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# RESEARCH & TREATMENT UPDATES

**MAY 2026**



**CCRAN**  
Colorectal Cancer  
Resource &  
Action Network



**RISCC**  
Réseau d'informations  
et soutien pour le  
cancer colorectal

*A PATIENT-FOCUSED ORGANIZATION*

# COLORECTAL CANCER TREATMENT & CLINICAL RESEARCH UPDATES

## Month Ending May 22nd, 2026

**The following colorectal cancer treatment and research updates extend from April 10th, 2026 to May 22nd, 2026, inclusive and are intended for informational purposes only.**

This content is not intended to be a substitute for professional medical advice. Always consult your treating physician or guidance of a qualified health professional with any questions you may have regarding your health or medical condition. Never disregard the advice of a medical professional or delay in seeking it because of something you have read on this website.

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# Drug/Systemic Therapies



## **1.MOUNTAINEER-03: A Study of Tucatinib with Trastuzumab and mFOLFOX6 Versus Standard of Care Treatment in First-line HER2+ mCRC (Mar 16/26)**

**Update type:** Recruiting study

**Study type:** Phase III, randomized clinical trial

**Population:** First-line HER2-positive metastatic or unresectable colorectal cancer

**Intervention:** Tucatinib + trastuzumab + mFOLFOX6

**Comparator:** Standard of care (mFOLFOX6 alone or with bevacizumab or cetuximab)

**Study focus:** Evaluates whether adding tucatinib and trastuzumab and chemotherapy improves outcomes compared with current first-line standard treatments, while assessing safety and tolerability.

### **Key inclusion criteria:**

- You have colorectal cancer that has spread or cannot be removed with surgery
- Your cancer is HER2-positive
- Your cancer is RAS wild-type
- You have either:
  - No brain metastases, or
  - Brain metastases that were previously treated and are not causing symptoms

### **Key exclusion criteria:**

- You have already received treatment for metastatic colorectal cancer (some limited chemotherapy before starting the trial may be allowed – your doctor can confirm)
- You have previously received HER-2 targeted therapy
- You have significant nerve damage (severe neuropathy)
- You recently had radiation therapy
- You have an active or untreated gastrointestinal (GI) perforation

### **Key findings from Phase II:**

- The combination of Tucatinib + Trastuzumab achieved a 39.3% objective response rate.
- The median duration of response was 15.2 months.
- Patients' median progression-free survival was 8.1 months, and overall survival was 23.9 months.
- Most side effects were mild and manageable (diarrhea, fatigue, nausea).

### **Why it matters:**

This study is investigating if targeted therapies in combination with chemotherapy can be

effective and well tolerated for some patients with HER2-positive colorectal cancer, with potential use as an earlier line of therapy.

**Actively recruiting trial sites:**

**Ontario:**

- The Ottawa Hospital Cancer Centre (Ottawa)
- Sunnybrook Research Institute (Toronto)
- Mount Sinai Hospital (Toronto)

**Quebec:**

- Jewish General Hospital (Montreal)

**Saskatchewan:**

- Saskatoon Cancer Centre (Saskatoon)

To learn more about this trial, click [here](#).

To view the publication, click [here](#).

**2. CARMA BROS: Canadian Cancers with Rare Molecular Alterations (CARMA) – Basket Real-world Observational Study (BROS) (Dec 31/24)**

**Update type:** Recruiting study

**Study type:** Real-world, observational (data collection) study

**Population:** Canadian patients with cancer that has rare or uncommon molecular (genetic) alterations

**Study focus:** Collects real-world data to understand how cancers with rare molecular changes behave, how patients are treated across Canada, treatment outcomes, side effects, and quality of life. The study also looks at patterns such as brain metastases and how new targeted therapies are used over time.

**Key Inclusion criteria:**

- You were 18 years or older when you were diagnosed with cancer
- Your tumour has a rare or uncommon genetic alteration (e.g., ALK, EGFR, ROS1, BRAF, NTRK, KRAS G12C)
- You are receiving routine cancer care in Canada

**Why it matters:**

If your cancer has a rare genetic change, there is often limited information to guide treatment. By learning from real patient experiences across Canada, this study helps improve understanding of which treatments work best, how they affect quality of life, and supports better access to personalized, targeted care for people with rare molecular cancers.

To learn more about this study, click [here](#).

### **3. A Review of Current Research Related to Circulating Tumour DNA for Minimal Residual Disease (ctDNA-MRD)**

#### **A. Circulating Tumor DNA-based Assessment of Minimal Residual Disease in Colorectal Cancer: Prognostic and Predictive Implications (Feb 25/26)**

**Update type:** Completed study findings

**Study type:** Literature review (evidence synthesis)

##### **What is ctDNA?**

- Small DNA fragments from cancer cells in the bloodstream carrying tumour-specific mutations.
- It is detected via liquid biopsy, a non-invasive alternative to tissue biopsies.
- ctDNA testing can be performed using tumour-informed ctDNA or tumor-agnostic ctDNA approaches.
- ctDNA reveals important tumour information such as genetic mutations, copy number changes, DNA methylation patterns, and structural rearrangements.
- This information helps clinicians track the disease, monitor treatment response, and detect recurrence early.

##### **What is Minimal Residual Disease (MRD)?**

- Small numbers of cancer cells remaining after treatment, often undetectable by imaging, which can lead to recurrence if not addressed.
- ctDNA testing can detect MRD in the bloodstream even when scans appear normal.
- Early MRD detection helps to identify high-risk patients, personalize post-treatment care, and consider additional therapies sooner.
- ctDNA testing can be performed after surgery (2-4 weeks) to detect MRD, during adjuvant therapy to monitor treatment response, and during follow-up to detect early recurrence.

##### **Limitations and implications:**

- Some tumours release very small amounts of ctDNA, making detection difficult.
- Testing methods and thresholds are still being standardized, and negative ctDNA results do not guarantee that patients remain cancer-free
- ctDNA testing is still undergoing clinical trials
- ctDNA has the potential to detect recurrence earlier, personalize treatment, reduce overtreatment, and improve long-term outcomes.

To learn more, click [here](#).

#### **B. DYNAMIC-III Trial at ESMO 2025 Presidential: ctDNA-guided Adjuvant Chemotherapy in Stage III Colon Cancer (Nov 14/25)**

**Update type:** Completed study findings

**Study type:** Phase II/III randomized clinical trial

**Population:** Patients with stage III colon cancer after surgery

##### **Treatment approach studied:**

Use of a tumour-informed blood test (circulating tumour DNA, or ctDNA) for minimal residual disease after surgery to help guide decisions about follow-up chemotherapy.

**Comparator:** ctDNA-guided treatment decisions versus standard post-surgery care.

**Study focus:**

The study looked at whether ctDNA testing after surgery could help safely reduce or tailor chemotherapy for patients at lower risk of the cancer coming back, while still maintaining good outcomes.

**Key findings:**

- Patients with no ctDNA detected after surgery had a low risk of recurrence
- Using ctDNA results allowed some patients to receive less chemotherapy, including shorter treatment duration, less intensive regimens, or careful observation
- This approach reduced exposure to oxaliplatin, a drug linked to nerve damage
- Survival outcomes remained favourable, particularly for patients considered lower risk based on clinical features

**Why it matters:**

After surgery for stage III colon cancer, chemotherapy is often given to reduce the risk of recurrence—but not everyone benefits equally. This study suggests that a blood test can help identify people who may be able to safely receive less chemotherapy, reducing side effects while still maintaining strong cancer outcomes. It supports a more personalized approach to treatment after surgery.

To learn about this study, click [here](#).

**C. A Review of Current Research Related to Circulating Tumour DNA for Minimal Residual Disease (ctDNA-MRD) CRC.10: Colon Cancer Adjuvant Chemotherapy Based on Evaluation of Residual Disease (Dec 30/24)**

**Update type:** Recruiting study

**Study type:** Phase II/III randomized clinical trial

**Population:** Patients with early-stage colon cancer after surgery (Stage IIB, IIC, or Stage III)

**Intervention:** Adjuvant chemotherapy guided by circulating tumour DNA (ctDNA) results after surgery

**Study focus:** Evaluates whether testing for circulating tumour DNA (ctDNA) for minimal residual disease after surgery can help decide who needs chemotherapy and what type of chemotherapy is most appropriate. Patients without detectable ctDNA may be able to avoid unnecessary chemotherapy, while patients with detectable ctDNA may benefit from more tailored treatment.

**Key inclusion criteria:**

- You have had surgery to fully remove your colon cancer
- Your cancer was a Stage IIB, IIC, or Stage III colon adenocarcinoma
- There is no evidence of cancer spread on recent imaging
- Your tumour is not MSI-H or dMMR
- You are well enough to receive chemotherapy

**Key exclusion criteria:**

- Your cancer has spread to other organs

- Your tumour was not an adenocarcinoma
- You have already received chemotherapy or radiation for colon cancer (with limited exceptions)
- You have certain serious medical conditions that would make chemotherapy unsafe

**Why it matters:**

This study aims to personalize treatment after colon cancer surgery. By using a blood test to detect small amounts of remaining cancer circulating in the bloodstream, some patients may be able to safely avoid chemotherapy, while others can receive treatment better matched to their risk of recurrence.

**Contacts for trial:**

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To learn more about this study, click [here](#).

Please connect with CCRAN to receive a list of other participating clinical trial sites in Canada.

#### 4. Access to Fruquintinib (FRUZAQLA) for Previously Treated mCRC (May 14 /26)

**Update type:** Approved treatment & patient access program

**Population:** Adults with metastatic colorectal cancer (mCRC) who have already received, or are not candidates for, standard therapies

**Treatment:** FRUZAQLA™ (Fruquintinib) – oral targeted therapy

**What this treatment is for:**

FRUZAQLA™ is approved for patients with mCRC whose cancer has progressed after (or who are not candidates for) commonly used treatments, including chemotherapy, anti-VEGF therapy, anti-EGFR therapy (if RAS wild-type), and later-line options such as Trifluridine-Tipiracil (Lonsurf) or Regorafenib (Stivarga).

**Access and patient support:**

Takeda offers the OnePath® Patient Support Program, which helps eligible patients with treatment navigation, reimbursement support, and financial assistance while public or private coverage is being arranged.

**Why it matters:**

For people with advanced mCRC and limited remaining options, FRUZAQLA provides another potential treatment. Patient support programs like OnePath® can help reduce delays and barriers to access during a critical stage of care.

To learn more about OnePath® Patient Support Program, click [here](#).

**Fruquintinib is currently listed (publicly available) in:** Alberta, British Columbia, New Brunswick, Nova Scotia, Ontario\*, Quebec, Saskatchewan, and Newfoundland and Labrador.

**\*For Ontario Residents- Fruquintinib is now reimbursed by Ontario Drug Benefit (ODB) via the Exceptional Access Program (EAP).** You can find Fruquintinib's coverage status using ODB medication coverage search box [here](#).

## 5. Investigating the Effects of Atezolizumab in People Whose Tumour DNA or RNA Indicates Possible Sensitivity (CAPTIV-8) (June 20/25)

**Update type:** Recruiting study

**Study type:** Phase II clinical trial

**Population:** Adults with advanced or incurable solid tumours whose tumour DNA and RNA analysis suggests they may respond to immunotherapy

**Treatment:** Atezolizumab (immunotherapy), given every 3 weeks

### **Study focus:**

This study is investigating whether detailed analysis of a tumour's DNA and RNA can help predict who may benefit from atezolizumab. Participants are assigned to one of several tumour-type cohorts (including breast, lung, gastrointestinal, gynecologic, genitourinary, sarcoma, and others). All participants receive the same treatment. Early results within each cohort help determine whether enrollment continues for that cancer type.

### **Key inclusion criteria:**

- You are 18 years or older
- You have an advanced solid tumour that cannot be cured
- Your tumour has undergone whole genome and RNA testing through a program such as Personalized OncoGenomics (or equivalent)
- Molecular analysis suggests your cancer may be sensitive to immunotherapy
- You have measurable disease and are well enough to receive treatment

### **Key exclusion criteria:**

- You have previously received PD-1 or PD-L1 immunotherapy
- You have an active autoimmune disease requiring treatment
- You are pregnant or breastfeeding
- You have serious uncontrolled infections, lung inflammation, or significant heart disease
- You require ongoing immune-suppressing medications

### **Why it matters:**

This study uses advanced genomic testing to help match patients to immunotherapy based on the biology of their cancer, rather than tumour type alone. It reflects a more personalized approach to cancer treatment and may help identify who is most likely to benefit from immunotherapy.

### **Actively recruiting trial sites:**

#### **Vancouver:**

- BC Cancer (Vancouver); Contact: Janessa Laskin, MD; 604-877-6000 ext. 672617, [jlaskin@bccancer.bc.ca](mailto:jlaskin@bccancer.bc.ca)

To learn more about this study, click [here](#).

## 6. Patient Support Program Offered by Bristol Myers Squibb Canada – Nivolumab + Ipilimumab (OPDIVO® + YERVOY®) for the First-Line Treatment of Adult Patients with Unresectable or Metastatic Colorectal Cancer + Ontario FAST Program Accelerated Access (Apr 9/26)

Bristol Myers Squibb Canada Co. (BMS) is pleased to announce a new patient access program designed to provide patients access to nivolumab + ipilimumab (OPDIVO® + YERVOY®) for the first-line treatment of adult patients with unresectable or metastatic MSI-H or dMMR CRC, as approved by Health Canada on July 16th, 2025.

Following the positive CDA funding recommendation, Ontario has become the first jurisdiction in Canada to reimburse OPDIVO® plus YERVOY® for certain patients under the province's newly launched **Funding Accelerated for Specific Treatments (FAST) program**. With its focus on accelerating review of therapies with demonstrated clinical benefit, such as OPDIVO® plus YERVOY®, the FAST program will enable eligible individuals with MSI-H or dMMR metastatic colorectal cancer to gain access to treatment more quickly.

Importantly, access to nivolumab + ipilimumab continues to expand across Canada. As of April 1, 2026, four additional provinces—Nova Scotia, Saskatchewan, Manitoba, and British Columbia—have officially listed this combination as a first-line treatment option. Combined with earlier listings in Ontario (November 28, 2025) and Quebec (February 4, 2026), **a total of six provinces now provide public access to this therapy.**

For further reading: [Article 1](#), [Article 2](#) (French), and [Article 3](#)

## 7. Comprehensive Genomic/Biomarker Testing in Canada – OncoHelix (Aug 12/25)

OncoHelix is a Canadian laboratory located at the University of Calgary, offers comprehensive genomic profiling to help match cancer patients with the most effective treatments.

### Testing options include:

#### **OncoHelix-1 – Tumour tissue test (324 genes)**

Designed to match the FoundationOne® test, considered a gold standard in cancer genomics. Detects tumour alterations such as SNVs, CNVs, Indels, and fusions. Matches patients with approved therapies, identifies clinical trial opportunities, and provides insights into drug resistance. Includes key colorectal cancer biomarkers: KRAS, NRAS, BRAF, ERBB2 (HER2), EGFR, PIK3CA, RET, VEGF, and TRK fusions. Reports Microsatellite Instability (MSI), Tumour Mutational Burden (TMB), and Homologous Recombination Deficiency (HRD) to help guide immunotherapy decisions.

#### **OncoHelix-2 – Tumour tissue test (DNA+RNA: 170 genes)**

Designed to offer the flexibility of detecting genetic alterations in both DNA and RNA of a range of solid tumours. More affordable and reports on all key colorectal cancer biomarkers that is recommended if MSI testing has been completed.

#### **OncoHelix 3 – Tumour tissue test (DNA+RNA: 523 genes) NEW!**

Provides comprehensive pan-cancer biomarker profiling, analyzing 523 genes associated with over 1600 active clinical trials. The assay includes integrated tumour mutational burden (TMB), microsatellite instability (MSI) assessment and homologous recombination deficiency (HRD) analysis with BRCA1/2 variant detection. The turnaround time is 3 weeks.

It is recommended for patients:

- That are undergoing initial molecular testing for a newly diagnosed tumour
- That are presenting with de novo metastatic disease
- With progression after first-line therapy who need biomarker testing to guide treatment
- That need rapid identification of alterations to inform timely treatment decisions

### **OncoHelix-4 – Liquid biopsy test (146 genes)**

It is a blood test that looks for cancer-related genetic changes using a small blood sample. It checks 146 genes and is especially helpful when tumour tissue is not available or when cancer has spread. The test can help identify possible targeted treatment options, clinical trial opportunities, and reasons why a cancer may stop responding to treatment.

The OncoHelix Requisition Form can be found [here](#).

## **8. Botensilimab + Balstilimab vs Best Supportive Care as Therapy in Chemo-refractory, Unresectable, Colorectal Adenocarcinoma (BATTMAN) (Sept 18/25)**

**Update type:** Recruiting study

**Study type:** Randomized, Interventional, Phase III

### **Study focus:**

This study is evaluating whether the immunotherapy combination of botensilimab and balstilimab can improve overall survival in patients with chemo-refractory, unresectable microsatellite stable (MSS) colorectal adenocarcinoma compared with current standard management.

**Comparator:** Botensilimab + Balstilimab versus best supportive care

### **Key inclusion criteria:**

- Colorectal adenocarcinoma that is not dMMR or MSI-H.
- Received and failed all prior available therapies
- ECOG performance status 0-1
- Measurable or evaluable disease according to RECIST 1.1
- Life expectancy  $\geq$  12 weeks
- Age  $\geq$  18 years
- Adequate organ and bone marrow function prior to randomization.
- Participant agrees to use effective contraception if of childbearing potential.

### **Key exclusion criteria:**

- Tumours that are dMMR or MSI-H
- History of primary immunodeficiency, solid organ transplant, or allogenic bone marrow transplant
- Recent use of immunosuppressive medications (with some exceptions)
- Active or prior autoimmune or inflammatory disorders
- Active brain metastases or leptomeningeal metastases
- Recent live attenuated vaccine (within 30 days)
- Recent anti-cancer therapy, radiotherapy, or investigational drugs
- Bowel obstruction, refractory ascites, or significant ongoing diarrhea
- Allergy to study drugs or conditions preventing compliance with the protocol
- Prior exposure to anti-PD-1/PD-L1/CTLA-4 therapy

**Why it matters:**

Patients with chemo-refractory, unresectable MSS colorectal cancer currently have very limited options and are managed with best supportive care when standard therapies fail. Evaluating the combination of botensilimab and balstilimab could provide a new therapeutic option that improves survival, slows tumour growth, and enhances quality of life.

**Actively recruiting sites:** British Columbia, Ontario, Quebec, and Saskatchewan  
For more information about the recruiting sites, click [here](#).

Study contact: Chris O'Callaghan; 613-533-6430, cocallaghan@ctg.queensu.ca  
To learn more, click [here](#).

**9. The OrigAMI Trials: Amivantamab + Chemotherapy versus Standard Regimens in First-Line and Second-Line KRAS/NRAS and BRAF Wild-Type Metastatic Colorectal Cancer****A. A Study of Amivantamab and mFOLFOX6 or FOLFIRI Versus Cetuximab and mFOLFOX6 or FOLFIRI as First-Line Treatment in Participants with KRAS/NRAS and BRAF Wild-type Unresectable or Metastatic Left-sided Colorectal Cancer (OrigAMI-2) (Feb 13/ 26)**

**Update type:** Recruiting study

**Study type:** Phase 3 randomized, open-label trial

**Comparators:** Amivantamab with chemotherapy vs cetuximab with chemotherapy

**Study focus:**

This study aims to compare how long the participants remain disease free when treated with amivantamab combined with standard chemotherapy (FOLFOX or FOLFIRI) versus cetuximab combined with standard chemotherapy as first-line treatment in participants with KRAS/NRAS and BRAF wild-type unresectable or metastatic left-sided colorectal cancer.

**Key inclusion criteria:**

- Confirmed left-sided colorectal adenocarcinoma that is metastatic or unresectable
- KRAS, NRAS, and BRAF are wild-type
- Willing to provide fresh tumour tissue

**Key exclusion criteria:**

- History of/ currently has interstitial lung disease (ILD) /pneumonitis/pulmonary fibrosis
- Allergic/ intolerant to study drugs or chemotherapy components
- Has another cancer that could interfere with study results
- Tumours with dMMR/MSI-H or HER-2 positive/ amplified status
- Prior treatment with drugs targeting EGFR or MET

**Why it matters:**

The primary outcome measure of this trial, progression-free survival, shows how long a treatment can keep cancer under control before it worsens. This trial will help determine which targeted therapy may delay disease progression more effectively. Identifying a treatment that keeps the cancer stable for longer can improve first-line treatment decisions and potentially lead to better outcomes for patients with left-sided metastatic CRC.

## **Actively recruiting trial sites:**

### **Alberta:**

- Arthur J E Child Comprehensive Cancer Centre (Calgary)

### **Ontario:**

- Ottawa Hospital (Ottawa)
- Princess Margaret Cancer Centre (Toronto)

### **Quebec:**

- Centre de Recherche du CHUM (Montreal)

To learn more, click [here](#).

## **B. A Study of Amivantamab and FOLFIRI Versus Cetuximab/ Bevacizumab and FOLFIRI in Participants with KRAS/ NRAS and BRAF Wild-Type Colorectal Cancer Who Have Previously Received Chemotherapy (OrigAMI-3) (Feb 13/26)**

**Update type:** Recruiting study

*There are currently no recruiting trial sites in Canada.*

**Study type:** Randomized, open-label, phase III trial

### **Study focus:**

This study evaluates the progression free survival and overall survival of participants with KRAS/ NRAS and BRAF wild-type recurrent mCRC, when treated with amivantamab and FOLFIRI versus cetuximab or bevacizumab and FOLFIRI as second-line treatment.

### **Key inclusion criteria:**

- Confirmed colorectal adenocarcinoma that is recurrent, unresectable, or metastatic
- Confirmed KRAS/ NRAS and BRAF mutant status
- ECOG performance status of 0 or 1
- 18 years and older
- Must have received 1 line of systemic therapy (fluoropyrimidine-based and oxaliplatin-based) for mCRC, with disease progression after this line of therapy

### **Key exclusion criteria:**

- Has a history of or currently has interstitial lung disease, pneumonitis, or pulmonary fibrosis
- Has prior or concurrent second malignancy that can interfere with efficacy of study treatments
- Participants with dMMR/MSI-H status who have not received immunotherapy treatments
- Participants with HER2-positive/ amplified tumour
- Has prior exposure to irinotecan, or any agents that target EGFR or MET

### **Why it matters:**

This study evaluates whether adding amivantamab to standard chemotherapy can improve survival outcomes compared to current targeted options (cetuximab or bevacizumab) in patients with RAS/BRAF wild-type metastatic colorectal cancer who have already received treatment. If successful, it could introduce a new, more effective targeted therapy option in the second-line setting, where treatment choices remain limited.

To learn more, click [here](#).

## 10. A Study of Bispecific Antibody MCLA-158 in Patients with Advanced Solid Tumours (Jan 29/25)

**Update type:** Recruiting

*There are currently no recruiting trial sites in Canada.*

Study type: Phase I/II open label, non-randomized, interventional study

### **Study focus:**

The study is evaluating the safety, optimal dosing, and anti-tumour activity of MCLA-158 (petosemtamab) in metastatic colorectal cancer (RAS/BRAF wild-type) patients. It will evaluate MCLA-158 as a monotherapy and as a combination therapy with FOLFOX and FOLFIRI.

### **Key inclusion criteria:**

- Participants with advanced or metastatic solid cancers, including colorectal cancer, that cannot be cured with standard treatment
- ECOG performance status of 0 or 1
- Life expectancy  $\geq$  12 weeks
- Left ventricular ejection fraction  $\geq$  50%
- 18 years or older
- Expansion cohort for mCRC specifically (open to enrollment):
- RAS/BRAF wild-type
- No oncogenic missense mutations in KRAS, NRAS, BRAF, or EGFR ectodomain and no HER2 amplification
- Microsatellite stable (MSS) tumour
- No prior anti-EGFR therapy

### **Key exclusion criteria:**

- Central nervous system metastases that are symptomatic or untreated
- Known leptomeningeal involvement
- Recent treatment with other cancer therapies or participation in another clinical trial
- Recent major surgery or radiation
- Uncontrolled hypertension (systolic BP  $>$  150 mmHg and/or diastolic BP  $>$  100 mmHg)
- History of congestive heart failure or cardiac arrhythmia requiring treatment
- History of myocardial infarction or prior malignancies
- History of interstitial lung disease
- Participants with current medical conditions or active infections (Hepatitis B or C)
- Pregnant or breastfeeding

### **Why it matters:**

This study explores a new targeted treatment option for patients with mCRC. MCLA-158 (petosemtamab) is especially promising because it blocks cancer cell growth and targets cancer stem cells believed to drive treatment resistance and recurrence, addressing a key reason why colorectal cancer comes back after treatment.

To learn more, click [here](#).

## 11. Encorafenib, Cetuximab, and mFOLFOX6 in BRAF-Mutated Colorectal Cancer (BREAKWATER) (June 20/25)

**Update type:** Completed study findings

**Study type:** Phase III, randomized clinical trial

**Population:** Patients with previously untreated BRAF V600E-mutated metastatic colorectal cancer

**Treatment:** Encorafenib + Cetuximab + mFOLFOX6 (chemotherapy)

**Comparator:** Standard chemotherapy, with or without bevacizumab

**Study focus:** Evaluated whether adding targeted therapy (encorafenib and cetuximab) to chemotherapy improves outcomes compared with standard first-line treatment in patients with BRAF V600E-mutated metastatic colorectal cancer.

### Key findings:

- The targeted combination led to higher tumour response rates
- Cancer progression was delayed (~13 months vs. ~7 months)
- Overall survival was significantly longer (~30 months vs. ~15 months) compared with standard care
- Side effects were consistent with known safety profiles

### Why it matters:

If your colorectal cancer has a BRAF V600E mutation, this study shows that starting treatment with targeted therapy plus chemotherapy can help control the cancer longer and may help you live longer than standard chemotherapy alone.

### Access and patient support:

Pfizer offers a Patient Support Program (PSP) to help eligible patients access encorafenib when used with cetuximab and FOLFOX in the first-line setting.

For further reading: [Article 1](#), [Article 2](#)

## 12. STELLAR-303 Trial at ESMO 2025: Zanzalintinib Plus Atezolizumab in MSS Metastatic Colorectal Cancer (Nov 14/25)

**Update type:** Completed study findings

**Study type:** Randomized clinical trial

### Study focus:

This clinical trial evaluated the safety of zanzalintinib (multi-kinase inhibitor) plus atezolizumab (PD-L1 inhibitor) versus regorafenib in patients with relapsed or refractory microsatellite-stable (MSS) metastatic colorectal cancer. It aimed to improve outcomes in populations historically resistant immunotherapy.

## Key findings:

- People taking zanzalintinib plus atezolizumab had a modestly improved median overall survival (OS) of 10.9 months, compared to 9.4 months for those taking regorafenib.
- In patients without cancer in the liver, the combination treatment showed a median overall survival of 15.9 months versus 12.7 months with regorafenib.
- The overall survival of patients on the combination was 46% at 12 months and 20% at 24 months.
- The progression-free survival (the time before the disease got worse) was longer with the combination at 3.7 months versus 2.0 months with regorafenib.
- Benefits were seen regardless of patients' geographical location, genetic mutations (RAS), presence of liver metastases, or previous treatments.
- Side effects were manageable. The most common side effects were high blood pressure (15%), fatigue (6%), diarrhea (6%), and protein in the urine (6%).

## Why it matters:

This is the first phase III study to show that a combination of immunotherapy drugs can help people with MSS metastatic colorectal cancer, a type that usually doesn't respond well to immunotherapy. It shows a new treatment option without traditional chemotherapy that can benefit many kinds of patients.

For further reading: [Article 1](#), [Article 2](#)

## STELLAR-303 (NCT05425940) Study Design

### Patient Population

- Aged ≥18 years
- Documented to not have MSI-H or dMMR status
- mCRC that radiographically progressed on or was refractory or intolerant to prior standard-of-care therapy, which had to include all the following (if approved and available in the country where the patient is randomized):
  - Fluoropyrimidine, irinotecan and oxaliplatin ± anti-VEGF antibody
  - Anti-EGFR antibody (if RAS wild type)
  - BRAF inhibitor (if known BRAF V600E mutation)

### Stratification Factors

- Geographic region (Asia/rest of the world)
- RAS status (wild type/mutant)
- Presence of liver metastases (yes/no)

R 1:1

N=901

Zanzalintinib 100 mg PO QD +  
Atezolizumab 1200 mg IV Q3W  
(n=451)\*

Regorafenib 160 mg PO QD  
(days 1–21 of each 28-day cycle)  
(n=450)\*

### Endpoints

#### Dual primary

OS in the ITT population  
OS in patients without liver metastases (nimITT)

#### Key secondary

PFS,<sup>†</sup> ORR,<sup>†</sup> Safety<sup>‡</sup>

\*Treatment beyond radiographic progression was allowed per investigator discretion. †According to Response Evaluation Criteria in Solid Tumors version 1.1. Statistical significance cannot be claimed until superiority of OS in both the ITT and non-liver metastases ITT populations has been demonstrated in the final analysis. ‡According to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0. dMMR, deficient mismatch repair; EGFR, epidermal growth factor receptor; ITT, intention to treat; IV, intravenous; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability high; nimITT, subset of patients without liver metastases; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PO, oral administration; QD, every 1 week; QD, once daily; VEGF, vascular endothelial growth factor. Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

### **13. Advances in Immunotherapy for Colorectal Cancer: Overcoming Resistance in Mismatch Repair-Proficient Tumours (Feb 19/26)**

**Study type:** Review of existing evidence

**Study focus:**

This study reviewed existing evidence and emerging strategies in CRC immunotherapies and proposed a structured translational framework to extend immunotherapy benefits beyond the MSI-H subset.

**Key findings:**

- Most MSS colorectal cancers remain resistant to current immunotherapies due to low immunogenicity, impaired antigen presentation, T-cell exclusion, and a highly suppressive tumour microenvironment, particularly in cases with liver metastases.
- Emerging strategies include combination checkpoint blockade (PD-1 with CTLA-4, LAG-3, or TIGIT inhibitors), mRNA based neoantigen vaccines, integration of targeted therapies with Immune Checkpoint Inhibitors (ICIs) (KRAS-G12C, BRAF, MEK inhibitors), tumour microenvironment modulation via VEGF inhibition and anti-angiogenics, oncolytic viruses and microbiome manipulation.

**Why it matters:**

Expanding immunotherapy strategies beyond those targeted only for MSI-H tumours could improve treatment options and outcomes for people with mismatch repair-proficient CRC.

To learn more, click [here](#).

### **14. The Impact of Metformin Use on Survival Outcomes in Colorectal Cancer: A Systematic Review and Meta-Analysis (Jan 15/26)**

**Update type:** Completed study findings

**Study type:** Systematic review and meta-analysis

**Study focus:**

The review evaluated the association between Metformin use and prognostic outcomes in patients with colorectal cancer. The analysis included 31 cohort studies comprising of 167,683 participants, examining outcomes such as all-cause mortality (ACM), cancer-specific mortality (CSM), overall survival (OS), disease free survival (DFS), and recurrence-free survival (RFS).

**Key inclusion criteria for the cohort studies reviewed:**

- Cohort studies with participant population being adults with a histologically confirmed diagnosis of colorectal cancer
- Studies had to report at least one of these: all-cause mortality (ACM), cancer-specific mortality (CSM), overall survival (OS), disease free survival (DFS), and recurrence-free survival (RFS)

**Key findings:**

- Metformin exposure was significantly associated with reduced ACM and CSM.
- A significant improvement in overall survival was observed, particularly in patients with type 2 Diabetes Mellitus (T2DM).
- No significant association was observed between metformin use and recurrence-free survival.

- The benefits of Metformin were most prevalent among colorectal cancer patients with diabetes, whereas non-diabetic patients showed no significant association with overall survival or cancer-specific mortality.
- Effects varied depending on cancer stage, tumour location, and patient characteristics, but overall Metformin was associated with better survival outcomes in colorectal cancer patients with diabetes.

**Why it matters:**

Diabetes can increase the risk of developing CRC. This review found that Metformin, a commonly prescribed medication for Type 2 Diabetes, may offer a dual benefit for CRC patients with diabetes by helping manage their diabetes while also supporting better cancer outcomes.

To learn more about this study, click [here](#).

**15. Neoadjuvant Chemotherapy with CAPOX versus Chemoradiation for Locally Advanced Rectal Cancer with Uninvolved Mesorectal Fascia (CONVERT): Final Results of a Phase III Trial (Feb 19/26)**

**Update type:** Completed study

**Study type:** Randomized control trial

**Comparators:** Neoadjuvant chemoradiotherapy (nCRT) vs chemotherapy (nCT)

**Study focus:**

This study examines whether neoadjuvant chemotherapy (nCT) with capecitabine plus oxaliplatin (CAPOX) can provide outcomes comparable to the standard neoadjuvant chemoradiotherapy (nCRT) with capecitabine in locally advanced rectal cancer with uninvolved mesorectal fascia.

**Key findings:**

- After 3 years, the cancer recurrence rates, disease free survival, and overall survival were similar between both treatment groups
- Patients who received chemotherapy alone had fewer long-term side effects, including less bowel inflammation.

**Why it matters:**

For patients with locally advanced rectal cancer who do not have mesorectal fascia involvement, chemotherapy alone before surgery may achieve similar survival outcomes as chemoradiotherapy while reducing long-term side effects associated with radiation. This supports more personalized treatment strategies and potentially reduces patients' exposure to radiation.

To learn more, click [here](#).

**16. Epidermal Growth Factor Receptor Inhibitor Rechallenge: A Worthy Option in the Crowded Refractory Advanced Colorectal Cancer Space (Mar 4/26)**

**Study type:** Systematic review and meta-analysis

**Study focus:**

The study examines whether rechallenging patients with epidermal growth factor receptor

(EGFR) inhibitors, such as cetuximab and panitumumab, is an effective treatment strategy for patients with refractory metastatic colorectal cancer who previously responded to EGFR-targeted therapy but later developed resistance.

**Key findings:**

- EGFR-inhibitor rechallenge showed clinical benefit in 937 patients with RAS/RAF wild-type metastatic colorectal cancer.
- Progression-free survival was 3.83 months, and overall survival was 10.43 months.
- The objective response rate was 14.6% and the disease control rate was 58.9%
- EGFR rechallenge resulted in longer progression-free survival than other systemic therapies (5.94 vs 3.87 months), but overall survival was similar.
- Patients without RAS/RAF mutations detected in ctDNA had better survival outcomes than those with detectable resistance mutations.

**Why it matters:**

Treatment options for advanced, refractory colorectal cancer have limited survival benefits and cause significant side effects. EGFR-inhibitor rechallenge may provide a meaningful later-line treatment option, especially for patients without resistance mutations.

To learn more, click [here](#).

**17. Atezolizumab plus FOLFOX for Stage III Mismatch Repair-Deficient Colon Cancer - ATOMIC Trial Establishes New Standard of Care (Mar 25/26)**

**Update type:** Completed study findings

**Study type:** Phase III randomized controlled trial

**Study focus:** The study evaluated whether adding the immunotherapy drug atezolizumab to standard adjuvant chemotherapy (FOLFOX) improves outcomes in patients with resected stage III mismatch repair-deficient (dMMR) colon cancer.

**Key findings:**

- Adding atezolizumab reduced the risk of recurrence or death by 50% compared to chemotherapy alone.
- 3-year disease-free survival: 86.3% (atezolizumab + FOLFOX) vs 76.2% (FOLFOX alone)
- No significant difference in overall survival observed yet (data still maturing).
- Higher rates of grade 3-4 adverse events with combination therapy (84.1% vs 71.9%).
- Benefit appears strongest in patients who receive adequate chemotherapy exposure (>6 cycles).

**Why it matters:**

This is the first phase 3 trial to show a clear benefit of immunotherapy in early-stage (non-metastatic) dMMR colon cancer, marking a major shift in treatment.

The findings have already been incorporated into NCCN guidelines, establishing atezolizumab + FOLFOX as a new standard of care for patients with stage III dMMR colon cancer in the United States. This has not yet been approved/ funded in Canada – stay tuned for when this comes to Canada.

To learn more, click [here](#).

## 18. First-Line Nivolumab plus FOLFOXIRI/ Bevacizumab in Advanced RAS/BRAF-Mutated Colorectal Cancer: Efficacy, Safety, and Biomarker Discovery from the Phase II NIVACOR Trial (Mar 25/26)

**Update type:** Completed study findings

**Study type:** Phase II trial

**Study focus:** The trial evaluated the activity and safety of FOLFOXIRI/ bevacizumab combined with nivolumab as a first-line therapy in patients with RAS/BRAF-mutated mCRC. The study also evaluated the results of CGP and RNA sequencing analyses performed to identify possible biomarkers of activity of this combination in pMMR/MSS tumours.

### **Key findings:**

- 76.7% of participants experienced tumour shrinkage; out of which about 10% had complete response (no visible cancer) and 67% had a partial response.
- 20.6% of participants had stable disease, meaning their cancer did not grow.
- Tumours had a median time to response of approximately 2 months.
- The median progression free survival was 10.1 months.
- The treatment worked similarly in both the RAS and BRAF-mutation subgroup.
- Patients with different tumour biology (MSS vs MSI) also showed comparable benefits.
- 86% of patients experienced at least one treatment related side effect (eg. diarrhea, fatigue, low white cells, nerve effects, and nausea).
- 66% of participants experienced serious side effects, mostly neutropenia and diarrhea.
- Patients with higher mutational burden had longer disease control.
- Changes in PI3K/AKT pathway were associated with improved outcomes.

### **Why it matters:**

This study shows that a combination treatment including chemotherapy, immunotherapy, and targeted therapy can achieve high response rates and disease control in patients with RAS/BRAF-mutated mCRC.

To learn more, click [here](#).

# Surgical Therapies

## 19. Hepatic Artery Infusion Pump (HAIP) Chemotherapy Program – Sunnybrook Odette Cancer Centre (Dec 17/24)

### **About the program:**

The hepatic artery infusion pump (HAIP) chemotherapy program is a first-in-Canada for individuals where colon or rectal cancer (colorectal cancer) has spread to the liver and cannot be removed with surgery.

### **What is HAIP:**

Hepatic artery infusion pump (HAIP) chemotherapy is a specialized chemotherapy treatment for colorectal cancer that has spread to the liver and cannot be safely removed via surgery. A small device is surgically implanted in the abdomen to deliver chemotherapy directly into the liver through the hepatic artery. This targeted approach allows high doses of medication to reach liver tumours while limiting exposure to the rest of the body. The goal is to shrink tumours enough to make surgical removal possible.

### **How does it work:**

HAIP works by taking advantage of the liver's unique blood supply. Healthy liver tissue receives blood from the portal vein, while liver tumours rely on the hepatic artery. Delivering chemotherapy through the hepatic artery targets cancer cells while minimizing exposure to healthy tissue. The drug commonly used for the therapy, floxuridine (FUDR), is broken down in the liver, allowing high local doses with fewer systemic side effects compared to traditional chemotherapy.

### **Key eligibility Criteria:**

- Patients whose colorectal cancer has spread to the liver
- None or very limited cancer outside of the liver
- Tumours cannot be removed surgically
- Physically fit enough to undergo surgery and motivated to pursue aggressive treatment
- Adequate liver blood flow confirmed through specialized testing

### **Treatment process:**

- Surgical implantation of the HAIP (1-2 hours)
- Post surgery nuclear medicine scan to confirm chemotherapy will reach the liver safely
- Chemotherapy delivery begins roughly 2 weeks after implantation

### **Effectiveness of HAIP:**

- About 25% of patients become eligible for surgery after HAIP to remove the cancer from their liver.
- Of the 120 patients treated at Sunnybrook, 88% of patients demonstrated a positive response to HAIP chemotherapy. After HAIP chemotherapy, 21.5% of patients were able to undergo a liver resection and 5.7% of patients became eligible for a liver transplant.
- The treatment uses highly targeted therapy with fewer whole-body side effects compared to traditional chemotherapy.



Contact: Christina Kim (Nurse practitioner)

If you believe you may benefit from this therapy and/or would like to learn more about the clinical trial, your medical oncologist or surgeon may fax a referral to 416-480-6179.

To learn more, click [here](#).

## 20. In Vivo Lung Perfusion (IVLP) for Colorectal Lung Metastases (Jan 9/25)

**Update type:** Recruiting study

**Study type:** Phase 1, interventional, non-randomized trial

### **Study focus:**

This study is investigating a technique called in vivo lung perfusion (IVLP) for delivering chemotherapy directly into the lungs at the time of surgery. The purpose of this study is to test the safety of the IVLP technique and find the dose that seems right in humans. Participants are given oxaliplatin into one lung via IVLP and monitored for side effects. The other lung will not be infused with anything, so that researchers can limit unforeseen toxicity to a single lung and see if one lung does better than the other.

### **Key inclusion criteria:**

- Diagnosis of colorectal carcinoma
- Presence of bilateral pulmonary metastases
- 3 or more lung lesions in total
- Age 18-70 years
- ECOG 0-2; ECOG is a performance status scale used to assess a patient's functional abilities.(ECOG 0: fully active, ECOG 1: strenuous physical activity restricted, ECOG 2: capable of all self-care)
- Absence of extra-pulmonary disease, except liver metastases suitable to curative treatment.

### **Key exclusion criteria:**

- Patient has previously received more than 1000 mg of oxaliplatin
- Left Ventricular Ejection Fraction <50%
- History of significant pulmonary disease or pneumonitis
- Pregnant or lactating females

- Age 71 or older, or less than 18 years
- Hypersensitivity to oxaliplatin
- Patients with Heparin-induced thrombocytopenia (HIT)

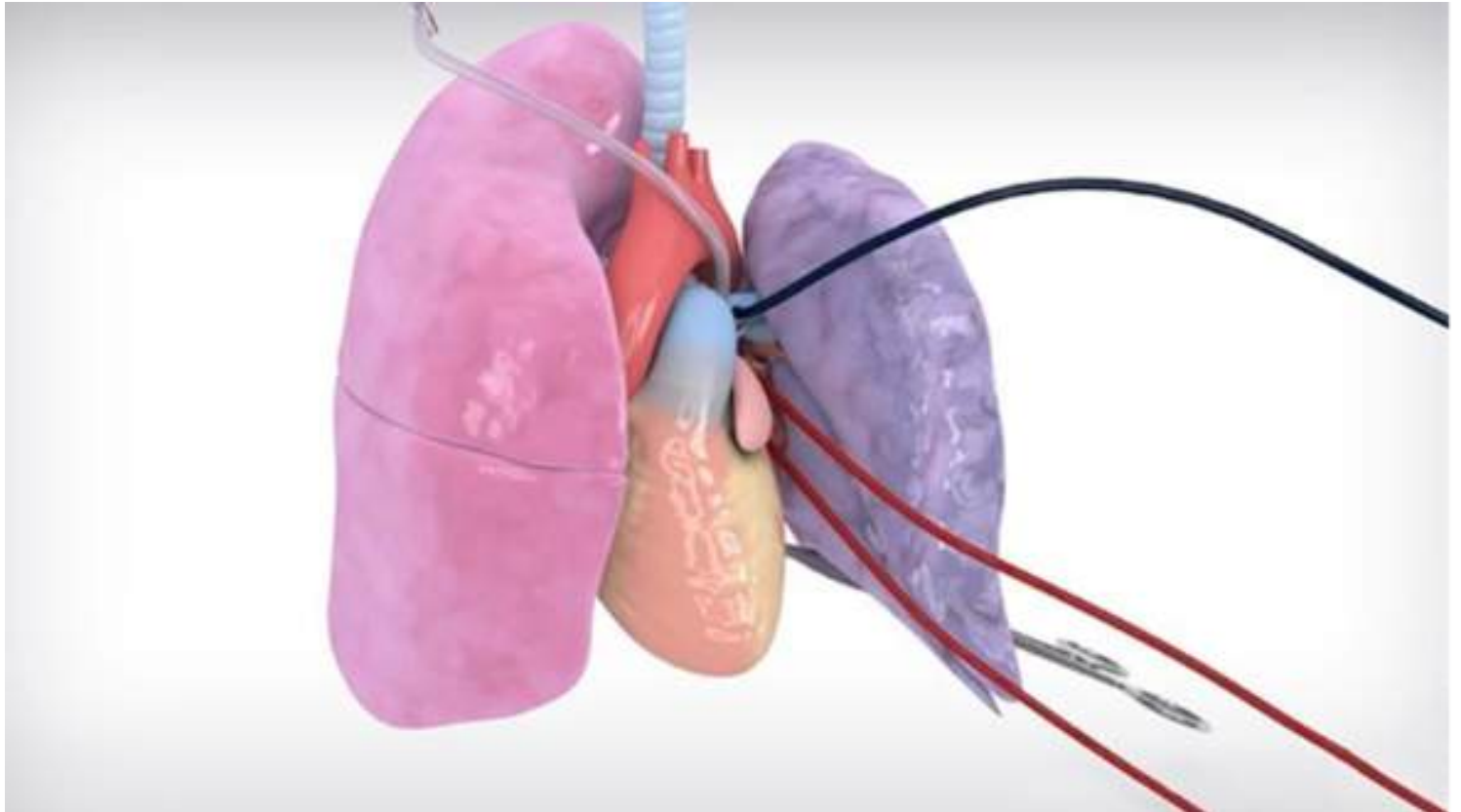
**Actively recruiting trial sites:**

**Ontario:**

- University Health Network, Toronto General Hospital (Toronto); Dr. Marcelo Cypel

The primary outcome is safety as measured by acute lung injury findings and the estimated primary completion date is January 1, 2027.

To learn more, click [here](#).



*In Vivo Lung Perfusion Model*

Image Source: <https://pie.med.utoronto.ca/TVASurg/project/in-vivo-lung-perfusion/>

## **21. Does Surgical Intervention Contribute to Survival for Patients with Para-Aortic Lymph Node Metastasis from Colorectal Cancer? (Apr 18/25)**

**Study type:** Supplementary analysis of a multicentre retrospective observational cohort study (JSCCR-PALNM project)

**Study focus:**

The study examined the impact of surgical resection on survival for patients with para-aortic lymph node metastasis (PALNM) from colorectal cancer compared to chemotherapy alone, using real-world database of patients treated at dedicated institutions for colorectal cancer in Japan.

**Key findings:**

-The patients who had surgery survived longer than those who received chemotherapy alone.

- On average, surgery extended survival by almost 2 years (4.4 years with surgery vs 2.5 years with chemotherapy).
- Only 1 in 4 patients remained relapse free at 3 and 5 years after surgery.
- Surgery was most beneficial for patients who had solitary PALNM, poorly differentiated tumours and other distant metastases that were still removable.
- Surgery showed less survival benefit for patients with multiple affected lymph nodes, lymph node spread above the renal vein and right-sided primary tumours.

**Why it matters:**

PALNM has often been managed with chemotherapy alone. This study provides strong evidence that surgical resection can significantly improve overall survival in selected patients with resectable PALNM.

To learn more, click [here](#).

**22. Liver Transplant Programs in Canada (Mar 31/26)**

Liver transplant may be a viable treatment option for patients with metastatic disease that is confined to the liver, with unresectable liver metastases and otherwise stable disease.

Below is a table with Liver Transplant programs across Canada:

Province	City		Contact
Ontario	Toronto	Toronto General Hospital (UHN)	416-340-4800, ext. 4848
	London	London Health Sciences Centre (LHSC)	519-685-8500
Québec	Montréal	Centre Hospitalier de l'Université de Montréal (CHUM)	514-890-8000, ext. 26616
	Montréal	McGill University Health Centre	514-934-1934, ext. 36590
	Montréal	CHU Sainte-Justine	514-345-4931
	Québec City	CHU de Québec – Laval University	418-525-4444, ext. 15262

New Brunswick	St. John	Horizon Health – Saint John Regional Hospital	506-648-6850
	Bathurst	Réseau de santé Vitalité	506-869-2441
Nova Scotia	Sydney	Cape Breton Regional Hospital	902-567-8067
Saskatchewan	Saskatoon/ Regina	Saskatchewan Transplant Program	Saskatoon: 306-655-5054 Regina: 306-766-6477
Alberta	Calgary	Give Life Alberta	1-866-408-5465

### **Living Liver Donor Programs:**

Living donor liver transplants allow for shorter wait times and often excellent outcomes.

Dedicated programs exist at:

#### **University Health Network (UHN) – Toronto**

- Largest in Canada
- To learn more, click [here](#).

#### **Alberta Health Services – Edmonton**

- Adult and pediatric
- To learn more click [here](#).

#### **London Health Sciences Centre (LHSC)**

- Living Liver Donation
- To learn more, click [here](#).

To access a list of Canadian Transplant Programs and Organ Procurement Organizations, click [here](#).

### **23. Efficacy and Safety of Intraoperative Hyperthermic Intraperitoneal Chemotherapy for Locally Advanced Colorectal Cancer (HIPECT4): Final Analysis of Randomized Clinical Trial (Mar 31/26)**

**Update type:** Completed study findings

**Study type:** Randomized clinical trial

**Study focus:** The study aimed to evaluate whether adding intraoperative HIPEC with mitomycin C improves peritoneal disease control in patients with locally advanced colorectal cancer after 36 months of follow-up. It also examined long term survival outcomes and identified subgroups that may benefit most.

**Key findings:**

- HIPEC significantly improved peritoneal control compared to standard treatment alone.
- It reduced peritoneal recurrence and changed the pattern of relapse (less peritoneal, more systemic).
- No significant difference in overall survival or disease-free survival at 3 years between groups.
- Greater benefit in subgroups: Patients with confirmed pT4 disease and those who received adjuvant chemotherapy.
- HIPEC did not increase toxicity or morbidity.

**Why it matters:**

The study shows that adding HIPEC can reduce the risk of peritoneal recurrence in patients with locally advanced colon cancer without increasing toxicity. However, no difference in overall survival or disease-free survival were observed between the HIPEC and control groups. These findings suggest HIPEC may help improve local disease control, while its impact on overall survival and disease-free survival remains unproven.

To learn more, click [here](#).

# Radiation Therapies/ Interventional Radiation



## 24. Ultra-high Dose Radiation for Liver Metastasis Using MR-guided Treatment with Stereotactic Ablative Single-fraction (ULTRAS) (Mar 21/25)

**Update type:** Recruiting study

**Study type:** Phase III, interventional randomized control trial

### **Study focus:**

The study aims to compare whether giving an ultra-high dose (experimental) of radiation in a single treatment session using MR-Linac is more effective than a standard high-dose (control) radiation for treating liver metastases. It aims to identify predictors of treatment response and side effects by analyzing various factors such as imaging markers and genetic profiles.

### **Key inclusion Criteria:**

- Have a confirmed cancer diagnoses that has spread to the liver (colorectal adenocarcinoma, pancreatic adenocarcinoma, head and neck SCC, cervix SCC, skin SCC and NSCLC)
- Have 1-3 liver tumours suitable for SBRT
- Have good liver function (Child-Pugh score A)
- 18 years or older and in good physical condition
- Must have an ECOG performance status of 0-2.
- Expected life expectancy > 6 months.
- Are not pregnant or breastfeeding and agree to use effective contraceptive during treatment

### **Key exclusion Criteria:**

- Liver metastases from primary cancer other than those listed in the eligibility criteria
- Have more than 5 liver metastases requiring treatment or have tumours too close to important bile ducts and structures
- Previously received radiation that could interfere with this treatment or are currently receiving other cancer treatments
- Have medical conditions that could make radiation unsafe
- Cannot undergo MRIs

### **Why it matters:**

Previous studies have shown that SBRT can be effective for treating liver metastases, but the optimal radiation dose has not yet been determined. This study aims to address that gap by comparing ultra-high dose SBRT with standard dose SBRT to determine which approach is most effective.

### **Actively recruiting trial sites:**

#### **Ontario:**

-Princess Margaret Cancer Centre (Toronto); Contact: Ali Hosni, MD; 416-946-2360, [ali.hosni.abdalaty@uhn.ca](mailto:ali.hosni.abdalaty@uhn.ca)

To learn more about the study, click [here](#).

# Clinical Trial Navigation



## **25. Merck Patient Resource: Clinical Trials Site (Nov 14/25)**

Merck now has a new patient resource. They have introduced a Canadian clinical trials site! Within the site you will find lists of all the Merck trials taking place within an easy to navigate website for patients.

To learn more, click [here](#).

## **26. Cancer Trials Canada (Apr 9/26)**

The Canadian Cancer Society (CCS) and the Quebec – Clinical Research Organization in Cancer (Q-CROC) have launched a national, bilingual website that provides up-to-date Canadian clinical trial information.

To learn more, click [here](#).

To access the Cancer Trials Canada website, click [here](#).

## **27. Second Look Cancer (Apr 10/26)**

Second Look Cancer is a clinical trial matching platform that uses key details such as your cancer type, biomarkers, treatment history and so on to identify and rank the most relevant clinical trials for you based on eligibility criteria.

To learn more, click [here](#).

## **28. Biomarker Help (Apr 10/26)**

Biomarker Help is a platform that analyzes your biomarker test report to provide personalized treatment insights including approved therapies, clinical trials and off-label options.

To learn more, click [here](#).



## 29. National Guideline for Lynch Syndrome Aims to Prevent Cancers and Save Lives (Nov 14/25)

**Study type:** Clinical survey and literature review

**Study focus:**

The Canadian Lynch Syndrome Working group, consisting of 37 multidisciplinary experts, aimed to improve testing and management of Lynch Syndrome, an inherited genetic mutation in the body's mismatch repair (MMR) system that increases a person's risk of developing cancer. This study is the first national study to provide a standard of care for the assessment of Lynch Syndrome in Canada, by establishing 18 consensus statements addressing Lynch Syndrome diagnostic pathways and patient advocacy across Canada.

**Key recommendations:**

- Universal Lynch Syndrome screening for people with colorectal and endometrial cancers
- Genetic testing for family members of people with Lynch Syndrome
- The creation of provincial surveillance protocols for Lynch Syndrome-associated cancers
- Increase in physician education about Lynch Syndrome and improved education strategies and communication across all specialists.

**Why it matters:**

The recommendations from this study can be used as a guideline to streamline policies and practices across Canada and can serve as a resource for providing care for individuals with Lynch Syndrome.

To learn more about this study, click [here](#). The full publication can be found [here](#).

## 30. Blood-Based Circulating Tumour DNA (ctDNA) Tests for Colorectal Cancer Screening: Systematic Review and Meta-Analysis of Diagnostic Accuracy (Apr 1/26)

**Update type:** Completed study findings

**Study type:** Systematic review and meta-analysis

**Study focus:**

This study evaluates how accurate blood-based ctDNA tests are for detecting colorectal cancer and advanced precancerous lesions in average-risk, asymptomatic patients. It aims to determine whether ctDNA can be a reliable, non-invasive option for population-level colorectal cancer screening.

**Key findings:**

- ctDNA tests demonstrated moderate sensitivity (72%) and high specificity (91%) for detecting CRC.
- ctDNA test performance improved with tumour stage, with sensitivity increasing from 53% in Stage I to 89% in Stage IV CRC.

- Sensitivity for advanced precancerous lesions (APL) was very low (13%), indicating very limited ability to detect early, preventable cancer.
- In a screening population, ctDNA produced approximately 9% false positive results, contributing to unnecessary follow-up colonoscopies.
- ctDNA testing showed a very high negative predictive value (99.8%), indicating strong ability to rule out CRC when results are negative.
- Next-generation methylation-based ctDNA testing demonstrated improved performance, with sensitivity increasing to 81% and reduced heterogeneity compared to earlier assays.
- ctDNA tests have similar CRC detection to FIT tests but are poor at detecting precancerous lesions.

### **Why it matters:**

This study shows that while blood-based ctDNA testing could make colorectal cancer screening more accessible and increase participation, it currently misses most precancerous lesions. As a result, ctDNA is better suited as a complementary tool rather than a replacement for existing CRC screening methods.

To learn more, click [here](#).

## **31. Prince Edward Island first in Canada to Lower Colorectal Cancer Screening Age (Mar 30/26)**

PEI has become the first province in Canada to lower the average-risk colorectal cancer screening age from 50 to 45 years, marking a significant advancement in early detection and cancer prevention. Individuals aged 45-74 in PEI can now access the fecal immunochemical test (FIT), enabling early identification of cancers and precancerous changes when treatment is most effective.

This decision reflects the growing evidence highlighting the rise of early age onset colorectal cancer and the importance of adapting screening programs to reflect current disease trends.

CCRAN has been advocating for lowering the screening age to 45 for 6 years through various initiatives. CCRAN continues to advance its advocacy efforts, urging other provinces to follow PEI's lead and adopt evidence-based screening updates to ensure timely and equitable access to colorectal cancer screening across Canada.

To read more, click [here](#).

## **32. Ontario to Lower Colorectal Cancer Screening Age to 45 years – Effective July 1, 2026 (May 5/26)**

Ontario Health (Cancer Care Ontario) has announced that individuals with average-risk for colorectal cancer in Ontario will begin screening with fecal immunochemical test (FIT) at age 45 beginning July 1, 2026.

Additionally, the program is lowering the threshold for an abnormal FIT result, which is expected to increase the detection of colorectal cancers and pre-cancerous polyps. As a result, a higher volume of FIT-positive colonoscopies is anticipated. Ontario Health's ColonCancerCheck program continues to recommend colonoscopy within 8 weeks of an abnormal FIT result due to the higher likelihood of detecting cancer in this group.

To learn more, click [here](#).



## 32. Exercise for Cancer to Enhance Living Well (EXCEL) Study (Dec 29/24)

**Update type:** Recruiting study

**Study type:** Hybrid implementation effectiveness study

**Study focus:**

Exercise for Cancer to Enhance Living Well (EXCEL) is a 5-year Canada-wide project that uses an integrated knowledge translation approach to implement evidence-based exercise delivery for cancer survivors in remote/ rural and underserved communities.

**Key inclusion Criteria:**

- Have a diagnosis of cancer
- Are over the age of 18 years
- Can participate in mild levels of activity
- Are about to have treatment, are currently having treatment, or have had cancer treatment within the last 5 years
- Can read/write in English
- Can access online programs, if necessary, to participate in the exercise programs.

**Key exclusion Criteria:**

- Unable to read/write in English
- Are unable to participate in exercise
- For online programs, do not have internet or computer access

**Contact:** Email [wellnesslab@ucalgary.ca](mailto:wellnesslab@ucalgary.ca) to learn more and sign up.

To learn more about this study click [here](#).

To access the EXCEL study webpage, click [here](#).

To hear about participant experiences, click [here](#).



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### 33. A Randomized Phase III Trial of the Impact of a Structured Exercise Program on Disease-Free Survival (DFS) in Stage 3 or High-Risk Stage 2 Colon Cancer: Canadian Cancer Trials Group (CCTG) CO.21 (CHALLENGE) (June 20/25)

**Update type:** Active, not recruiting

**Study type:** Phase 3 randomized trial

#### Study focus:

This study aimed to test the hypothesis that a meaningful increase in recreational physical activity (PA) after adjuvant therapy is achievable and will improve disease-free survival (DFS) in stage 3 or high-risk stage 2 colon cancer. From 2009 to 2024, 889 patients were randomized to a structured exercise program (SEP, 445 patients) or health education materials (HEM, 444 patients). The HEM participants received educational material promotion PA and healthy nutrition in addition to standard surveillance. The SEP participants worked with a PA consultant who delivered an exercise intervention using behaviour change methodology over 3 years.

#### Key findings:

- The structured exercise program (SEP) significantly improved survival, reduced recurrence and enhanced physical function compared to health education materials (HEM).
- After about 8 years of follow-up, fewer recurrences and deaths occurred in the SEP group.
- Disease free survival and overall survival was higher in the SEP group.

#### Why it matters:

These findings suggest the implementation of a structured exercise program should become a standard of care following treatment for early-stage colorectal cancer.

To read the full study, click [here](#).

Additional articles to learn more: [Article 1](#), [Article 2](#), [Article 3](#), [Article 4](#)

# Early Age Onset Cancer



## 35. Adolescents and Young Adults (AYA) and Early Age Onset Cancer (EAOC) Programs Across Canada (Apr 21/26)

Young adult and early age onset cancer programs play a critical role in ensuring that younger patients receive care that is tailored to their unique medical, emotional, and psychosocial needs. Individuals diagnosed with cancer under the age of 50 are often at different life stages than older adults, balancing careers, education, relationships, fertility planning, parenting young children, and financial responsibilities while navigating a cancer diagnosis and treatment.

As rates of early age onset cancers continues to rise, these programs help address gaps in care that may not be fully met within traditional oncology services. Programs focused on young adult and early age onset cancers provide multidisciplinary support that goes beyond treatment alone. These clinics bring together specialists such as oncologists, social workers, psychologists, genetic counsellors, and nurse navigators to provide coordinated, patient centred care that improves quality of life and overall patient outcomes.

Across Canada, specialized multidisciplinary programs are working to address gaps in care, improve access to tailored services, and enhance patient outcomes.

Below is a list of organizations and programs for the AYA and EAOC patient population:

Province	Organization	Age Group	Contact
	<u>Young Adult with <b>Colorectal Cancer</b> Clinic Sunnybrook Health Sciences Centre</u>	under 50	<b>Phone #:</b> 416-480-5000
Ontario	<u>University Health Network Princess Margaret Cancer Centre AYA Oncology Program</u>	39 or younger	<b>Program Coordinator:</b> Luxshiga Premakumar <b>Email:</b> aya@uhn.ca
	<u>London Health Sciences Centre AYA Oncology Program</u>	15-39	<b>Email:</b> ayaoncology@lhsc.on.ca
	<u>Southlake Health AYA Program</u>	18-43	<b>Email:</b> AYA@southlake.ca

Province	Organization	Age Group	Contact
Ontario	<u>William Osler Health System AYA Cancer Care Program</u>	18-39	<b>Phone #:</b> 905/416-494-2120
	<u>The Ottawa Hospital AYA Program</u>	15-39	<b>Email:</b> AYAProgram@toh.ca
Quebec	<u>Jackie Aziz AYA Program at Cedars Cancer Foundation</u>	18-39	<b>Email:</b> info@cedars.ca <b>Phone #:</b> 514-656-6662
	<u>Felix Program Quebec Cancer Foundation</u>	15-39	<b>Email:</b> cancerquebec.mtl@fqc.qc.ca <b>Phone #:</b> 514-527-2194
	<u>Jewish General Hospital AYA Oncology Program</u>	18-39	<b>Clinical Navigator:</b> Sherry Hogan <b>Phone #:</b> 514-340-8222 ext. 3460
	<u>Voboc Foundation</u>	15-39	<b>Email:</b> info@voboc.org <b>Phone #:</b> 514-695-9292
Alberta	<u>Alberta Health Services AYA Patient Navigator Program</u>	15-39	<b>Phone # (Edmonton):</b> 780-432-8932 <b>Phone # (Calgary):</b> 403-476-2791
British Columbia	<u>BC Cancer Childhood Adolescent and Young Adult Survivors Program</u>	0-39	<b>Program Lead:</b> Dr. Stuart Peacock <b>Admin Contact:</b> Lisa Scott <b>Phone #:</b> 604-675-8227
	<u>BC Cancer AYA Care and Support</u>	15-39	<b>Phone #:</b> 604-877-6000
	<u>Anew Research</u>	15-39	<b>Email:</b> hello@anewresearch.ca
Nova Scotia	<u>Nova Scotia Health Cancer Care Program</u>	15-39	<b>Phone #:</b> 1-844-491-5890
Manitoba	<u>CancerCare Manitoba Foundation</u>	15-39	<b>Phone #:</b> 204-787-4143

### **36. Diverging Global Incidence Trends of Early-Onset Cancers: Comparisons with Incidence Trends of Later-Onset Cancers and Mortality Trends of Early-Onset Cancers (Jan 15/26)**

**Study type:** Observational

**Study focus:**

This study examined whether the incidence trend of early age onset cancers (20-49 years) differs from that of later onset cancers ( $\geq 50$  years) and whether both the incidence and mortality of early onset cancers have increased concurrently.

**Key findings:**

- Early-onset cancer incidence increased in multiple cancer types across at least 10 countries between 2000 – 2017
- In several cancers, early onset incidence increased faster than later-onset incidence, particularly in high-HDI countries.
- Early-onset colorectal cancer showed consistent increases in both incidence and mortality in several high-income countries.
- Early-onset uterine cancer incidence and mortality increased in multiple countries.
- Rising obesity prevalence in younger populations was positively correlated with increasing early-onset incidence for several cancers.
- The study recommended strengthening primary prevention efforts (diet, lifestyle), implementing risk-based screening strategies, advancing genetic research, and developing early detection strategies tailored to younger populations.

**Why it matters:**

The study found that the incidence of many early age onset cancers is rising faster than later-onset cancers, with cancers such as colorectal cancer showing an increase in both incidence and mortality. Addressing risk factors and improving early detection could reduce preventable cases, improve survival, and lessen long-term health, social, and economic impacts.

To learn more, click [here](#).

### **37. An Environmental Scan of Services for Adolescents and Young Adults Diagnosed with Cancer Across Canadian Pediatric and Adult Tertiary Care Centres (Feb 7/26)**

**Study type:** Survey-based environmental scan

**Study focus:**

This study conducted a survey-based environmental scan of adolescent and young adults (AYA; 15-39 years) cancer services across Canadian pediatric and adult hospitals. They reported on program logistics, availability of specialized AYA services, staff training, collaboration between pediatric and adult centres, funding sources, and specific areas of care such as fertility, sexual health, palliative care, distress screening, fatigue management, and access to clinical trials

**Key findings:**

- Only about half of responding centres offered AYA specific services (54% pediatric; 47% adult), and approximately one third of centres without programs were actively developing them.
- Most AYA services were concentrated in Ontario, Alberta, and Manitoba, with little to no AYA-specific programming available in Atlantic Canada, Saskatchewan, or the Yukon.

- Compared with a similar 2011 scan, improvements were observed in oncofertility services, sexual health resources, palliative care (particularly in pediatric settings), and return-to-work/school supports.
- Only 5 of the centres offered specialized AYA training, and 11 centres employed dedicated AYA staff (e.g., clinical nurse specialists, navigators, program coordinators).
- Most AYA programs relied heavily on philanthropic donations, with fewer centres supported by stable provincial healthcare funding, raising concerns about long-term sustainability and equity.
- Centres reported barriers to clinical trial enrollment for AYAs such as difficulty identifying trials for rare cancers, limited availability of trials, and lack of time or awareness.
- AYA specific services commonly included support groups, patient navigation, individual counselling, caregiver supports, fertility resources and referral pathways, and sexual health resources.

**Why it matters:**

The study highlights the geographic and structural inequities in access to AYA-specific cancer services across Canada despite progress over the last decade. The findings emphasize the importance of a coordinated national AYA cancer strategy that includes standardized training, sustainable funding, improved collaboration across disciplines, and expanded access to psychosocial and clinical trial supports to address ongoing gaps.

To learn more, click [here](#).

### **38. Leading Cancer Deaths in People Younger Than 50 Years (Feb 7/26)**

**Study type:** Observational study

**Study focus:** This study analyzed long term trends (1990–2023) in cancer mortality among people younger than 50 years in the U.S. Using national death certificates, researchers assessed how mortality rates changed overtime, and which cancers now account for the greatest number of deaths.

**Key findings:**

- Overall cancer mortality in people under 50 declined by 44% from 1990–2023.
- Mortality decreased for all leading cancers except colorectal cancer.
- Colorectal cancer mortality increased by about 1.1% per year since 2005, making it the leading cause of cancer death in this age group by 2023.
- In contrast, lung cancer, breast cancer, leukemia, and brain cancer mortality all declined during the study period.
- CRC rose from fifth-leading cause of death in the early 1990s to the first overall in 2023.
- Most younger patients with CRC are diagnosed at advanced stages (about 3 in 4 cases).

**Why it matters:**

Rising CRC-related mortality suggests the need to understand causes, improve prevention, increase awareness of warning symptoms, and promote early screening to reduce advanced diagnoses and deaths.

To learn more, click [here](#).

### **39. The Role of the Gut Microbiome in Early Age Onset Cancer (May 5/26)**

Recent studies consistently show that early-onset colorectal cancer has a distinct gut microbiome profile, marked by enrichment of pro-carcinogenic bacteria (e.g., *Escherichia coli*, *Bacteroides fragilis*, *Fusobacterium nucleatum*) and loss of protective species. These microbes promote cancer through inflammation, immune modulation, and direct DNA damage, with stronger host-microbe interactions observed in younger patients. Evidence from hereditary cancer models further suggests that bacterial biofilms and toxin-producing species can initiate and accelerate early tumor development.

Clinically, the microbiome is emerging as both a biomarker for early detection and a modifier of treatment response, with beneficial bacteria linked to better therapy outcomes and harmful taxa associated with resistance. These findings support growing interest in microbiome-targeted strategies—including diet, probiotics, and fecal microbiota transplantation—as potential tools for prevention and treatment.

For further reading: [Article 1](#), [Article 2](#), [Article 3](#)

## 40. Precision in Practice: Costs and Benefits of Comprehensive Genomic Profiling for Five Stage 4 Cancers (Jan 15/26)

### Research focus:

The Colorectal Cancer Resource & Action Network (CCRAN), in partnership with The Conference Board of Canada, has released a new report entitled Precision in Practice: Exploring the Costs and Benefits of Comprehensive Genomic Profiling for Five Metastatic Cancers. This research examines how broader access to genomic testing can improve patient outcomes, enhance system efficiency, and unlock greater value across Canada's cancer care landscape.

### Purpose:

As Canada faces rising cancer rates, mounting system pressures, and growing interest in personalized care, this report provides timely insight into the costs and benefits of expanding access to comprehensive genomic profiling, helping leaders make informed decisions in a rapidly evolving landscape.

The potential costs and benefits of public funding was evaluated for universal comprehensive genomic profiling with next-generation sequencing (CGP-NGS) across Canada for 5 newly diagnosed stage 4 cancers (lung, colorectal, pancreas, breast and prostate) versus the current standard of care.

### Key findings:

- CGP-NGS could result in cost savings ranging from \$87 million to \$134 million for the healthcare system between 2025-2030, compared with the current standard of care.
- Savings are driven by reducing the cost of multiple tests and treatment delays.
- Targeted cancer treatments rather than diagnostic testing account for most costs. Testing contributes to just 0.3 to 4.1% of the overall cost per patient.
- For the five stage 4 cancer types considered, universal CGP-NGS could contribute to an additional 3440 life years gained and over \$180 million in economic benefits from 2025-2030.

### Key recommendations:

- Stronger real-world evidence on CGP-NGS application in Canada
- Funding alignment between genomic tests and their corresponding targeted therapies
- Transparent and effective clinician-patient dialogue
- Expansion of centralized testing infrastructure
- A collaborative national framework involving government, industry, clinicians, patients and advocates, and innovation partners

This new evidence will underpin the next steps of CCRAN's National Collective Biomarker Campaign.

### Why it matters:

As Canada faces rising cancer rates, mounting system pressures, and growing interest in personalized care, this report provides timely insight into the costs and benefits of

expanding access to comprehensive genomic profiling, helping leaders make informed decisions in a rapidly evolving landscape.

To learn more, click [here](#).

## 41. The Evolving Landscape of the Colorectal Cancer Vaccines: From Biological Mechanisms to Translational Therapeutics (Feb 19/26)

**Study type:** Literature Review

**Study focus:** This study focuses on therapeutic cancer vaccines for colorectal cancer, reviewing different vaccine types, target antigens and clinical trial evidence. It examines their safety, immunogenicity, challenges in development and potential use in combination therapies to improve treatment outcomes.

### Key findings:

- A synthetic long peptide (SLP) vaccine designed to target the cancer related protein p53 was safe and helped the immune system recognize cancer cells. It worked better when combined with IFN- $\alpha$  immune therapy.
- Vaccines targeting Melanoma-associated antigen (MAGE) can activate the immune system, but clinical benefits in CRC are limited.
- Peptide-based vaccines are highly specific to tumour targets and are cost effective. However, they have low immunogenicity, may not work for everyone, and require booster doses.
- mRNA vaccines induce strong T-cell responses, and show early clinical promise, especially with immune checkpoint inhibitors (ICIs) in MSI-H CRC.
- OncoVax, a vaccine made from the patients' own tumour cells, has been shown to be safe when used with chemotherapy. However, integrating OncoVax with surgical resection showed limited efficacy in early trials.
- GVAX, a vaccine made from non-patient tumour cells, has shown signs of stimulating anti-tumour immune responses in patients with advanced pMMR CRC.
- Dendritic cell vaccines effectively help the immune system recognize cancer cells and prolong disease-free survival.
- Vector-based vaccines lack efficacy due to clinical trial design issues, and with repeated doses, the immune system begins to destroy the delivery virus before it can work, meaning less of the vaccine is effective over time.
- Combination strategies (vaccines + ICIs, chemotherapy or agents targeting the tumour microenvironment) help overcome immune suppression and improve outcomes.
- Challenges include tumours that suppress the immune system, limited neoantigens in some tumours that make them harder to detect, reduced immune response in liver metastases, microbiome effects, tumour heterogeneity, and production/ storage costs of these vaccines.

### Why it matters:

These findings highlight that therapeutic cancer vaccines can safely induce antigen-specific immune responses in CRC patients, offering a potential strategy to target tumours that are otherwise resistant to immunotherapy. The findings indicate the potential of combination approaches (vaccines + ICIs, chemotherapy, or TME-modulating agents) to improve treatment outcomes.

To learn more, click [here](#).

**Screen it! Treat it! Beat it!**  
**Together, anything is possible!**