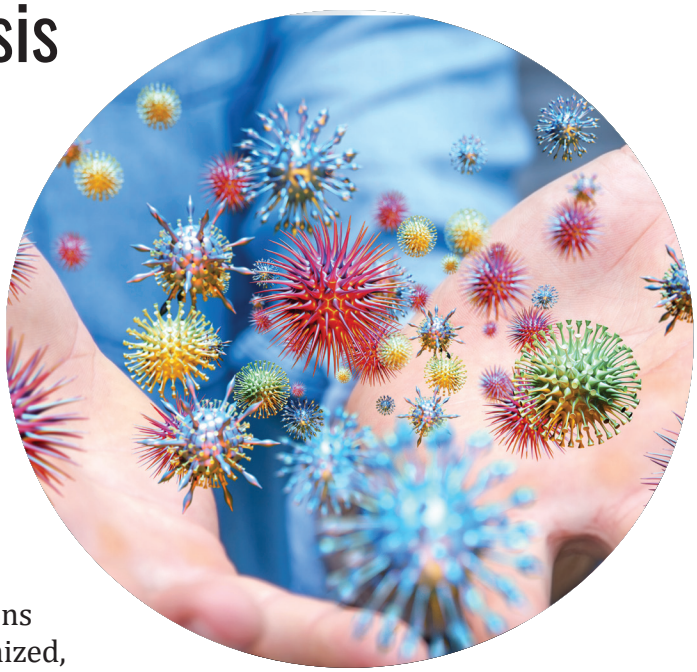
Despite the growing recognition in cancer research that sociodemographic factors can influence health outcomes, equitable access, and overall survival, these variables are not routinely collected in cancer clinical trials. Collecting comprehensive sociodemographic data is a critical step toward ensuring trial results are generalizable and interventions benefit all segments of the population.

SC.32S is a multicentre cohort study with the primary objective of evaluating the feasibility of collecting comprehensive demographic and social determinants of health data using a standardized patient survey among patients consenting to CCTG trials and patients already in a CCTG trial. Secondary objectives are to assess the acceptability of this sociodemographic survey to trial patients and describe the demographic profile of patients enrolling in CCTG trials. Also researchers will compare these data to Canadian population-level benchmarks to determine its representativeness. No separate control group will be used in this study. Instead, population statistics (e.g. Statistics Canada) will serve as a comparator to determine representativeness and historical trial recruitment metrics will contextualize any impact of the survey on trial participation. The study aims to enroll a total of 1000 patients.

Trial Glossary

- CO.21 CHALLENGE | A Phase III Study of the Impact of a Physical Activity Program on Disease-Free Survival in Patients with High Risk Stage II or Stage III Colon Cancer: A Randomized Controlled Trial
- ICC.1 NCI COVID | NCI COVID-19 in Cancer Patients Study: A Longitudinal Natural History Study
- SC.26 EASE | Emotion and Symptom-focused Engagement: A Multi-Site Randomized Controlled Trial of an Intervention for Individuals with Acute Leukemia
- SC.28 SEAMLESS – A Pragmatic Multi-Site Randomized Waitlist-Controlled Trial of a Smartphone App-Based Mindfulness Intervention for French and English Speaker Cancer Survivors
- SC.29 - A Randomized Phase III Study Comparing Stereotactic Body Radiotherapy versus Conventional Palliative Radiotherapy for Participants with Painful Non-Spine Bone Metastases
- SC.30 RATIONAL-PT – Role of Antibiotic Therapy or Immunoglobulin On iNfections in hAematoLogy Platform Trial
- SC.31 TEMPO – Using SMART to optimize the stepped care delivery of TEMPO – a Tailored, dyadic, wEb-based physical activity and self-Management PrOgram for men with prostate cancer and their caregivers

Committee on Economic Analysis



2025 Overview

The Committee on Economic Analysis (CEA) has made progress this year toward the objective of defining when an economic analysis should be conducted alongside CCTG clinical trials. Key considerations have been identified, including the evaluation of new therapies with anticipated high treatment or drug acquisition costs. Also considered were therapies expected to change clinical practice in Canada, and study designs that allow for adequate collection of data to support statistical, model-based, or methodological analyses. In addition, the potential value of economic evaluations alongside non-inferiority or equivalence trials has been recognized, and the importance of collecting economic data to support future evaluations of new therapies.

The CEA has also developed two new "Cost-Effectiveness Analysis" forms to be completed for CCTG trials. *The New Trial Economics Collection Form* outlines the objectives of economic analyses proposed for each trial and specifies the necessary data collection. For trials gathering individual-level cost data, it identifies the top 3-5 main cost drivers and links them to the Resource Utilization Assessment (RUA). Additionally, the Assessment of RUA Collection on Current Trials Form involves reviewing the RUA Case Report Forms (CRFs) used in ongoing trials to determine if any data collection can be removed or minimized. Thus far, the review has reduced the data elements required from 14 elements to 6, greatly reducing the data collection burden.

2026 Priorities

- Economic analyses sub-studies are in development notably for the CO.21 trial
- Impact project
- Financial toxicity working group environmental scan
- Administrative data linkage working group
- Trainee and post-doc support

Trial Glossary

- LY.12 NCT00078949A | Phase III Study of Gemcitabine, Dexamethasone, and Cisplatin Compared to Dexamethasone, Cytarabine, and Cisplatin Plus/Minus Rituximab [(R) -GDP VS (R) -DHAP] as Salvage Chemotherapy for Patients with Relapsed or Refractory Aggressive Histology Non-Hodgkin's Lymphoma Prior to Autologous Stem Cell Transplant and Followed by Maintenance Rituximab Versus Observation.
- CO.21 CHALLENGE | Structured Exercise after Adjuvant Chemotherapy for Colon Cancer

Trial Spotlight

The association of health care contact days with economic measures in the CCTG LY.12 trial

A secondary analysis of the CCTG LY.12 trial which evaluated two pre-transplant chemotherapy regimens for lymphoma. Researchers looked at trial resource use and patient-reported data to calculate contact days, direct costs, and indirect costs such as lost productivity. They assessed the association between the number of contact days and cost outcomes using linear regression models and Pearson correlation coefficients.

In clinical trials, formal economic data collection and analysis require intensive resources so there is a need to identify feasible and scalable measures of costs. In this secondary analysis, days with health care contact outside the home demonstrated a moderate correlation with direct health system costs and a weak correlation with indirect patient and caregiver costs. Contact days thus have the potential as a surrogate measure of direct health system costs, which deserves further exploration as prospective trials incorporate time toxicity analyses.

Researchers are seeing a correlation coefficient of approximately 0.6 between contact days and direct costs, and approximately 0.3 with indirect costs.

Committee Executive

Dr. Kelvin Chan
Co-Chair

Dr. Matthew Cheung
Co-Chair

Dr. Annette Hay
Senior Investigator

Dr. John Queenan
Senior Investigator

Jasmine Heuring
Patient Representative

Dr. Bingshu Chen
Senior Biostatistician

Dr. Wei Tu
Senior Biostatician

Stuart Peacock
Tim Hanna
Natasha Leighl
Jeffrey Hoch
Janice Smith Kwon (Gyne Liaison)
Neil Reaume (GI Liaison)
Jeffrey Graham (GI Liaison)
Marc Kerba (Supportive Care Liaison)
Winson Cheung (Quality of Life Liaison)

Anca Prica (Quality of Life Liaison
Pierre Villeneuve (Hematology Liaison)
Alexander Louie (Thoracic Liaison)
Ambika Parmar (Head & Neck Liaison)
Carlo De Angelis (Pharma Rep)
Nicole LookHong (Melanoma Liaison)
Danielle Rodin (Breast Liaison)
Michael Yan (Brain Liaison)
Patti O'Brien (Study Coordinator)

Quality of Life Committee

2025 Overview

In 2025, the Quality of Life (QoL) Committee contributed to three newly activated trials that incorporated QoL outcomes. QoL was included as a secondary endpoint in CO.33 (a colorectal trial) and BR.38 (a lung cancer trial), and as a tertiary endpoint in HE.2 (a liver cancer trial).

This year saw the publication of three papers that focused on QoL results. The first is from CCTG CX.5 SHAPE trial comparing simple versus radical hysterectomy (JCO 43: 167-179). The other was a retrospective cohort study investigating financial difficulty among cancer patients participating in clinical trials (JNCI 2025). Finally, a validation study analyzing the prognostic value of baseline EORTC QLQ-C30 scores for overall survival across 46 clinical trials covering seventeen cancer types (eClinicalMedicine ISSN 2589-5370).

The committee remains invested in the CCTG IT Department's System Patient Reported OUTcomes (SPROUT) application. SPROUT requires further development to allow direct collection of QoL information from participants' iOS and Android devices. SPROUT will enhance CCTG's capacity to engage remote trial participants while reducing data collection burden.

The Committee also supported a Canadian Cancer Society Challenge Grant submission led by Dr. Wei Tu. The funding application would support the development of a novel project to properly utilize artificial intelligence to collect QoL information from study participants using natural language processing techniques.

Several changes were made to the committee executive, including the appointment of Dr. John Queenan as Senior Investigator—while Dr. Joe Pater continues to provide invaluable guidance and support. The executive also welcomed four new liaisons and a new Patient Representative, Hilary Horlock.

2026 Priorities

- Find opportunities for patient reported outcomes and QoL as primary endpoints in CCTG led trials
- Continue collaboration with Supportive Care trials
- Collaborate with IT to validate the web based and mobile versions of SPROUT
- Explore further AI applications in QoL and PRO data in collaboration with Dr. Wei Tu's team
- Actively seek technical and methodological collaborations where the opportunity arises

Trial Glossary

- CO.33 BATTMAN | Botensilimab + Balstilimab vs Best Supportive Care as Therapy in Chemo-refractory, Unresectable, Colorectal Adeno-carcinoma
- HE.2 | A Phase II Study of STRIDE (durvalumab + tremelimumab) with Lenvatinib versus STRIDE Alone in Patients with Unresectable Hepatocellular Carcinoma (SLIDE-HCC)
- BR.38 CURB2 | Consolidative Use of Radiotherapy to Block Oligoprogression In Patients with Metastatic Non-Small-Cell Lung Cancer-A Randomized Phase 3 Trial
- CX.5 SHAPE | 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

Publication Spotlight

Financial difficulty among patients with cancer participating in clinical trials and its association with patient survival and quality of life

Bishal Gyawali, MD, PhD, FASCO, Nan Chen, MSc, Dongsheng Tu, PhD, Joseph Pater, MD, MSc | Journal of the National Cancer Institute, Volume 117, Issue 11, November 2025

The financial difficulty among patients with cancer participating in clinical trials and their relationship with mortality, quality of life, and toxicity outcomes have been understudied. This study investigated the incidence of financial difficulty among Canadian patients participating in trials to assess the relationship between financial difficulty and clinical outcomes.

This retrospective cohort study included patients participating in 14 systemic therapy trials conducted by the Canadian Cancer Trials Group for adult patients with advanced cancer. The association of financial difficulty with trial characteristics and patient outcomes (mortality, QoL, and toxicity) was studied.

Overall, 37% of these patients encountered financial difficulty at baseline and 25% experienced worsening financial difficulty after trial enrollment. One-third of patients experience financial difficulty, with one-quarter of them experiencing worsening of financial difficulty with trial participation, and both were related to worse patient outcomes. Researchers believe that policy changes are needed to address the cause of financial difficulty in patients with cancer.

Committee Executive

Dr. Joelle Helou
Co-Chair
GU Liaison

Dr. Winson Cheung
Co-Chair
GI Liaison

Dr. John Queenan
Senior Investigator

Dr. Joseph Pater
Senior Investigator

Dr. Dongsheng Tu
Senior Biostatician

Hilary Horlock
Patient Representative

Michael Brundage (Past Chair)
Christine Simmons (Sarcoma Liaison)
Amaris Balitsky (Hematology Liaison)
Julie Lemieux (Breast Liaison)
Terry Ng (IND Liaison)
Hira Mian (Hematology Liaison)
Nhu-Tram Nguyen (Head & Neck Liaison)
Daniel Khalaf (Genitourinary Liaison)
Kelvin Chan (Economic Analysis)
Matthew Cheung (Economic Analysis)

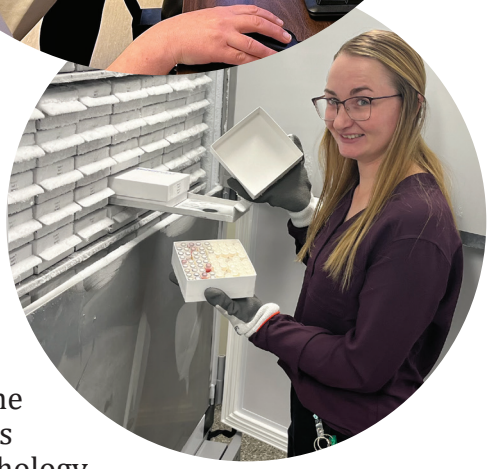
Anca Prica (Hematology Liaison
Doris Howell (Supportive Care Liaison)
David Boren (Study Coordinator)
Biniam Kidane (Thoracic Liaison)
Iwa Kong (Gynecological Liaison)
Michael McKenzie (Supportive Care)
Sonya Lam (CRA)
Christopher Lee (Melanoma Liaison)
Nhu-Tram Nguyen (Head & Neck Liaison)

Correlative Sciences & Tumour Biology Committee

2025 Overview

The CCTG Correlative Sciences & Tumour Biology Committee (CSTB) is leading evidence generation on the use of circulating tumor DNA (ctDNA) as an early marker of treatment response. This includes work led by Dr. Alex Wyatt and the RECIST Working group to develop a framework for incorporating ctDNA changes into response metrics for metastatic cancers. Dr Wyatt has also led a successful CIHR grant proposal to support evidence generation from historic samples collected during patient treatment journeys to inform this response marker.

In addition, the CSTB initiated a master collaboration with an industry partner to develop evidence around the use of ctDNA as an early surrogate for clinical outcomes from biobanked samples collected during previously completed CCTG trials. A request for proposals with industry partners was completed in 2025 and Guardant Health was selected as the industry partner for this project. Negotiation of the master collaboration is underway and a call to disease site committees to submit potential clinical trials for consideration as part of the initiative has been released. Data generated by this initiative will significantly advance available data supporting assessment of ctDNA as a measure of response and will position CCTG as a leader in this field.



During the 2025 CCTG Annual Meeting, a pathology workshop was held. The focus was to bring together the pathology community to address challenges and barriers to pathology workflows on clinical trials, reduce strain on pathology departments, and enhance the ability of Canada to lead in evidence generation from our clinical trials. The outcome of the workshop is a white paper outlining core principles of a) Engagement of Pathologists in Trial Design, b) Feedback Metrics and Compensation Models, c) Digital Pathology as an Enabler, d) Recognizing academic contributions, and e) Knowledge translation of consent and ethics governance.

The highly anticipated move into the new facilities for CCTG's Tumour Tissue Data Repository (TTDR) was completed in the fall. The new space supports clinical trials and research, providing access to the largest cancer clinical trials tumour bank in Canada, with tissue samples collected from CCTG trials around the world.

2026 Priorities

- Finalize pathology workshop white paper to support pathology departments in integrating research in the Canadian research environment
- Initiate a consent and pathology governance summary sheet to support comfort with biobanking, GCP and sample release for pathology departments participating on clinical trials
- Consider a pilot of de-centralized banking of samples from a clinical trial to reduce burden on local pathology departments
- CCTG representation at Canadian Pathology Meetings to raise awareness about research opportunities and CCTG standard operating procedures to enhance comfort with providing samples for correlative analyses
- Start the monthly correlative sciences webinar focused on resources available around Canada
- Continue to engage translational research investigators to provide input into new trial designs
- Ensure there is representative pathology expertise to evaluate proposed correlative questions and appropriate sample collection in all new studies.

Committee Executive

Dr. Alex Wyatt
Co-Chair

Dr. Alan Spatz
Co-Chair

Dr. Lois Shepherd
Senior Investigator

Dr. Jonathan Loree
Senior Investigator

Dr. Keyue Ding
Senior Biostatistician

Shakeel Virk
TTDR Manager

Catherine Wreford

Spotlight

Correlative sciences webinar series

To start 2026, CSTB will launch a new initiative, a webinar each month featuring translational research groups, core facilities, and biobanks around the country. The aim is to increase awareness of resources available to investigators for correlative analyses in Canada, thereby increasing transdisciplinary collaboration and optimizing the use of Canadian expertise. With this new initiative, CSTB also aims to refresh the committee's membership through outreach activities.

The series will launch in January 2026 where researchers attending the first session will learn about the capabilities of the Tumor Tissue Data Repository (TTDR), CCTG's bio-bank. Future meetings will feature national core facilities that provide sample analyses to investigators.

Clinical Trial Health Equity

2025 Overview

In 2025, CCTG continued to advance its commitment to embedding equity, diversity, inclusivity, indigenization, and accessibility (EDIIA) in our research, clinical trial activities, and network. This was accomplished by the successful completion of our EDIIA Action Plan and by expanding our health equity work through our newly established Health Equity Committee.

2025 was the first full year for CCTG's Health Equity Standing Committee. The Committee provides strategic oversight and expertise to ensure equity considerations are integrated across CCTG's research, clinical trial activities, and organizational practices. The committee has grown to include over 40 CCTG network members and community advisors from across Canada. They also successfully recruited two Health Equity Leads, Dr. Caroline Hamm and Dr. Julie My Van Nguyen, to support the equity initiatives developed for PR.25 and HN.13 and the Health Equity Committee.

Over the past year, CCTG focused on identifying and addressing barriers to clinical trial access, providing learning opportunities for central office staff and network members, and supporting trial committees and network leadership in addressing health equity within their research and trials. CCTG's health equity work was presented at several meetings and conferences including the Canadian Cancer Research Conference.

2026 Priorities

- Focus on identifying new health equity priorities with patient partners, network leadership, and Health Equity Committee
- Focus on outreach, engagement, and collaboration to establish partnerships with equity deserving communities
- Advance equitable access to trials
- Address barriers to trial participation to ensure clinical trial participants are more reflective of the Canada cancer populations

Spotlight

Equity Pilot Trials: PR.25 & HN.13

Equity pilot trial initiatives have begun to be implemented for PR.25, investigating platinum and taxane chemotherapy in advanced prostate cancer patients, and HN.13, comparing stereotactic body radiation therapy with standard palliative radiation for head and neck cancer.

Further progress was made with equity activities by providing additional equity training to trial investigators and site teams, developing the trial specific Diversity Action Plans, implementing the reimbursement policy for participant trial related expenses, and translating patient-facing materials into additional languages. Two trial specific workshops were held at the 2025 Annual Spring Meeting that brought together the trial committees and investigators for both trials to discuss the trials, progress on the equity initiatives, and address barriers to accrual.

CCTG Health Equity Leads

Dr. Julie My Van Nguyen

Julie My Van Nguyen is an Associate Professor in the Department of Obstetrics and Gynecology at McMaster University and an attending physician in the Division of Gynecologic Oncology at the Juravinski Hospital and Cancer Centre. She holds a Master of Science in Healthcare Improvement and Patient Safety. Several of her research projects aim to improve care for frail and/or older adults by identifying and optimizing modifiable risk factors to enhance tolerance of surgical and systemic treatments. In parallel, she leads equity, diversity, and inclusion (EDI) research initiatives.

"I look forward to continuing my work with the CCTG Health Equity Committee to advance equitable access to clinical trials, such that research findings are representative, clinically relevant to diverse patient populations, and can translate into meaningful improvements in outcomes for all patients."

Dr. Caroline Hamm

Dr. Hamm is an Associate Professor in the Department of Oncology at Western University. She is also the Chair of the Windsor Division of Oncology at Schulich School of Medicine. She is heavily involved in regional research activities as the chair of Windsor Regional Hospital Academic and Research Committee and co-chair of the WE-SPARK Health Institute Research Committee. Her research interests include triple negative breast cancer, cellular therapy and accrual to clinical trials. She has led the Clinical Trials Navigator project since inception. This program is working with national partners to improve patient access to clinical trials.

"Improving equity in clinical trials is required to ensure that the efficacy of new treatments identified through clinical trials also demonstrates effectiveness in the real world. Our clinical trials patient population has to mirror our patient population. To realize this, effort must be spent on identifying under-represented populations and strategies to engage these populations."

Committee Membership

CCTG Central Office
Anna Johnson (Chair)
Michelle Audoin (Patient Representative)
Florencia Comelles
Susannah Groen
Mariam Jafri
Stephanie Jesshope
Jonathan Loree
John Queenan

Nova Scotia
Kim Meeking
Ravi Ramjeesingh
Julian Surujballi

Quebec
Jean-Marc Bourque
Nathalie Daaboul
Parvaneh Fallah

Ontario
Rosemée Cantave
Courtney Coschi
Andrea Covelli
Shivani Dadwal
Sarah Devereaux
Josee-Lyne Ethier
Italo Fernandes
Caroline Hamm
Tina Hsu
Julie My Van Nguyen
Nhu Tram Nguyen
Elena Parvez
Sheron Perera
Danielle Rodin
Abdulazeez Salawu
Simron Singh
Silvana Spadafora
Rohini Venkatesh

Manitoba
Lynda Balneaves
Tara Horrill

Saskatchewan
Shahid Ahmed
Lynn Dwernychuk

Alberta
Tana Dhruva
Doreen Ezeife
Brian Kelly
Patricia Tang
Oladayo Olaleye

British Columbia
Jessica Chan
Leah Lambert
Michael McKenzie

Education & Training at CCTG

A key CCTG priority is the ongoing scholarship, education, and professional development of students, clinical research staff, trainees, and investigators. CCTG is committed to advancing learning and career growth through structured exposure to trial design, operations, and analysis with targeted educational programs.

Over the past year, the group has made considerable progress in supporting our educational mandate. Educational opportunities for clinical research staff were offered through a "Lunch and Learn" Series and a Clinical Research Associate (CRA) Training Practicum workshop at the 2025 Annual Spring Meeting. These initiatives provided practical information and hands-on training for network centre staff on the initiation and conduct of CCTG studies and will continue in 2026.

The Investigational New Drug Program completed the work to establish the Early Clinical Trials Virtual Education Series—a regular forum for presentation and discussion of topics relevant to early drug trial investigation to reduce the burden on individual institutions. This series will available across Canada to oncology fellows, residents, other trainees and early career investigators with the first session planned for early 2026.

A new educational program was developed aimed at promoting leadership development within our mid-career investigator community. The development was completed on the Investigator Leadership, Mentoring, and Training (VISION) Program which will provide program participants the opportunity to engage in expert-lead workshops designed to educate on leadership principles, empowering the next generation of leaders to represent CCTG nationally and internationally. A call for applications will be distributed in January 2026 with the first in-person workshop being held in April 2026.

This past year also saw the continuation of the successful New Investigator Practicum with 12 early career participants representing cancer centres from across Canada.

2026 Priorities

- Launch the VISION Program with the first workshop scheduled to be held in person preceding the 2026 Annual Spring Meeting
- Start enrollment to the IND Early Clinical Trials Educational Series
- Launch of the Correlative Sciences and Tumour Biology monthly series to enhance awareness to national correlative science resources.
- The New Investigator Clinical Trial Course will be offered in August 2026
- Explore opportunities to expand fellowship and graduate trainee programs
- Continuing curriculum development to support clinical trial education across the entire training continuum, from undergraduate trainees to early/mid-career investigators

New Investigator Practicum

A training program in cancer clinical trial conduct

Dr. Janet Dancey
Co-Lead

Dr. Penelope Bradbury
Co-Lead

The CCTG New Investigator Cancer Trials Practicum is approaching its ninth year and continues to deliver a highly reviewed training program. The program includes practical trial experience at cancer sites throughout Canada over a one-year period. This unique program and the first of its kind in Canada, enables the best and brightest new Canadian oncology researchers to acquire training and experience in cancer clinical trial conduct.

VISION | Investigator Leadership Training

CCTG Scientific Leadership Training

Dr. Wendy Parulekar

The CCTG VISION - Investigator Leadership Training Program will be a new education and mentorship course designed to enhance the leadership skills of the next generation of clinical trialists. The program aims to equip current and emerging cancer research leaders with the knowledge and expertise, represent CCTG.

The program will run over eight months from April-November 2026. VISION encorporates personalized leadership coaching based on behavioral assessment tools. This is combined with interactive virtual group discussions facilitated by invited subject-matter experts.

Anna Spreafico

Laura Pearce

New Investigator Clinical Trials Course

Educating new Canadian investigators in clinical trial conduct

The biennial New Investigator Clinical Trials Course (NICTC) is an important component of the CCTG mandate to provide and facilitate investigator education and training. It is a 2.5 day course designed to educate new investigators from across the country about the essentials of clinical trial conduct in the Canadian research environment. The 2026 course marks the tenth biennial offering of the course, which was established in 2007.

Using lecture and interactive workshop formats, this course provides an overview of clinical trial design and conduct for investigators. Topics include the fundamentals of phase I-III clinical trial design, biostatistics in clinical trials, correlative biology, quality of life and economic evaluation in the research setting. Practical aspects of clinical trial conduct will also be addressed including how to set up a clinical trials unit, understanding and complying with national and international regulatory standards, contract negotiation, and career planning for the clinical trialist.

Funding Successes & Grant Applications

SPOTLIGHT - US National Clinical Trials Network

CCTG successfully renewed its program grant from the US National Institutes of Health to participate in the NCTN as the Canadian Collaborating Clinical Trials Network. This grant supports per case funding, salaries for staff, and operating and maintenance costs. Currently, 44% of the Group's portfolio is comprised of NCTN trials, including 13 CCTG-led trials, and CCTG scientific leaders participate in all NCTN committees and taskforces and contribute to expanded US group partnerships. The funding amount has not been announced.

Grants Submitted
15

Funding Total
$1,707,600M
(1 Pending)

Grants Funded
4

2025 Funding

In 2025, CCTG was successful in obtaining $1.5M in funding from the Canadian Institutes of Health Research (CIHR), Canada's federal funding agency for health research, to support conduct of SR.8 HARMONY, a multicentre, randomized, phase III trial addressing a significant unmet need in the treatment of high-risk soft-tissue sarcoma (STS). The trial aims to evaluate whether the addition of cemiplimab, an anti-PD-1 immunotherapy drug, can reduce the risk of recurrence. The study will simultaneously assess whether a shorter preoperative radiation schedule (hypofractionated RT) offers comparable local control to the standard, longer regimen.

Funding was also secured from the Sinclair Cancer Research Institute at Queen's University aimed at assessing the impact of CCTG trials on survival of patients in Canada. The impact of Canadian academic cancer trials on population outcomes remains unknown. As the largest oncology cooperative group in Canada, CCTG offers a high-impact case to assess this gap providing critical information to the public and to funders of academic trials. Understanding how trial benefits translate into population benefits could ensure the survival gains are achieved through optimal and equitable adoption of innovations into routine practice.

2025 Contracts

Data/Correlative
26

Contracts Total
290

Funding/Trail
4

Solving Cancer Together

CCTG Strategic Plan 2022-2027

The Solving Cancer Together strategic plan is coming to to its conclusion. Over the last five years the group has driven scientific progress, new treatments and supported the national network. Through the actions of our patient representatives, network leaders and members, international collaborators, industry partners, central office team, and funders, we continue to create meaningful change. The development of the frame work for the next strategic plan is underway.

Cell Therapy

- Novel Therapy Trials that include Phase 1 trials with First-in-Human (FIH) academic cell therapy constructs
- IND.246 and GCAR1 trials submitted to Health Canada October 2025
- The TACTful trial Health Canada submission target is mid 2026
- IND.245 SOC supportive trial had the bridging trial contract executed

Pre-operative Clinical Trials

- IND.242 neoadjuvant platform ongoing development
- IND.242A platform master protocol sub study publication published in April 2025
- Expanded biobanking and digital pathology capacity with the official opening of new space for the TTDR
- Expanding collaborations with pathology and surgical trainees

Data Science

- Patient Reported Outcome and Quality of Life AI project in development
- Determine capacity for genomic and digital imaging analyses
- Collaborating with national health data platforms underway
- Social determinants of health - Canadian Longitudinal Study on Aging (SDoH-CLSA) pilot underway
- LIFE study near completion with data linkages (CCTG, CCO, StatCan)
- Initiated exploratory collaborations with large Canadian longitudinal cohorts