

COLORECTAL CANCER TREATMENT & CLINICAL RESEARCH UPDATES

Month Ending April 18th, 2024

The following colorectal cancer treatment and research updates extend from March 18th, 2024, to April 18th, 2024, 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 a medical condition. Never disregard the advice of a medical professional or delay in seeking it because of something you have read on this website.

CONTENT



- 1. TRK Fusion Cancer and How to Test for It
- 2. OH-CCO Biomarker Testing Program
- 3. Immunotherapy Combined with Targeted Therapy in Patients with BRAF V600E-Mutated CRC
- 4. Skincare Tips while on Cetuximab or Panitumumab Treatment for CRC
- 5. PERIOP-06 Study at Sunnybrook Hospital to Treat Liver Metastases
- 6. Now Available in Canada: AVENIO 324 Gene CGP Panel Matched to FoundationONE CDx Panel
- 7. AZUR-1 and AZUR-2 Dostarlimab Trials Open in Canada
- 8. A Study of Tucatinib with Trastuzumab and mFOLFOX6 Versus Standard of Care Treatment in First-Line HER2+ mCRC
- 9. CARMA BROS: CAnadian CAncers with Rare Molecular Alterations (CARMA) Basket Real-world Observational Study (BROS)
- 10. If it's a Target, it's a Pan-Cancer Target: Tissue is Not the Issue
- 11. Targeting KRAS G12C Mutation in CRC, A Review: New Arrows in the Quiver



- 12. Hepatic Artery Infusion Pump (HAIP) Chemotherapy Program Sunnybrook Hospital
- 13. Living Donor Liver Transplantation for Unresectable CRC Liver Metastases
- 14. In Vivo Lung Perfusion (IVLP) for CRC Metastatic to Lung



15. Study Offered at the Odette Cancer Centre to Treat Recurrent Rectal Cancer



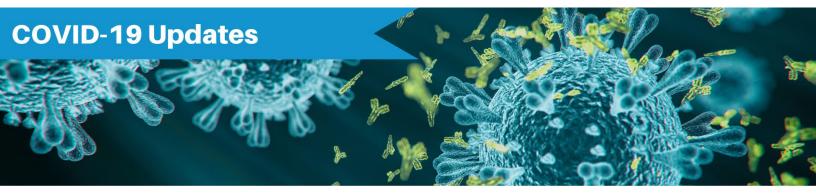
16. Trends in the Incidence of Young-Onset CRC with a Focus on Years Approaching Screening Age



- 17. Young Adult CRC Clinic Available at Sunnybrook Hospital
- 18. CCRAN's Partnership with "Count Me In"
- 19. CCRAN Has Launched 4 New Information/Support Groups Based on Age and Disease Stage
- 20. LifeLabs Launched Signatera, Offering Canadians an Innovative and Personalized Approach to Managing Cancer
- 21. Natera Announces Publication of Prospective, Multi-Site CIRCULATE Study in Nature Medicine Demonstrating Signatera's Ability to Predict Chemotherapy Benefit in CRC
- 22. The Childhood Cancer Identity Project (CCHIP): Examination of Cancer Identity and Wellbeing in Adult Survivors of Childhood Cancer
- 23. YACC's Recovery Study



24. EXercise for Cancer to Enhance Living Well (EXCEL) Study

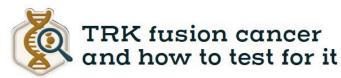


25. Frequently Asked Questions for COVID-19

Drug / Systemic Therapies

1. TRK Fusion Cancer and How to Test for It (Apr.13/24)





What is TRK fusion cancer?

- TRK (pronounced track) fusion cancer is a term used to describe cancers that are caused by a change to the neurotrophic tyrosine receptor kinase (NTRK) gene called a fusion
- During this fusion, an NTRK (pronounced en-track) gene joins together, or fuses, with a different gene
- This joining causes the body to make TRK fusion proteins, which can **cause cancer cells to multiply** and form a tumour
- ullet The presence of TRK fusion proteins may be associated with ullet more aggressive cancer



Having TRK fusion cancer doesn't change your original diagnosis, it just means that your **tumour is driven by an NTRK gene fusion**

Testing is the only way to find out if NTRK gene fusion is driving your cancer



Who should be tested for NTRK gene fusions?



Your doctor may consider testing in people:

- $\ensuremath{\bullet}$ with solid tumours that are metastatic, and
- who are likely to experience severe complications from surgical resection, and
- when there are no satisfactory treatments options available

It's important to know what's driving your cancer to help your doctor take action

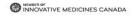


Fast TRK is a clinical testing program for diagnosing NTRK gene fusions

Sponsored by Bayer, this is a complimentary service for healthcare professionals to find out if their patients' cancer has an NTRK gene fusion

Talk to your doctor about which tests are recommended for you





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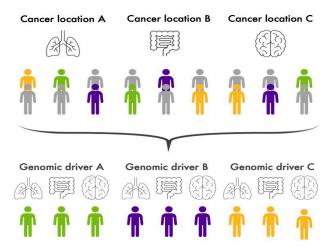
Tumour-Agnostic Therapies

Advances in precision medicine have brought therapies that specifically target what is driving a patient's cancer



Treatment with more traditional cancer therapies is based on where the tumour is located in the body

<u>Tumour agnostic</u> therapies target a specific genomic change in the cancer cells regardless of where the tumour is located in the body





Genomic changes in cancer cells are identified through diagnostic testing of the cancer cells.

The results help clinicians decide on a treatment for each patient.



Patients undergo a biopsy to obtain a sample for testing

Tissue is sent to lab to test for genomic changes

Results sent to clinician to help decide on treatment

Advantages of tumour agnostic therapies



Targets the genomic change that is the root cause of the cancer to suppress tumour growth



Harnesses our growing understanding of cancer biology



Offers an innovative, new and effective approach to treating cancer

Change required to adopt tumour agnostic therapies in Canada



A shift in mindset: this is a new concept that differs from the traditional approach of treating cancer based on tumour location



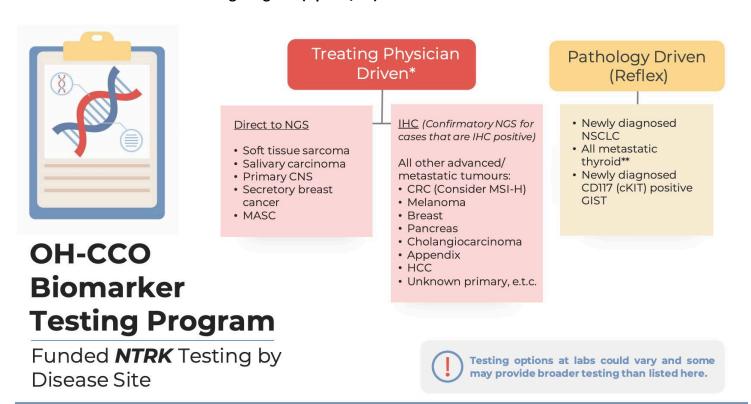
Access to genomic testing: Identifying patients who would benefit from treatments requires a robust testing infrastructure



An evolved, more adaptive assessment of treatments for public coverage is required that includes recognition of smaller patient populations, new clinical trial methods, and ability to examine new data over time

MAC-VIT-CA-0007-1

2. OH-CCO Biomarker Testing Program (Apr.11/24)



Based on <u>Ontario Health Cancer Care Ontario Comprehensive Biomarker</u> <u>Testing Program</u>. As of October 1, 2023, V2324.2.

*Must be ordered by physicians including, but not limited to, medical oncologists **Including sporadic medullary and RAI-refractory well differentiated OH, Ontario Health; CCO, Cancer Care Ontario; NTRK, neurotrophic tyrosine receptor kinase; NGS, next generation sequencing; IHC, immunohistochemistry; NSCLC, nonsmall-cell lung carcinoma; GIST, gastrointestinal stromal tumour; CNS, central nervous system; MASC, mammary analogue secretory carcinoma; CRC, colorectal cancer; MSI-H, high microsatellite instability; HCC, hepatocellular carcinoma; RAI, radioactive iodine.

List of Sites for the program (NTRK on pg.19)



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3. Immunotherapy Combined with Targeted Therapy in Patients with BRAF V600E–Mutated CRC (Apr.15/24)

In one of the first clinical trials combining immunotherapy and targeted therapy for patients with BRAF V600E—mutated colorectal cancer (CRC), researchers discovered that a combination regimen of **dabrafenib**, **trametinib**, and **spartalizumab** resulted in long-lasting responses. The study successfully met its primary endpoint and achieved a confirmed response rate of 24.3%, compared with a response rate of 7% in a prior trial where patients were treated with each of the same targeted therapies individually. The researchers also reported improved outcomes in one of the trial's secondary endpoints: durability. Previously, patients with BRAF V600E—mutated CRC have seen only a short-lived clinical benefit after treatment with BRAF or MEK inhibitors. But the combination therapy resulted in an increased durability of response, with a median progression-free survival of <u>5 months</u> compared with <u>3.5 months</u> with BRAF or MEK inhibitors alone. The researchers noted that 57% of the patients continued with the treatment for more than 6 months and 18% continued for more than 1 year.

The findings suggested how targeted therapies in combination with immunotherapies may drive a greater immune response and improve treatment overall. This merits further clinical investigation and preclinical experiments to determine the best targeted approach to increase immune reactivity against [BRAF-mutated] CRC. The researchers acknowledged that the implications of their research may go well beyond CRC.

 $\underline{https://ascopost.com/news/january-2023/immunotherapy-combined-with-targeted-therapy-in-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer/linear-patients-with-braf-v600e-mutated-colorectal-cancer-patients-with-braf-v600e-mutated-color-patients-with-braf-v6$

4. Skincare Tips while on Cetuximab or Panitumumab Treatment for CRC (Mar.28/24)

Amgen has collaborated with FUSE Health and Dr. Nathan Lamond (Medical Oncologist, Dalhousie University) to produce a 5-minute video on the importance of good skin hygiene for patients on EGFRi therapy. During this talk, Dr. Lamond discusses the importance of good skin care to help prevent or lessen skin side effects caused by certain cancer treatments such as cetuximab and panitumumab used to treat colorectal cancer (CRC). Dr. Lamond provides tips for protecting the skin and using appropriate soaps, cleansers, moisturizers, sunscreens, and lip balms.

To view the video:

https://www.youtube.com/watch?v=y2KuGAEK8Mc

5. PERIOP-06 Study at Sunnybrook Hospital to Treat Liver Metastases (Mar.30/24)

We are inviting you to take part in a voluntary research study | PERIOP-06

Why are we doing this study?

The purpose of the PERIOP-06 clinical trial is to see how effective a new medication is. This new medication is called QBECO and is made by a Canadian company called Qu Biologics. We want to see if QBECO can prevent or slow colorectal cancer from coming back in patients who have had surgery to remove cancer that has spread to the liver. To do this, you will be randomly assigned to receive either QBECO or a placebo (a drug that looks like the study drug but contains no medication) so we can compare QBECO to the usual care. Both you and your study doctor will not know if you are receiving the study drug or placebo.

What are the possible benefits of taking part in this study?

- The QBECO medication may benefit you more than the usual care for vour cancer.
- There is evidence that QBECO may be effective in preventing the growth of colorectal cancer in humans from a previous Phase I clinical trial.
- The information learned from this study might help other patients in the future.
- You will have close follow ups for 5 years after surgery.

What are the possible disadvantages & risks of taking part in this study?

- QBECO may not benefit you more than the usual care for your cancer.
- You may experience side effects from the QBECO medication.
- You can find more information below and in Section 13: "What risks can I expect from taking part in this study?" of the informed consent document.

Do I have to take part in this study?

Your participation is voluntary. You may choose not to participate. If you choose to participate, you may change your mind at any time. Regardless of your choice, your medical team will continue to take care of you.

Common Side Effects of QBECO

In 100 people receiving QBECO more than 5 and up to 15 may have the following side effects:

- Tenderness at the injection site. This typically gets better in 2 days. If the redness or swelling is bigger than 7 cm, please contact a member of the study team.
- Temporary mild fatigue following the first few doses of QBECO
- Temporary nausea
- Temporary fever
- Temporary headache
- Increased General Inflammation

Additional Drug Risks

QBECO is not known to interact with other drugs.

Rare And Serious Side Effects of QBECO

In 100 people receiving QBECO, 3 or fewer may have:

- **Pancreatitis**
 - Symptoms include: Abdominal or back pain, nausea, vomiting
- Hepatitis [inflammation of the liver]
- Electrolyte abnormalities [determined with lab test]
- Kidney failure

These serious side effects have only been reported in patients who were given QBECO to treat Crohn's disease and ulcerative colitis. No serious side effects were reported in 109 patients who received QBECO for advanced cancer.

What should I do if I am experiencing symptoms?

If you are experiencing these or any symptoms that you think are related to the study treatment, you should contact your cancer surgeon or the study coordinator to discuss. If the symptoms are serious and require emergency medical attention, then you should present to the emergency room and inform the medical team that you are participating in this study.

Visual Summary of Trial Activities

Day Relative to Surgery		Details	Trial Activities				
			Blood Sample	QBECO Therapy or Placebo	MRI/CT scan	Other Assessments	Notes
Eligibility Screening	#	The research team will confirm eligibility. Routine bloodwork will be done.			•	Survey and pregnancy test (if appropriate)	
-11 to -1 days		You will give yourself a subcutaneous injection (QBECO therapy or placebo) every 2 days before surgery for at least 11 days.		Jacob			If your surgery is delayed, you can take QBECO (or placebo) up to 120 days before surgery
Day of Surgery		You will have your surgery following the usual care procedures. Additionally, a sample of tumor tissue will be collected.	S			Compliance and side effect assessment	The compliance and side effect assessment may be collected over the phone the day before the surgery
+1 and +4 (±1) Day(s)		You will be monitored in the hospital following your surgery. QBECO or placebo will be taken every 2 days.	<u>\$</u>	SCH		Survey on day 4 (±1) only	
+7 to 41 Days	3	You will continue to give yourself a subcutaneous injection of QBECO therapy or placebo every 2 days after your surgery for 41 days.		ACCEN			
+6 (±10 d) weeks	斷	Once your injections are complete, you will have a follow-up appointment.	S			Survey and side effect assessment	
+3, 6, 9, 12, 15, 18, 21, and 24 Months	# "	To check for the progression of cancer, imaging and blood samples will be done every three months for 2 years after surgery.			•	Compliance and side effect assessment will be at 3 months only	There will be a range of ± 14 days for your 3 month visit and a range of ± 28 days for all remaining visits
+2.5 to 5 Years	#	To check for the progression of cancer, imaging and a blood sample will be done every 6 months until 5 years after your surgery.			•		There will be a range of ± 28 days for all visits
Legend:		Approximately half-day hospital visit	1	Overnight ho	spital visit	At your ho	ouse



Here is a link to the consent form, containing additional information about the study:



6. Now Available in Canada: AVENIO 324 Gene CGP Panel Matched to FoundationONE CDx Panel (Apr.1/24)

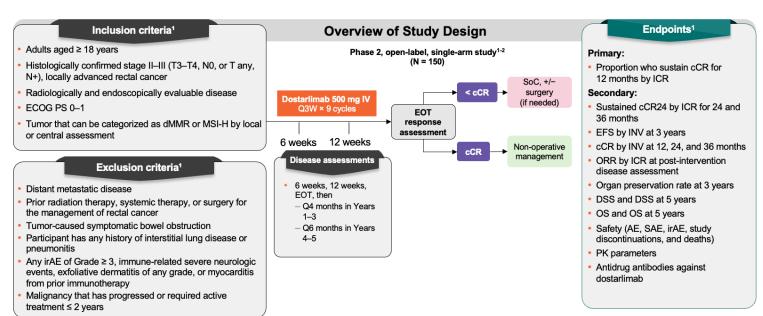


For more information, please visit the OncoHelix website.

7. AZUR-1 and AZUR-2 Dostarlimab Trials Open in Canada (Apr.13/24)

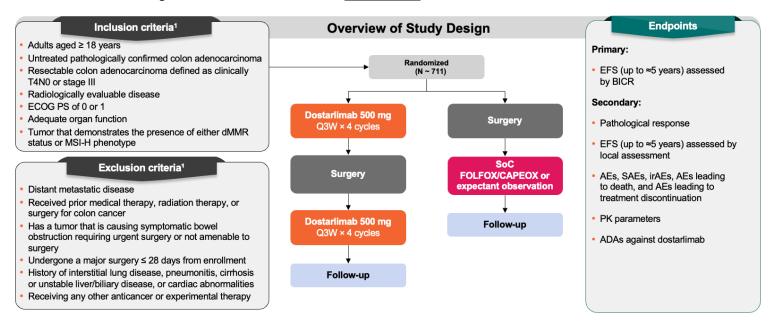
Dostarlimab is an IgG 4 isotype humanized monoclonal antibody meaning it is made in a lab to serve as substitute antibodies that can restore, enhance, modify or mimic the immune system's attack on unwanted cells. In this case, dostarlimab blocks the interaction of PD-1 to its ligands PD-L1 and PD-L2 found on tumor cells. By blocking PD-1 activity, dostarlimab activates T cells allowing them to attack cancer cells by detecting and killing them. Dostarlimab has been approved for adult patients with mismatch repair-deficient (MMR-D) recurrent or advanced endometrial cancer (EC) in the US, and for MMR-D/microsatellite instability-high (MSI-H) recurrent or advanced EC in the EU. The drug is being investigated in multiple tumor types and in combination with other anticancer agents.

AZUR-1: Phase 2 StudyA single-arm, open label study of dostarlimab monotherapy in participants with untreated stage 2/3 MMR-D/MSI-H locally advanced <u>rectal cancer</u>.



AZUR-2: Phase 3 Study

An open-label, randomized study of peri-operative dostarlimab monotherapy vs standard of care in participants with untreated T4NO or stage 3 MMR-D/MSI-H resectable <u>colon cancer</u>.



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

https://www.gsk.com/en-gb/media/press-releases/european-commission-approves-gsk-s-jemperli-dostarlimab-the-first-anti-pd-1-therapy-approved-for-recurrent-or-advanced-endometrial-cancer/

8. A Study of Tucatinib with Trastuzumab and mFOLFOX6 Versus Standard of Care Treatment in First-line HER2+ mCRC (Mar.23/24)

This phase 3 **Mountaineer** study is being done to find out if tucatinib with other cancer drugs works better than standard of care to treat participants with HER2 positive colorectal cancer (CRC). This study will also test what side effects happen when participants take this combination of drugs.

Participants in this study have CRC that has spread through the body (metastatic) and/or cannot be removed with surgery (unresectable). Participants will be assigned randomly to the tucatinib group or standard of care group. The tucatinib group will get tucatinib, trastuzumab, and mFOLFOX6. The standard of care group will get either:

- mFOLFOX6 alone,
- mFOLFOX6 with bevacizumab, or
- mFOLFOX6 with cetuximab mFOLFOX6 is a combination of multiple drugs. All the drugs given in this study are used to treat this type of cancer.

The primary outcome measure is progression-free survival (PFS). Some of the secondary outcome measures include overall survival (OS), confirmed objective response rate (cORR), duration of response (DOR). The estimated primary completion date is August 31, 2025. To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor within the link below.

https://classic.clinicaltrials.gov/ct2/show/study/NCT05253651?term=MOUNTAINEER-03&draw=2&rank=1

CARMA BROS: CAnadian CAncers with Rare Molecular Alterations (CARMA) - Basket Real-world Observational Study (BROS) (Apr.12/24)

This study will collect data on Canadian cancer patients that have uncommon/rare changes in their tumors, such as alterations/rearrangements in the genetic material inside cells - known as deoxyribonucleic acid, or DNA, which acts as a map and gives directions to the cells on how to make other substances the body needs - because some of these changes have been found to respond to different drugs that help to stop the cancer. These rare changes occur in genes such as but not limited to ALK, EGFR, ROS1, BRAF, and NTRK which have targeted drugs in a family known as tyrosine kinase inhibitors (TKIs), and KRAS G12C mutation, which now has a targeted inhibitor drug therapy for patients with non small cell lung cancer (NSCLC). The goals for the study are to compare the natural history of such cancers and the treatment outcomes, including toxicities and patient-reported outcomes, for the different therapies.

Primary outcome measures include composite of progression free survival (PFS) or overall survival (OS). The secondary outcome measures include brain metastasis/other metastatic tumours, EORTC quality of life questionnaires (QLQ) - cancer patient-reported health related quality of life, EQ-5D-5L - patient-reported health related quality of life measure, and patient-reported economic impact. The estimated primary completion date is December 2025. To learn

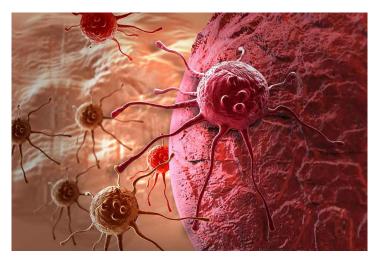
more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor within the link below.

https://classic.clinicaltrials.gov/ct2/show/study/NCT04151342?term=CARMA+BROS&draw=2&rank=1

10. If it's a Target, it's a Pan-Cancer Target: Tissue is Not the Issue (Mar.21/24)

Cancer is traditionally diagnosed and treated on the basis of its organ of origin (e.g., lung or colon cancer). However, this does not reveal the underlying oncogenic drivers. Understanding tumor drivers requires molecular technology, which has advanced at a remarkable rate, and it has become increasingly apparent that cancer is a disease of the genome. As a result, there are now multiple tissue-agnostic Food and Drug Administration (FDA) approvals for patients with cancer (larotrectinib/entrectinib, for NTRK fusions; selpercatinib, RET fusions; dabrafenib plus trametinib, BRAFV600E mutations; pembrolizumab/dostarlimab, microsatellite instability; and pembrolizumab for high tumor mutational burden; pemigatinib is also approved for FGFR1- rearranged myeloid/lymphoid neoplasms). Tissue-agnostic approvals imply that the organ of origin is not considered pertinent for the FDA approval. In other words, a treatment is approved for its ability to target a specific molecular abnormality, and all patients with that abnormality, regardless of the organ of origin of their tumor, can receive that treatment. These approvals have been enabled by the advent of molecular genomic testing and, more recently, clinical-grade next-generation sequencing (NGS), which can simultaneously probe tumors for thousands of possible abnormalities in any one of hundreds of cancer-causing genes.

In addition to established tissue-agnostic approvals, multiple new gene anomalies are emerging as potential tissue-agnostic targets. These include but are not limited to, ALK, BRCA, ERBB2 (HER2), IDH1/2, KIT, and KRAS G12C, NRG, and Von Hippel-Lindau (VHL) as well as homologous repair deficiency (HRD). They can be effectively targeted by several types of medications: antibodies, antibody-drug conjugates and small molecule inhibitors. Each of these genes, when aberrant, can be impacted by one or more medications, and there are already approvals in distinct cancers bearing the related biomarker and/or robust clinical evidence for activity in diverse cancer types. Many tissue-agnostic approvals center on rare/ultra-



rare biomarkers (often < 1 % of cancers), necessitating screening hundreds of tumors to find a single one harboring the cognate molecular alteration. Approval has generally been based on small single-arm studies (<30-100 patients) with high response rates (>30 % to >75 %) of remarkable durability. Because of biomarker rarity, single-gene testing is not practical; next generation sequencing of hundreds of genes must be performed to obtain timely answers.

Resistance to biomarker-driven therapeutics is often due to secondary mutations or co-driver gene defects, thus studies are now addressing the need for customized drug combinations matched to the complex molecular alteration portfolio in each tumor. Future investigation should expand tissue-agnostic therapeutics to encompass both hematologic and solid malignancies and include biomarkers beyond those that are DNA-based. Finally, a large body of evidence now suggests that validated molecular biomarkers are pharmacologically tractable across cancers – it it's a target, it's a pan-cancer target.

https://www.cancertreatmentreviews.com/article/S0305-7372(24)00048-3/fulltext#secst060
Image Source: https://www.enzolifesciences.com/science-center/technotes/2022/april/targeting-biomarkers-for-tissue-agnostic-therapies-for-cancertreatment/

11. Targeting KRAS G12C Mutation in CRC, A Review: New Arrows in the Quiver (Mar.14/24)

Kirsten rat sarcoma virus oncogene homolog (KRAS) is the most frequently mutated oncogene in human cancer. In colorectal cancer (CRC), KRAS mutations are present in more than 50% of cases, and the KRAS glycine-to-cysteine mutation at codon 12 (KRAS G12C) occurs in up to 4% of patients. This mutation is associated with short responses to standard chemotherapy and worse overall survival compared to non-G12C mutations.

In recent years, several *KRAS* G12C inhibitors, including adagrasib, sotorasib, and divarasib among others, have been developed as monotherapy or in combination with anti-EGFR agents, demonstrating meaningful clinical activity, although all patients eventually progressed. The identification of negative feedback through the EGFR receptor has led to the development of KRAS inhibitors plus an anti-EGFR combination, thus boosting antitumor activity. Currently, several KRAS G12C inhibitors are under development, and results from phase I and phase II clinical trials are promising.

Moreover, the phase III CodeBreaK 300 trial demonstrates the superiority of sotorasib-panitumumab over trifluridine/tipiracil, **establishing a new standard of care for patients with CRC** harboring *KRAS* G12C mutations. Other combinations such as adagrasib-cetuximab, divarasib-cetuximab, or FOLFIRI-panitumumab-sotorasib have also shown a meaningful response rate and are currently under evaluation. However, data from these trials, despite being promising,

need to be carefully interpreted as they come from small, non-randomized phase I and phase II clinical trials. However, it could be expected that the combination of these new KRAS inhibitors plus anti-EGFR may improve the patients' clinical outcomes significantly.

Nonetheless, most of these patients will eventually relapse. In this regard, liquid biopsy has been demonstrated to be a reliable tool in CRC to monitor response, to forecast prognosis, and to identify genomic mechanisms of resistance. This consists mainly of acquired genomic alterations in the MAPK and PI3K pathways and tyrosine kinase receptor alterations, but gene fusions, histological changes, or conformational changes in the kinase have also been described. There are new arrows in the quiver for *KRAS*-mutated CRC.

https://www.mdpi.com/1422-0067/25/6/3304

Surgical Therapies

12. Hepatic Artery Infusion Pump (HAIP) Chemotherapy Program – Sunnybrook Odette Cancer Centre (Apr.1/24)

The HAIP 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. The program involves a coordinated, multidisciplinary team approach to care, with close collaboration across surgical oncology, medical oncology (chemotherapy), interventional radiology, nuclear medicine, and oncology nursing. The Hepatic Artery Infusion Pump (HAIP) is a small, disc-shaped device that is surgically implanted just below the skin of the patient and is connected via a catheter to the hepatic (main) artery of the liver. About 95 percent of the chemotherapy that is directed through this pump stays in the liver, sparing the rest of the body from side effects. Patients receive HAIP-directed chemotherapy in addition to regular intravenous (IV) chemotherapy (systemic chemotherapy), to reduce the number and size of tumours. **Drs. Paul Karanicolas and Michael Raphael** are the program leads and happy to see patients who may be eligible for the therapy.





Presently at Sunnybrook Odette Cancer Centre, HAIP is being used in patients with colorectal cancer that has spread to the liver that cannot be removed surgically and has not spread to anywhere else in the body. Patients who have few (1-5) and very small tumors in the lungs may be considered if the lung disease is deemed treatable prior to HAIP. 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**. For more information on the HAIP clinical trial, please click on the link provided below.

http://sunnybrook.ca/content/?page=colorectal-colon-bowel-haip-chemotherapy

13. Living Donor Liver Transplantation for Unresectable CRC Liver Metastases (Apr.2/24)

Approximately half of all colorectal cancer (CRC) patients develop metastases, commonly to the liver and lung. Surgical removal of liver metastases (LM) is the only treatment option, though only 20-40% of patients are candidates for surgical therapy. Surgical therapy adds a significant survival benefit, with 5-year survival after liver resection for LM of 40-50%, compared to 10-20% 5-year survival for chemotherapy alone. Liver transplantation (LT) would remove all evident disease in cases where the colorectal metastases are isolated to the liver but considered unresectable.



Image Source: https://www.slideshare.net/AhmedAdel65/preoperative

While CRC LM is considered a contraindication for LT at most cancer centers, a single center in Oslo, Norway demonstrated a 5-year survival of 56%. A clinical trial sponsored by the University Health Network in Toronto will offer live donor liver transplantation (LDLT) to select patients with unresectable metastases limited to the liver and are non-progressing on standard chemotherapy. Patients will be screened for liver transplant suitability and must also have a healthy living donor come forward for evaluation. Patients who undergo LDLT will be followed for survival, disease-free survival, and quality of life for 5 years and compared to a control group who discontinue the study before transplantation due to reasons other than cancer progression.

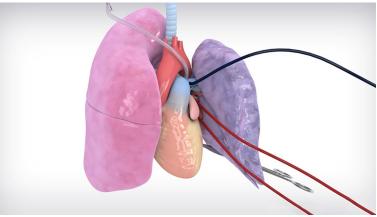
https://clinicaltrials.gov/ct2/show/NCT02864485

14. In Vivo Lung Perfusion (IVLP) for CRC Metastatic to Lung (Apr.9/24)

A new study is investigating a technique called In Vivo Lung Perfusion (IVLP) for delivering chemotherapy directly into the lungs at the time of surgery. Delivering chemotherapy directly to the lungs could potentially kill any microscopic cancer cells that are present in the lungs at the time of surgery, while sparing other major organs in the body from the side effects of chemotherapy.

At the University Health Network, this IVLP technique has been used recently in a Phase I study in patients with sarcoma, and they are now expanding on that experience to include patients with colorectal metastases. 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 are watched very closely to see what side effects they have and to make sure the side effects are not severe. If the side effects are not severe, then more participants are asked to join the study and are given a higher dose of oxaliplatin. Participants joining the study later on will get higher doses of oxaliplatin than participants who join earlier. This will continue until a dose is found that causes severe but temporary 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.

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



In Vivo Lung Perfusion Model

https://clinicaltrials.gov/ct2/show/NCT05611034?term=ivlp&draw=2&rank=1 Image Source: https://pie.med.utoronto.ca/TVASurg/project/in-vivo-lung-perfusion/

Radiation Therapies / Interventional Radiation

15. Study Offered at the Odette Cancer Centre to Treat Recurrent Rectal Cancer (Apr.9/24)

Magnetic resonance-guided focused ultrasound (MRg-FU) is a less invasive; outpatient modality being investigated for the thermal treatment of cancer. In MRg-FU, a specially designed transducer is used to focus a beam of low-

intensity ultrasound energy into a small volume at a specific target site in the body. MR is used to identify and delineate the tumour, focus the ultrasound beam on the target, and provide a real--time thermal mapping to ensure accurate heating of the designated target with minimal affect to the adjacent healthy tissue. The focused ultrasound beam produces therapeutic hyperthermia (40-42°C) in the target field, causing protein denaturation and cell damage. Currently, there is no prospective clinical data reported on the use of MRg-FU in the setting of recurrent rectal cancer. Recurrent rectal cancer is a vexing clinical problem. Current retreatment protocols have limited efficacy. The addition of hyperthermia to radiation and chemotherapy may enhance the therapeutic response. With recent advances in technology, the investigators hypothesize that MRg-FU is technically feasible and can be safely used in combination with concurrent re-irradiation and chemotherapy for the treatment of recurrent rectal cancer without increased side-effects. The study is being offered at the Odette Cancer Centre. Here is the link to the study protocol:



Screening

16. Trends in the Incidence of Young-Onset CRC with a Focus on Years Approaching Screening Age (Apr.10/24)

With recent evidence for the increasing risk of **young-onset colorectal cancer (yCRC)**, the objective of this population-based longitudinal study was to evaluate the incidence of yCRC in one-year age increments, particularly focusing on the screening age of 50 years. The study was conducted using linked administrative health databases in British Columbia, Canada including a provincial cancer registry, inpatient/outpatient visits, and vital statistics from January 1, 1986 to December 31, 2016. Researchers calculated the incidence rates per 100,000 at every age from 20 to 60 years and estimated annual percent change in incidence (APCi) of yCRC using joinpoint regression analysis. 3,614 individuals were identified with yCRC (49.9% women). The incidence of CRC steadily rose from 20 to 60 years, with a marked increase from 49 to 50 years. Furthermore, there was a trend of increased incidence of yCRC among women. Analyses stratified by age yielded APCi's of 2.49% and 0.12% for women aged 30-39 years and 40-49 years, respectively and 2.97% and 1.86% for men. These findings indicate a steady increase over one-year age increments in the risk of yCRC during the years approaching and beyond screening age. These findings highlight the need to raise awareness as well as continue discussions regarding considerations of lowering the screening age.

 $\underline{https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djaa220/6119347? quest Access Key=af490637-e51e-44d0-81b9-d1f2df7b60c9af40ces Access Key=af490637-e51e-44d0-81b9-d1f2df7b60ces Access Key=af490660ces Access Key=af49060ces Access Key=af49060ces Access Key=af49060ces Access Key=af49060ces Access Key=af49060ces Access Key=af49060ces Access K$

Other

17. Young Adult CRC Clinic Available at Sunnybrook (Apr.5/24)

A recent study led by the University of Toronto doctors has observed a rise in colorectal cancer (CRC) rates in patients under the age of 50. The study mirrors findings from the U.S., Australia and Europe. The growing CRC rates in young people come after decades of declining rates in people over 50, which have occurred most likely due to increased use of CRC screening (through population-based screening programs) which can identify and remove precancerous polyps. Patients diagnosed under the age of 50 have a unique set of needs, challenges and worries. They are unlike those diagnosed over the age of 50. Dr. Shady Ashamalla (colorectal cancer surgical oncologist), along with Dr. Petra Wildgoose (Hepatobiliary and Colorectal Oncology Surgical Assistant), and their team at the Sunnybrook Health Sciences Centre understand the needs of this patient population.



Dr. Shady Ashamalla, Head Young Adult Colorectal Cancer Program



Dr. Petra Wildgoose, Lead Young Adult Colorectal Cancer Program

Both belong to a multidisciplinary team of experts in the **Young Adult Colorectal Cancer Clinic** who work with young CRC patients, regardless of disease stage, to create an individualized treatment plan to support each patient through their cancer journey. Patients' needs and concerns will be addressed as they relate to:

- Fertility concerns and issues
- Young children at home
- Dating/intimacy issues
- Challenges at work
- Concerns about hereditary cancer
- Relationships with family and friends
- Psychological stress due to any or all of the above

The team of experts consists of:

- Oncologists (medical, surgical, radiation)
- Social workers
- Psychologists
- Geneticists
- Nurse navigator

Should a patient wish to be referred to Sunnybrook, they may have their primary care physician, or their specialist refer them to Sunnybrook via the e-referral form, which can be accessed through the link appearing below. Once the referral is received, the Young Adult Colorectal Cancer Clinic will be notified if the patient is under the age of 50. An appointment will then be issued wherein the patient will meet with various members of the team to address their specific set of concerns.

http://sunnybrook.ca/content/?page=young-adult-colorectal-cancer-clinic

18. CCRAN's Partnership with "Count Me In" (Apr.1/24)

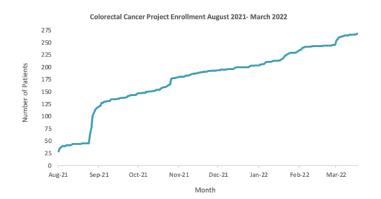
CCRAN is proud to partner with Count Me In, a nonprofit research initiative, on The Colorectal Cancer Project. This new project is open to anyone in the United States or Canada who has ever been diagnosed with colorectal cancer (CRC). Patients can find out more and join at <u>JoinCountMeIn.org/Colorectal</u>.

Through the project, patients are asked to complete surveys to share information about their experience with CRC, to share biological sample(s), and to allow for the research team to request copies of their medical records. The project team then de-identifies and shares data from these with the entire research community.

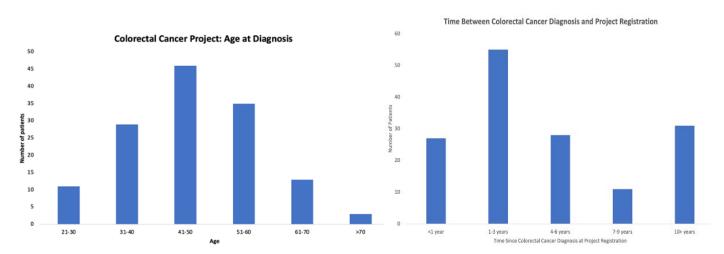
Every patient's story holds a piece of the puzzle that can help us better understand CRC. By discovering more about what drives cancer and sharing this data, CCRAN and the Colorectal Cancer Project believe insights can be gained to develop more effective therapies. One of the aims of the project is to reach populations that have been understudied, including individuals who are diagnosed with CRC at a young age, individuals from marginalized communities who have historically been excluded from research, and patients with metastatic CRC. Together, we can accelerate our understanding of CRC. To learn more or sign up to participate, visit JoinCountMeIn.org/Colorectal.

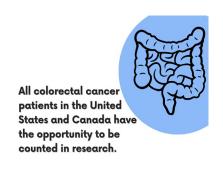


"Count Me In", a nonprofit cancer research initiative, is inviting all patients across the United States and Canada who have ever been diagnosed with colorectal cancer (CRC) to participate in research and help drive new discoveries related to this disease. The Colorectal Cancer Project will enable patients to easily share their samples, health information and personal lived experiences directly with researchers in order to accelerate the pace of research. Patients who have been diagnosed with CRC at any point in their lives can join the project by visiting JoinCountMeIn.org/colorectal. From there, patients will be invited to share information about their experience through surveys and to provide access to medical records as well as saliva samples and optional blood, stool, and/or stored tissue samples for study and analysis. Researchers from the Broad Institute of MIT and Harvard and Dana-Farber Cancer Institute use this information to generate databases of clinical, genomic, molecular, and patientreported data that is then de-identified and shared with researchers everywhere. To date, more than 9,000 patients with different cancers have joined Count Me In and shared their data. "We still do not know why there is an alarming rise in CRC in young adults", said Andrea Cercek, MD Co-Director, Center for Young Onset Colorectal and Gastrointestinal Cancers Memorial Sloan Kettering Cancer Center and co-scientific leader of the Colorectal Cancer Project. "What we do know is that this is a global phenomenon that affects otherwise healthy individuals with no known risk factors. The Colorectal Cancer Project will provide researchers important information that will lead to a better understanding of this disease."



Over 250 patients have joined the Colorectal Cancer Project since the launch in fall 2021. Every patient that joins the Colorectal Cancer Project enables us to learn more about colorectal cancer. Pts diagnosed at any age, whether newly diagnosed or years from their diagnosis, can enroll. If you have ever been diagnosed with colorectal cancer, you can visit <u>JoinCountMeln.org/Colorectal</u> to enroll and have a direct impact on research and future treatment strategies.





JoinCountMeln.org/Colorectal

Every colorectal cancer patient's story holds a piece of the puzzle that can help us better understand how to treat this disease. Join our partners at @joincountmein to help generate more data for CRC by sharing your medical records, samples, and unique experiences with researchers everywhere.

Learn more at <u>JoinCountMeIn.org/colorectal</u>

https://www.news-medical.net/news/20210914/Colorectal-Cancer-Project-launches-to-improve-understanding-of-the-disease-and-accelerate-research.aspx https://www.medicalnewstoday.com/articles/antibiotic-use-linked-to-increased-risk-of-colorectal-cancer#Use-of-antibiotics-and-an-increased-risk-of-cancer#Use-of-antibiotics-and-an-increased-risk-of-cancer#Use-of-antibiotics-and-an-increased-risk-of-cancer#Use-of-antibiotics-and-an-increased-risk-of-antibiotics-and-an-increased-risk-of-antibiotics-and-an-increased-risk-of-antibiotics-and-an-increased-risk-of-antibiotics-and-an-increased-risk-of-antibiotics-and-an-increa

19. CCRAN Has Launched 4 New Information/Support Groups Based On Age and Disease Stage (Apr.2/24)

CCRAN is pleased to announce a **new format** for monthly information / support group meetings. To ensure peer support is **relevant**, **meaningful and timely** for each participant, CCRAN has stratified the groups according to disease stage and early vs average onset colorectal cancer.

Meetings will begin with a brief presentation on a topic of relevance. Following the presentation, patients and caregivers will be assigned to the support group of relevance to them. Please RSVP to **Cassandra**Macaulay: Cassandra.m@ccran.org. We look forward to hosting you at our monthly information/support group meetings.

20. LifeLabs Has Launched Signatera, Offering Canadians an Innovative and Personalized Approach to Managing Cancer (Apr.1/24)

LifeLabs is pleased to share the launch of Signatera, a highly sensitive, personalized molecular residual disease (MRD) assay developed by Natera for treatment monitoring and molecular residual disease assessment in patients previously diagnosed with cancer. This innovative test uses circulating tumor DNA (ctDNA) and is personalized for each patient to help assess recurrence risk and identify relapse up to two years earlier than the current standard of care tools. The clinical utility of Signatera across cancer types has been validated by multiple studies. In those trials, Signatera demonstrated predictive values such as:



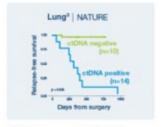
88% sensitivity to relapse

Average lead time 8.7 mos



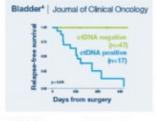
89% sensitivity to relapse

Average lead time 9.5 mos



92% sensitivity to relapse

Average lead time 4.0 mos



100% sensitivity to relapse

Average lead time 2.8 mos

Signatera testing involves two phases with pre-supplied collection kits. The first phase is an initial test that analyzes both a tumour tissue and blood sample, and the second phase involves subsequent blood tests on an as-needed basis. It is a safe, non-invasive way to monitor ctDNA levels to help physicians understand treatment efficacy and detect relapse without the inconvenience of repeated tissue biopsies and/or imaging.

 $\underline{https://www.life labs.com/life labs-launches-signater a-offering-canadians-an-innovative-and-personalized-approach-to-managing-cancer/$

21. Natera Announces Publication of Prospective, Multi-Site CIRCULATE Study in Nature Medicine Demonstrating Signatera's Ability to Predict Chemotherapy Benefit in CRC (Apr.17/24)

Natera, Inc., a global leader in cell-free DNA testing, announced the publication of a new study in *Nature Medicine*, which demonstrates the ability of the Signatera molecular residual disease (MRD) test to identify patients with stage II-IV colorectal cancer (CRC) who are at an increased risk of recurrence and predict who is likely to benefit from adjuvant chemotherapy (ACT).

The paper describes results from the GALAXY arm of the ongoing CIRCULATE-Japan trial, which is one of the largest and most comprehensive prospective studies of MRD testing in resectable CRC. The data builds on results previously presented at the 2022 ASCO Gastrointestinal Cancers Symposium (ASCO GI), now with median clinical follow-up extended to 16.74 months and DFS assessment at 18 months.

In the study, 1,039 patients with stage II-IV resectable CRC were monitored prospectively using the Signatera MRD test. Key takeaways include:

- Post-surgical MRD status was predictive of chemotherapy benefit
- Post-surgical MRD status was the most significant prognostic risk factor for recurrence, in a multivariate
 analysis that accounted for all clinicopathological risk factors currently used for prognostication (HR 10.82, pvalue <0.001).
- **Pre-surgical detection rate of 95.9%** in patients with pathologic stage II-III disease and 93.1% in patients with stage II-IV disease.
- Signatera dynamics are indicative of treatment response

This study provides strong evidence that Signatera MRD-positive patients will benefit significantly from adjuvant therapy, while MRD-negative patients may be safely observed, regardless of clinical or pathological stage.

https://www.natera.com/company/news/natera-announces-publication-of-prospective-multi-site-circulate-study-in-nature-medicine-demonstrating-signateras-ability-to-predict-chemotherapy-benefit-in-colorectal-cancer/

22. The Childhood Cancer Identity Project (CCHIP): Examination of Cancer Identity and Wellbeing in Adult Survivors of Childhood Cancer (Mar.30/24)

The Childhood Cancer Identity Project (CCHIP) aims to better understand how individuals view themselves after cancer treatment has ended, referred to as cancer identity. The project also intends to understand the impact cancer identity has on mental and physical health. Following completion of this study, the findings will be used to integrate cancer identity into overall care of childhood cancer survivors. Findings may also support the use of patient-preferred terminology in clinical practices, aftercare clinics, research, and among the public.

Adult survivors of childhood cancer are welcome to complete the survey using the following link: https://concordia.yul1.qualtrics.com/jfe/form/SV eRvL6U1F8Yv1BfU

23. YACC's Recovery Study (Apr.8/24)

BIG NEWS! Young Adult Cancer Canada (YACC) is launching its next research project, the Recover Study! This longitudinal community-led study aims to better understand what it means to have cancer as a young adult and how it affects your quality of life over time.



It takes longer to recover from cancer than to be treated for it. At Young Adult Cancer Canada (YACC), recovery is about more than remission, it is about living a life worth loving, hopefully for the long road.

Recover is a community-led study where we work together to set the priorities and better understand life and cancer for young adults and how it affects your quality of life over time.

We hope to enrol 2000 people from all across Canada.

Gardez l'oeil ouvert car notre étude sera bientôt disponible en français.

Who can take part?

Young adults living in Canada who are over the age of 18 and were diagnosed with any type of cancer before the age of 40.

Why should I take part?

The information you provide will be used to increase awareness and develop programs to address the issues that young adults with cancer feel are most important.

You will be paid \$20 for each year you complete the survey.

How do I take part?

You will complete an online survey once a year for up to 5 years. Each survey will take approximately 30-45 minutes to complete.

How do I sign up?

For more information or to participate, please fill out the sign up form on recoverstudy.ca.



This project has been reviewed and approved by the Community Research Ethics Board. If you feel you have not been treated according to the descriptions in our information, or your rights as a participant in research have been violated during the course of this project, you may contact the Chair, Community Research Ethics Board, at:

Community Research Ethics Office (Canada) Corp. c/o Centre for Community Based Research, 140 Westmount Road North, Waterloo ON N2L 3G6

Email: creoadmin@communityresearchethics.com

Recover Recruitment Poster, Version 1, 1-September-2023

Nutrition / Healthy Lifestyle

24. EXercise for Cancer to Enhance Living Well (EXCEL) Study (Mar.29/24)

Exercise for Cancer to Enhance Living Well (EXCEL) is a 5-year Canada-wide project, which offers free, 8-12-week exercise classes designed specifically for individuals undergoing or recovering from cancer treatment. Classes are delivered online through a secure video-conferencing platform, and where possible, in-person. These group classes run for 60 minutes, twice a week for 8-12 weeks. They are offered three times a year: January, April, and September. The Spring 2024 program will be running **April 9th – June 27th**. **Sign up TODAY to secure a spot in class!** Feel free to email wellnesslab@ucalgary.ca to learn more and sign up.

Physical activity can help overcome treatment-related side effects such as fatigue and pain, improve mental health by reducing anxiety and depression, and improve overall quality of life for individuals living with and beyond cancer. Studies show that physical activity may even reduce the risk of recurrence for some cancers. Many urban centres in Canada offer cancer-specific exercise programs, however, rural and remote areas tend to lack exercise resources to support cancer survivors, resulting in lower activity levels, poorer health, and diminished quality of life. Thus, EXCEL targets cancer survivors living in rural and remote regions across Canada, empowering them to move more and providing opportunities to benefit from physical activity.

To learn more about the EXCEL study: https://kinesiology.ucalgary.ca/labs/health-and-wellness/research/research-studies/exercise-cancer-enhance-living-well-excel

To hear about participant experiences: https://www.youtube.com/watch?v=c01oo4Yd3oA



COVID-19 Updates

25. Frequently Asked Questions for COVID-19

Q: What is COVID-19 (or novel Coronavirus Disease - 19)?

A: Coronaviruses are a large family of viruses that can cause illnesses in humans and animals. Coronaviruses can cause illnesses that range in severity from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS) and most recently, COVID-19. COVID-19 or novel coronavirus originated from an outbreak in Wuhan, China in December 2019. The most common symptoms associated with COVID-19 can include fever, fatigue, and a dry cough. Though additional symptoms have now been linked with the disease, which may include aches and pains, nasal congestion, runny nose, sore throat, diarrhea, skin rash and vomiting. It is also possible to become infected with COVID-19 and not experience any symptoms or feeling ill. The spread of COVID-19 is mainly through the transmission of droplets from the nose or mouth when a person coughs, exhales or sneezes. These droplets land on surfaces around a nearby person. COVID-19 can be transmitted to that nearby person who may end up touching the surface contaminated with COVID-19 and then end up touching their nose, mouth, or eyes. A person can also contract COVID-19 through inhaling these droplets from someone with COVID-19. Although research is still ongoing, it is important to note that older populations (over the age of 65), those with a compromised immune system and those with preexisting conditions including heart disease, high blood pressure, lung disease, diabetes or cancer may be at a higher risk of severe illness due to COVID-19.

 $\underline{https://www.who.int/news-room/q-a-detail/q-acoronaviruses}$

Q: What can I do to avoid getting Coronavirus?

- A: There are various ways in which we can reduce our risk of contracting COVID-19. Below are some measures suggested by the World Health Organization
- 1. Keep at least 2 metres (or 6 feet) between yourself and other people. This will reduce the risk of inhaling droplets from those infected with COVID-19.
- 2. Regularly clean your hands for at least 20 seconds with warm water and soap, or an alcohol-based hand rub. This will kill any viruses on your hands.
- 3. Avoid touching your eyes, nose and mouth. If the virus is on your hands, it can enter the body through these areas.

- 4. Follow good respiratory hygiene by covering your mouth and nose with a tissue or elbow when you cough and sneeze. This prevents the droplets from settling on surfaces or being released into the air around you.
- 5. Stay home as much as possible, especially if you are feeling unwell. If you think you may have the Coronavirus, please see "What should I do if I think I have Coronavirus?" section.
- 6. Please wear a face covering or mask in public when physical distancing is not possible.

https://www.who.int/news-room/q-adetail/q-a-coronaviruses

Q: Are there special precautions that people with cancer can take?

A: People with cancer (and other chronic ailments such as heart disease, diabetes, high blood pressure and lung disease) are at a higher risk of severe illness due to COVID-19 as cancer is considered a pre-existing health issue. Some cancer treatments including chemotherapy, radiation and surgery can weaken the immune system, making it harder for the body to fight infections and viruses, such as Coronavirus. It is important to diligently follow the World Health Organization's recommendations above to reduce the risk of contracting COVID-19. If you have any concerns about your risk, it is best to contact your doctor or healthcare team.

Q. Will anything change with regards to my cancer related medical visits?

As each patient and treatment plan is unique, it is always best to contact your health care provider for updated information about your treatment plan. In some cases, it is safe to delay cancer treatment until after the pandemic risk has decreased. In other cases, it may be safe to attend a clinic that is separate from where COVID-19 patients are being treated. Oral treatment options could be prescribed by your care provider virtually, without the need to attend the clinic. Finally, some follow-up appointments or discussions could be held virtually (via skype or zoom for example) or over the phone to minimize your risk. As we know, conditions and protocols are changing daily due to the nature of the COVID-19 outbreak, and vary based on location, therefore, the best first step is to reach out to your care provider for guidance.

https://www.cancer.gov/contact/emergencypreparedness/coronavirus

Should you wish to contact your local public health agency, please see below.

Alberta

COVID-19 info for Albertans

Social media: Instagram @albertahealthservices, Facebook @albertahealthservices, Twitter @GoAHealth

Phone number: 811

British Columbia

British Columbia COVID-19

Social media: Facebook @ImmunizeBC, Twitter @CDCofBC

Phone number: 811

Manitoba

Manitoba COVID-19

Social media: Facebook @manitobagovernment, Twitter @mbgov

Phone number: 1-888-315-9257

New Brunswick

New Brunswick Coronavirus

Social media: Facebook @GovNB, Twitter @Gov_NB, Instagram @gnbca

Phone number: 811

Newfoundland and Labrador

Newfoundland and Labrador COVID-19 information

Social media: Facebook @GovNL, Twitter @GovNL, Instagram @govnlsocial

Phone number: 811 or 1-888-709-2929

Northwest Territories

Northwest Territories coronavirus disease (COVID-19)

Social media: Facebook @NTHSSA

Phone number: 811

Nova Scotia

Nova Scotia novel coronavirus (COVID-19)

Social media: Facebook @NovaScotiaHealthAuthority, Twitter @healthns, Instagram @novascotiahealthauthority

Phone number: 811

Nunavut

Nunavut COVID-19 (novel coronavirus)

Social media: Facebook @GovofNunavut, Twitter @GovofNunavut, Instagram @governmentofnunavut

Phone number: 1-888-975-8601

Ontario

Ontario: The 2019 Novel Coronavirus (COVID-19)

Social media: Facebook @ONThealth, Twitter @ONThealth, Instagram @ongov

Phone number: 1-866-797-0000

Prince Edward Island

Prince Edward Island COVID-19

Social media: Facebook @GovPe, Twitter @InfoPEI,

Quebec

Coronavirus disease (COVID-19) in Québec

Social media: Facebook @GouvQc, Twitter @sante_qc

Phone number: 1-877-644-4545

Saskatchewan

Saskatchewan COVID-19

Social media: Facebook @SKGov, Twitter @SKGov

Phone number: 811

Yukon

Yukon: Find information about coronavirus (COVID-19) Social media: Facebook @yukonhss, Twitter @hssyukon

Phone number: 811