

Welcome to the Surveillance **A**fter Extremity Tumor surger**Y** (SAFETY) Trial January Enrolment Update!

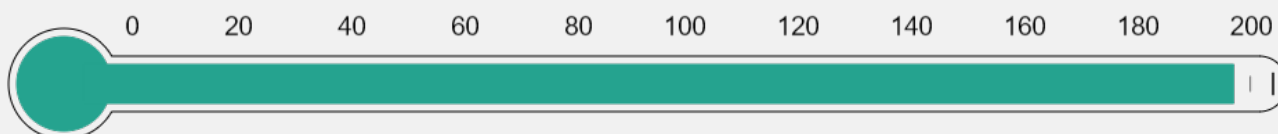
RECRUITMENT UPDATE

We are pleased to report that as of January 9th, 2023, **193** participants have been enrolled in the SAFETY trial.

Congratulations to our three highest enrolling sites of 2022: **Oregon Health and Science University, Hôpital Maisonneuve-Rosemont, and Parkview Cancer Institute!** Thank you to all of our enrolling sites and to the sites working hard to open to enrolment for the SAFETY trial in 2023.

Site	Country	Enrolled Since Last Update	Enrolled to Date	Projected Yearly Enrolment	2023 Enrolment
Juravinski Hospital and Cancer Centre	Canada	0	55	15	0
Hôpital Maisonneuve-Rosemont	Canada	0	21	10	0
Oregon Health and Science University	USA	0	17	15	0
Centro Traumatologico Ortopedico Hospital	Italy	0	11	10	0
Hospital de Clínicas de Porto Alegre	Brazil	0	8	8	0
Huntsman Cancer Institute	USA	0	8	12	0
Medical University Graz	Austria	1	7	8	1
Leiden University Medical Centre	NLD	0	7	12	0
L'Hôtel-Dieu de Quebec	Canada	0	6	5	0
Cleveland Clinic	USA	0	6	10	0
Parkview Cancer Institute	USA	0	6	10	0
University of Florida Health Shands Hospital	USA	0	6	10	0
McGill University Health Centre	Canada	1	5	5	1
University of California Davis Medical Center	USA	0	5	10	0
The Ottawa Hospital	Canada	0	4	5	0
Albany Medical Center	USA	0	4	8	0
Holden Comprehensive Cancer Centre	USA	0	4	6	0
Nova Scotia Health	Canada	0	3	5	0
NYU Langone Orthopaedic Hospital	USA	0	3	5	0
St. Vincent's Hospital Melbourne	Australia	0	2	8	0
Hartford HealthCare	USA	0	2	6	0
Montefiore Medical Centre	USA	0	2	6	0
Hospital Universitario Austral	Argentina	0	1	8	0
Mount Sinai Hospital	Canada	0	0	12	0
University of Malaya Medical Centre	Malaysia	0	0	10	0
Texas Tech Health Sciences Center El Paso	USA	0	0	10	0
Virginia Cancer Specialists	USA	0	0	10	0
Total		2	193	239	2

PILOT ENROLMENT



SAFETY UPDATES

PILOT UPDATE

We are seven participants away from completing pilot phase enrolment for the SAFETY trial. Thank you to our enrolling sites for their hard work in this phase of the trial!

Definitive phase enrolment will begin immediately upon completion of recruitment of the pilot phase. There will be no pause in enrolment and all pilot participants will be rolled directly into the definitive phase of the trial, as per the Study Protocol.

CONGRATULATIONS TO THE HIGHEST ENROLLING SITES OF 2022

Congratulations to our three highest enrolling sites of 2022: Rebecca Smith, Dr. James Hayden, Dr. Yee-Cheen Doung, and Dr. Kenneth Gundle at Oregon Health and Science University; Janie Barry, Hugo St. Yves, Dr. Georges Basile, Dr. Marc Isler, and Dr. Sophie Mottard at Hôpital Maisonneuve-Rosemont; and Ashley Romine, Dr. Christopher Johnson, and the research team at Parkview Cancer Institute.

SAFETY PEARLS

BASELINE TUMOR PATHOLOGY REPORT FORM REMINDER

Please use the patient's post-surgical pathology report to complete the Baseline Tumor Pathology Report Form instead of the biopsy report.

If unsure what to select for the Pathological Diagnosis Code, please consult with the Methods Centre.

DO ALL OPERATIONS OR SURGICAL INTERVENTIONS NEED TO BE REPORTED?

If patients undergo an operation or surgical intervention for an issue that is **not** related to their sarcoma, please do **not** complete the Unplanned Re-Operation Form (14) or Other Surgical Intervention Form (15). Please do the following for operations or surgical interventions not related to the patient's sarcoma:

- Report the event on the Adverse Event Form (12);
- Select Operative Management in Question 2; and
- Specify details.

PATIENT CANCER CARE COSTS DIARY

Reminders:

- Questions 8-11 should only contain costs related to the doctor's fees.
- Question 13 captures details of any paid **or** unpaid assistance.
- Question 14 should capture any costs for parking, gas, etc.
- **Patients must complete the Costs Diary at every intervention visit, even if patient incurred no costs.** Please remind patients that other common costs related to their sarcoma should be reported (e.g., hospital parking fees, gas, physiotherapy, over-the-counter medications, assistive devices, etc.).

WINDOW FOR APPROACHING ELIGIBLE PATIENTS

The window for approaching eligible patients is three months from completion of all active treatment (radiation, chemotherapy, surgery, wound healed or stable). If you are unsure if a patient is still eligible, please contact the Methods Centre to confirm.

METHODS CENTRE CONTACTS

If you have questions about any aspect of the SAFETY trial, please contact us:

Dr. Michelle Ghert, Principal Investigator
ghertm@mcmaster.ca

Tricia Schneider*, Senior Project Manager
schnep@mcmaster.ca

Tess Hudson, Primary Project Manager
hudsonstc@mcmaster.ca

Hadia Farrukh, Research Assistant
farrukhh@mcmaster.ca

* Tricia is currently on maternity leave. Please contact Tess with any study correspondence.