



Welcome to the eleventh edition of the Surveillance **AF**ter Extremity Tumor surger**Y** (SAFETY) Trial Newsletter!

RECRUITMENT UPDATE

Congratulations to **Dr. Nathan Mesko, Dr. Lukas Nystrom**, and the research team at **Cleveland Clinic** for opening enrolment for the SAFETY trial!

Congratulations to **Annie Arteau, Norbert Dion**, and the research team at **L'Hôtel-Dieu de Québec** for enrolling their first SAFETY trial participant!

We are pleased to report that as of 07 June 2021, **51** 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	4	28	64%
McGill University Health Centre	Canada	1	2	
Hôpital Maisonneuve-Rosemont	Canada	1	3	
L'Hôtel-Dieu de Québec	Canada	1	1	
Holden Comprehensive Cancer Centre	USA	0	2	
Montefiore Medical Centre	USA	0	0	
Albany Medical Center	USA	0	1	
University of Florida Health Shands Hospital	USA	1	4	
Cleveland Clinic	USA	0	0	
Hospital de Clínicas de Porto Alegre	Brazil	1	3	
Medical University Graz	Austria	0	2	
University of California Davis Medical Center	USA	0	1	
NYU Langone Orthopaedic Hospital	USA	0	1	
Centro Traumatologico Ortopedico Hospital	Italy	2	3	

SITE INITIATION UPDATE

Thank you to each of 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
Mount Sinai Hospital	Canada	In Progress	In Progress	N / A
The Ottawa Hospital	Canada	In Progress	In Progress	N / A
Huntsman Cancer Institute	USA	Full Approval	In Progress	N / A
Hospital Universitario Austral	Argentina	In Progress	In Progress	N / A
Oregon Health & Science University Hospital	USA	Full Approval	In Progress	N / A
Johns Hopkins Hospital	USA	Full Approval	Finalized	In Progress
Hospital Vall d'Hebron	Spain	In Progress	In Progress	N / A
University of California San Francisco	USA	In Progress	In Progress	N / A
Leiden University Medical Center	Netherlands	In Progress	Finalized	N / A
St. Vincent's Hospital Melbourne	Australia	In Progress	In Progress	N / A
Hartford Healthcare	USA	In Progress	In Progress	N / A
La Paz University Hospital	Spain	In Progress	In Progress	N / A
Clinica Imbanaco	Colombia	In Progress	In Progress	N / A
Kilimanjaro Christian Medical Center	Tanzania	In Progress	In Progress	N / A

SUCCESS BULLETIN

CLEVELAND CLINIC IS OPEN FOR ENROLMENT

Congratulations to Dr. Nathan Mesko, Dr. Lukas Nystrom, and the research team at Cleveland Clinic for opening enrolment for the SAFETY trial!



L'HOTEL-DIEU DE QUEBEC ENROLS THEIR FIRST PARTICIPANT

Congratulations to Annie Arteau, Norbert Dion, and the research team at L'Hôtel-Dieu de Québec for enrolling their first SAFETY trial participant!



SAFETY Pearls (Site Q & A)

Which forms should be completed for unconfirmed lung nodules?

If a patient has unconfirmed lung nodules, please complete an **Adverse Event Form (Form 16)** detailing the situation. In describing the event, there is an option for 'Other pulmonary event (Code 499)' that may be used for a suspected lung metastasis, for example.

Upon confirmation of a systemic recurrence, complete the **Systemic Recurrence Form (Form 13)**.

I confirmed the patient has a systemic recurrence. How do I proceed?

Please continue to follow the patient and complete the relevant forms for the study, which will be determined by the patient's treatment plan. There will likely be multiple protocol deviations. If you have questions about the correct forms to complete, please contact the Methods Centre and we will be happy to assist you.

What do I do if I included a patient who is ineligible?

If you have accidentally enrolled a patient who does not meet the eligibility requirements, please continue to follow the patient as per study protocol. The Adjudication Committee may remove them from the study following review.

Reminders

The SAFETY Case Report Forms (CRFs) recently underwent revision from V2.0 to V3.0. Changes include updating the **Baseline Characteristics Form (Form 3)** to use the 8th edition of the AJCC staging system. You can reference this staging system in the study resource binder. A Baseline Treatment Option on the **Systemic Therapy Log (Form 17)** and **Radiation Log (Form 18)** has also been added.

Please continue to send all completed CRFs to Tess at the Methods Centre.

METHODS CENTRE CONTACTS

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

Dr. Michelle Ghert, Principal Investigator
ghertm@mcmaster.ca
Tel: (905) 387-9495 ext. 64089

Tess Hudson, Research Coordinator
hudsontc@mcmaster.ca
Mobile: (519) 362-7247

Tricia Schneider, Project Manager
schnep@mcmaster.ca
Mobile: (289) 244-6087

Victoria Giglio, Research Assistant
gigliovt@mcmaster.ca
Mobile: (905) 550-2962