



SAFETY

Surveillance After Extremity Tumor Surgery

September 2020 ■ Edition 5

Welcome to the fourth edition of the **Surveillance **A**fter Extremity Tumor surgery**Y** (SAFETY)** Trial Newsletter!

RECRUITMENT UPDATE

Congratulations to **Dr. Benjamin Miller** and his research team at **Holder Comprehensive Cancer Centre** for completing all study initiation activities and now being enrollment ready!

We are pleased to report that as of 08 September 2020, **11** participants have been enrolled in the SAFETY trial!

Site	Country	Enrolled Since Last Update	Enrolled to Date	Pilot Phase Enrolment Target
Juravinski Hospital and Cancer Centre	Canada	1	10	14%
Holden Comprehensive Cancer Centre	USA	0	0	
Albany Medical Center	USA	0	1	
University of California Davis Medical Center	USA	0	0	

SITE INITIATION UPDATE

Thank you to all the following sites that are actively working to complete the required study initiation activities before participant recruitment commences. Please do not hesitate to contact the Methods Centre for any assistance.

Site	Country	Ethics Approval Status	Site Agreement Status	Site Training Status
McGill University Medical Centre	Canada	Provisional Approval	Finalized	N / A
Hôpital Maisonneuve-Rosemont	Canada	Full Approval	In Progress	N / A
Hôpital Hôtel-Dieu	Canada	Full Approval	In Progress	N / A
Huntsman Cancer Institute	USA	In Progress	In Progress	N / A
Hospital Universitario Austral	Argentina	In Progress	In Progress	N / A
University of Minnesota Medical Center	USA	In Progress	In Progress	N / A
Montefiore Medical Centre	USA	Provisional Approval	In Progress	N / A
Oregon Health & Science University Hospital	USA	In Progress	In Progress	N / A
Johns Hopkins Hospital	USA	In Progress	In Progress	N / A
Hospital Vall d'Hebron	Spain	In Progress	In Progress	N / A
University of Florida Health Shands Hospital	USA	In Progress	Finalized	N / A
Leiden University Medical Center	Netherlands	In Progress	In Progress	N / A
The Cleveland Clinic	USA	In Progress	In Progress	N / A
Hospital de Clinicas de Porto Alegre	Brazil	In Progress	In Progress	N / A
Medical University Graz	Austria	Full Approval	In Progress	N / A
Yale New Haven Hospital	USA	In Progress	In Progress	N / A
Centro Traumatologico Ortopedico Hospital	Italy	In Progress	In Progress	N / A
NYU Langone Orthopaedic Hospital / Perlmutter Cancer Center	USA	In Progress	In Progress	N / A
St. Vincent's Hospital Melbourne	Australia	In Progress	In Progress	N / A

Thank you to all the following sites that have expressed interest in participating in the SAFETY trial. We look forward to working with you soon once we have progressed further in the pilot phase.

Site	Country
The Ottawa Hospital	Canada
University of California San Francisco	USA
Dartmouth – Hitchcock Medical Center	USA
Hartford Healthcare	USA

STUDY OVERVIEW

Surveillance strategies have been identified as the top research priority in the extremity sarcoma field. The SAFETY trial will provide the necessary evidence to develop evidence-based surveillance guidelines and is poised to have a significant impact on post-operative care and outcomes of extremity STS patients.



The overarching objective of this trial is to answer the following research question:

Does the frequency and mode of surveillance affect patient survival following extremity STS surgery?

To do so, we will compare two surveillance frequencies (every 3 months vs. every 6 months) and two imaging modalities (chest CT scans vs. chest radiographs). Patients will be randomized to one of four treatment groups:

Clinical Assessment
+ **Chest radiograph**
Every **3 Months** for 2
Years

Clinical Assessment
+ **Chest radiograph**
Every **6 Months** for
2 Years

Clinical Assessment
+ **Chest CT Scan**
Every **3 Months** for 2
Years

Clinical Assessment
+ **Chest CT Scan**
Every **6 Months** for
2 Years

Upon completion of the 2-year 'intervention phase', study participants will continue to be followed in the study every 6 months for another 3 years. The primary outcome is overall survival at 5 years post-randomization.

SUCCESS BULLETIN!

CASE REPORT FORMS

The SAFETY CRFs recently underwent a revision for use in the electric data capture (EDC) system and to ensure the efficient collection of data points. Changes include:

- Re-formatting CRFs with barcodes and plate numbers for use in the EDC system;
- Change of the **PROMIS® Satisfaction with Social Roles & Activities Questionnaire (Form 21)** to the **Short Form Version 8a**;
- Additional event details on the **Local Recurrence Form (Form 12)** and **Systemic Recurrence Form (Form 13)**.

We will be in touch with you once your site has obtained full ethics approval to facilitate your site's transition to the new version of the CRFs.

Ethics Committee FAQ

1. **Please confirm whether insurance will pay for costs of surveillance in both arms? Will patients be responsible for additional costs by enrolling in this trial?**

Every arm in the SAFETY trial is considered within the standard of care by the NCCN guidelines for the post-operative follow-up of soft-tissue sarcoma patients. The patient and / or the patient's medical insurance provider should be responsible for the cost of care.

2. **Please clarify whether the primary outcome of the trial is binary 5-year survival or time-to-death.**

The primary outcome is binary 5-year survival. The results will be expressed as effect (hazards ratios for time-dependent outcomes, odds ratios for binary outcomes and mean difference for continuous outcomes), corresponding two-sided 95% confidence intervals and associated p-values.

TRICIA ON MATERNITY LEAVE!

A reminder that **Tricia** is now off on maternity leave until **December 31st 2020**. Please contact, **Victoria** during with time with any study questions.



Congratulations Tricia!

The recruitment target for the pilot phase of the SAFETY trial is **80** participants. To reach this target, the Methods Centre is actively seeking high volume sites with research support to join the pilot phase of the trial. If you may be interested in participating in this collaborative study, please visit www.SAFETYrct.com to complete the **SAFETY Physician Trial Application** or to access the study documents..

METHODS CENTRE CONTACTS

If you have questions about any aspect of the study, do not hesitate to contact:

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