



SAFETY

Surveillance After Extremity Tumor Surgery

June 2020 • Edition 4

Welcome to the fourth edition of the **Surveillance **A**fter Extremity Tumor surgery (**S**A**F**E**T**Y)** Trial Newsletter!

RECRUITMENT UPDATE

Congratulations to **Dr. Matt DiCaprio** and **Brad Plamer** at **Albany Medical Center** for enrolling their first SAFETY participant! The SAFETY trial is now an international, multi-center trial!

Congratualtions to **Dr. Steven Thorpe**, **Dr. R Lor Randall** and their research team at **UC Davis Medical Center** for completing all study initiaiton activities and now being enrollment ready!

We are pleased to report that as of 23 June 2020, **10** 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	9	13%
Albany Medical Center	USA	1	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	In Progress	In Progress	N / A
Hôpital Maisonneuve-Rosemont	Canada	In Progress	In Progress	N / A
Hôpital Hôtel-Dieu	Canada	In Progress	In Progress	N / A
Huntsman Cancer Institute	USA	In Progress	In Progress	N / A
Hospital Universitario Austral	Argentina	In Progress	In Progress	N / A
Holden Comprehensive Cancer Centre	USA	In Progress	Finalized	N / A
University of Minnesota Medical Center	USA	In Progress	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

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!

SAFETY TRIAL NOW INTERNATIONAL!

We are happy to report that the SAFETY trial is now an international, multi-center trial. Congratulations to Dr. Matt DiCaprio and Brad Palmer at Albany Medical College for being the first international site to enrol a participant!

We look forward to enrolling participants at many more international sites!

SAFETY WEBSITE

The SAFETY trial website is now live, which will serve as primary mode of communication for important information from the Methods Centre. If you are interested in becoming an investigator for the SAFETY Trial, please visit www.SAFETYrct.com to complete the **SAFETY Physician Trial Application** or to access the study documents.

CLINICAL TRIAL REGISTRATION

The SAFETY trial has been registered on ClinicalTrials.gov (NCT03944798).

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 know of any individuals who may be interested in participating in this collaborative study, please inform the **Methods Centre**.

METHODS CENTRE CONTACTS

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

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