SAFETY

Surveillance After Extremity Tumor Surgery

July 2022 ■ Newsletter

Welcome to the **S**urveillance **AF**ter **E**xtremity **T**umor surger**Y** (SAFETY) Trial July Newsletter!

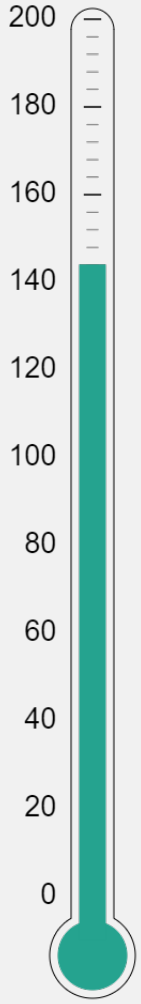
RECRUITMENT UPDATE

We are pleased to report that as of 05 July 2022, **144** participants have been enrolled in the SAFETY trial!

Congratulations to **Dr. Peter Ferguson** and the research team at **Mount Sinai Hospital** in **Toronto, Ontario, Canada,** for opening to enrolment in the SAFETY trial!

Site	Country	Enrolled Since Last Update	Enrolled to Date
Juravinski Hospital and Cancer Centre	Canada	3	49
Hôpital Maisonneuve-Rosemont	Canada	1	16
Centro Traumatologico Ortopedico Hospital	Italy	2	9
Oregon Health and Science University	USA	2	7
Leiden University Medical Centre	NLD	2	6
Huntsman Cancer Institute	USA	0	6
University of Florida Health Shands Hospital	USA	0	6
Hospital de Clínicas de Porto Alegre	Brazil	0	5
L'Hôtel-Dieu de Quebec	Canada	0	5
University of California Davis Medical Center	USA	0	5
Medical University Graz	Austria	0	4
Nova Scotia Health	Canada	1	3
The Ottawa Hospital	Canada	0	3
Albany Medical Center	USA	0	3
Cleveland Clinic	USA	0	3
Holden Comprehensive Cancer Centre	USA	0	3
NYU Langone Orthopaedic Hospital	USA	0	3
McGill University Health Centre	Canada	0	2
Hartford HealthCare	USA	0	2
Montefiore Medical Centre	USA	0	2
Parkview Cancer Institute	USA	1	2
Hospital Universitario Austral	Argentina	0	0
St. Vincent's Hospital Melbourne	Australia	0	0
Mount Sinai Hospital	Canada	0	0
Total		**12**	**144**

2022 ENROLMENT GOAL



SITE INITIATION UPDATE

Site	Country	Ethics Approval Status	Site Agreement Status	Site Training Status
Cliniques Universitaires Saint-Luc	Belgium	In Progress	In Progress	N / A
Universidade de Coimbra	Brazil	In Progress	In Progress	N / A
Eastern Regional Health Authority	Canada	In Progress	In Progress	N / A
American University of Beirut Medical Center	Lebanon	Full Approval	In Progress	N / A
University Malaya Medical Centre	Malaysia	Full Approval	In Progress	N / A
Hospital Vall d'Hebron	Spain	Full Approval	In Progress	N / A
Karolinska Institute	Sweden	In Progress	In Progress	N / A
Allegheny Health Network Research Institute	USA	In Progress	In Progress	N / A
Dartmouth-Hitchcock Medical Center	USA	Full Approval	In Progress	N / A
Johns Hopkins Hospital	USA	Full Approval	Finalized	Complete
Texas Tech University Health Sciences Center	USA	Full Approval	In Progress	N / A
University of Chicago Medical	USA	In Progress	In Progress	N / A
University of Washington Medical Center	USA	In Progress	In Progress	N / A
Virginia Cancer Specialists	USA	Full Approval	Finalized	N / A

SAFETY UPDATES

MOUNT SINAI HOSPITAL OPENS FOR ENROLMENT

Congratulations to Dr. Peter Ferguson and the research team at Mount Sinai Hospital for opening to enrolment in the SAFETY trial!

STUDY RESOURCES

You can find study resources at www.SAFETYrct.com by logging into the SAFETY Investigator section of our website using the information below:

Username: siteinvestigators
Password: SAFETYInvestigators1!

Here, you can find the Site Training Presentation, Study Visit Checklists, Study Resource Binder, and more.

DO I NEED TO COMPLETE A PROTOCOL DEVIATION FORM?

The Unscheduled Clinic Visit Form should be completed for any additional appointments with the orthopaedic oncologist. Visits with other specialties do not deviate from protocol.

One Protocol Deviation Form can be completed to capture multiple protocol deviations within a single intervention phase. For example, if a patient is seen in clinic for an unscheduled visit and obtains unscheduled thoracic imaging, both deviations can be recorded on a single Protocol Deviation Form.

One telephone visit per visit window is not classified as a protocol deviation. For example, for a telephone visit between the baseline visit and first intervention visit with the orthopaedic oncologist, a Protocol Deviation Form does not need to be completed.

COMPLETING THE PATIENT CANCER CARE COSTS DIARY

Please provide patients with a Patient Cancer Care Costs Diary at every study visit (including the baseline visit). A Costs Diary should be collected at every intervention visit, regardless of surveillance arm allocation.

Reminders:

- If the patient did not incur any costs, a Cost Diary still needs to be completed. Please let them know that they can select *No* to questions 6-14 if no costs were incurred.
- Q13 asks if the patient has received any assistance at home. Please remind patients to report both paid and unpaid assistance. For unpaid assistance, please instruct them to enter 0 for the out-of-pocket cost.
- If there is not enough room for entries, a single type of cost may be grouped as one entry (e.g., physiotherapy appointments) by adding the total cost and reporting the visit dates in the description.

We recommend bringing extra copies of the Costs Diary to clinic for those patients who forget their Costs Diary at home. In these cases, please have the patient complete the Costs Diary in clinic. Alternatively, the Costs Diary and Patient Questionnaires can be emailed to patients to complete and bring to the appointment or email to the Research Coordinator/Assistant/Nurse.

NEXT STEPS FOR RECURRENT DISEASE

The care of patients who have a recurrence (local or systemic) is not dictated or limited by the SAFETY trial protocol – these patients are off protocol. However, we would still like to capture all the treatments, surgeries, and imaging that they complete. As such, their intervention visits should still be completed with the orthopaedic oncologist (through telephone or telemedicine if the patient cannot come in person).

Required forms:

- Local and/or Systemic Recurrence Form
- Radiation Log and/or Systemic Therapy Log
- Intervention Phase Surveillance Visit Form
- Patient Cancer Care Costs Diary
- Patient Questionnaires

Forms to be completed as needed:

- Unscheduled Clinic Visit Form (for extra visits with the orthopaedic oncologist)
- Protocol Deviation Form (ex. for extra imaging)
- Adverse Event Form (ex. for chemotherapy-related events)
- Unplanned Re-operation Form and/or Other Surgical Intervention Form

Please gather data and record all treatments, surgeries, and imaging the patient receives at your site and at any external clinics or hospitals.

iDATAFAX TIPS

If an illegal value is entered in iDataFax, but the value is correct, please enter a reason and the Methods Centre will review the data point.

A reason can be entered by selecting the relevant data field and clicking the […] to the right of *Reason for Data Field* in the bottom left corner of the page.

A data point can be marked as a missing value by selecting the relevant data field and clicking *Field > Mark Field Missing* in the menu bar. Please only report missing fields for information that is not available.

TIPS FOR MANAGING PATIENTS WHO ARE HESITANT TO PARTICIPATE

Reason for Hesitation	Possible Responses
The patient is concerned about not being followed closely enough.	▪ Inform the patient that they can schedule an ad hoc visit at any time, even if it breaks the surveillance protocol to which they are assigned. ▪ Inform the patient that they will be advised on how to self-examine for a local recurrence.
The patient is concerned about too much radiation from CT scans.	▪ If the site investigator typically follows patients with thoracic CT scans every three months, inform the patient that their surgeon's standard of care for surveillance for patients outside of the study is identical to the most intensive study arm.
The patient is concerned about the costs associated with any additional visits.	▪ Inform the patient that parking and / or travel vouchers can be provided to alleviate additional travel costs associated with the study. This is site specific.
The patient believes that the study would cause issues with their insurance coverage.	▪ Inform the patient that all study arms in the 'intervention phase', as well as the 'post-intervention phase', are considered standard of care as per the NCCN guidelines.
The patient believes that the quality of care they would receive would be inferior to what they would receive outside of the study.	▪ Inform the patient that participation in clinical research typically results in superior care, with benefits including especially close monitoring and clinical support, possible access to new treatments / technologies, frequent training of staff, and reduction of resource use when demonstrated to be ineffective / unnecessarily costly.
The patient had a negative experience in a previous research study.	▪ Have a conversation with the patient about their specific concerns and discuss how they may be addressed in this study.
The patient considers the study too burdensome.	▪ If the site investigator typically follows patients every three months, inform the patient that their surgeon's standard of care for surveillance frequency for patients outside of the study is identical to the most intensive surveillance frequency. ▪ Inform the patient that the study questionnaires are completed only once every six months in the first two years of the study, and once yearly for the final three years of the study duration.
The patient is overwhelmed by their diagnosis.	N/A

METHODS CENTRE CONTACTS

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

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