SAFETY

Surveillance After Extremity Tumor Surgery

April 2021 ▪ Edition 10

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

RECRUITMENT UPDATE

Congratulations to **Dr. Michele Boffano** and his research team at the **Centro Traumatologico Ortopedico Hospital** for enrolling their first SAFETY trial participant!

Congratulations to **Dr. Andre Spiguel** and the research team at the **University of Florida Health Shands Hospital** for enrolling their first three SAFETY trial participants!

Congratulations to **Dr. Ricardo Becker** and his research team at **Hospital de Clínicas de Porto Alegre** for enrolling their first two SAFETY trial participants!

We are pleased to report that as of 27 April 2021, **40** 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	2	24	57%
McGill University Health Centre	Canada	0	1	
Hôpital Maisonneuve-Rosemont	Canada	0	2	
Hôpital Hôtel-Dieu Quebec	Canada	0	0	
Holden Comprehensive Cancer Centre	USA	1	2	
Montefiore Medical Centre	USA	0	0	
Albany Medical Center	USA	0	1	
University of Florida Health Shands Hospital	USA	3	3	
Hospital de Clínicas de Porto Alegre	Brazil	2	2	
Medical University Graz	Austria	2	2	
University of California Davis Medical Center	USA	0	1	
NYU Langone Orthopaedic Hospital	USA	0	1	
Centro Traumatologico Ortopedico Hospital	Italy	1	1	

SITE INITIATION UPDATE

Thank you to all 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	Awaiting Signatures	N / A
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
The Cleveland Clinic*	USA	Full Approval	Awaiting Signatures	Completed
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

SUCCESS BULLETIN

SAFETY CRFs

Thank you to all who sent in completed CRFs! If you have yet to do so, please scan and email all CRFs to Tess at the **Methods Centre**. We are making progress on the SAFETY database and look forward to activating it this summer!

HOSPITAL DE CLÌNICAS DE PORTO ALEGRE ENROLS THEIR FIRST PARTICIPANT

Congratulations to Dr. Ricardo Becker and his research team at Hospital de Clinìcas de Porto Alegre for enrolling their first SAFETY trial participant! We appreciate every site continuing to screen all eligible participants!



CENTRO TRAUMATOLOGICO ORTOPEDICO HOSPITAL ENROLS THEIR FIRST PARTICIPANT

Congratulations to Dr. Michele Boffano and his research team at the Centro Traumatologico Ortopedico Hospital for enrolling their first SAFETY trial participant! Keep up the fantastic momentum!


UF HEALTH SHANDS HOSPITAL ENROLS THEIR FIRST PARTICIPANT

Congratulations to Dr. Andre Spiguel and the research team at the University of Florida Health Shands Hospital for enrolling their first SAFETY trial participant! We are excited by the growing number of active and enrolling sites!


THE SAFETY TRIAL IS NOW ACTIVE IN FIVE COUNTRIES

The SAFETY trial is now active in five countries across three continents! We are very excited to continue to expand enrollment to new sites and new countries.

Thank you to our active and enrolling sites! Thank you to the Site Investigators and research team at each site for taking time out of your busy schedules to complete site training and enroll participants.

METHODS CENTRE CONTACTS

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

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SAFETY Pearls (Site Q & A)

WHAT SHOULD I DO IF PATIENTS HAVE QUESTIONS BEFORE CONSENT?

You can let them know **that patients have been enrolled in 5 countries** and that all treatment arms are within the standard of care. You can also refer to the Informed Consent Guidelines in the Study Resource Binder for Frequently Asked Questions.

WHO SHOULD HAVE ACCESS TO COMPLETED CONTACT FORMS (0.1) AND CONSENT FORMS?

This information should only be accessed by authorized study personnel during the trial and should not be stored in the participant's study file or sent to the Methods Centre. Please send all other study documents to the Methods Centre.

WHAT SHOULD I DO IF A PATIENT HAS UNDERGONE ANY NEOADJUVANT OR ADJUVANT CANCER THERAPIES FOR THE INCLUDED STS?

Please fill out a Radiation Log and/or a Systemic Therapy Log as directed on P. 6 of the Baseline Characteristics Form.

23. Has the patient undergone any neoadjuvant cancer therapies for the included soft-tissue tumor?
Select all that apply.

- ☐ **None**
- ☐ Neoadjuvant systemic therapy → If neoadjuvant systemic therapy, complete the appropriate number of systemic therapy entries in the Systemic Therapy Log.
- ☐ Neoadjuvant radiation → If neoadjuvant radiation, complete the appropriate number of radiation entries in the Radiation Log.

24. Has the patient undergone any **adjuvant** cancer therapies for the included soft-tissue tumor?
Select all that apply.

- ☐ **None**
- ☐ Adjuvant systemic therapy → If *adjuvant systemic therapy*, complete the appropriate number of systemic therapy entries in the **Systemic Therapy Log.**
- ☐ Adjuvant radiation → If *adjuvant radiation*, complete the appropriate number of radiation entries in the **Radiation Log.**

For the **Systemic Therapy Log (Form 17.1)**, complete the **Visit Data Details**, **Systemic Therapy Details**, and **Therapy Administration Details**. For example, at the Baseline Visit select Baseline for the Visit No. and specify the Start Date (and Stop Date if applicable). Include the Type, Name, and Number of cycles for the systemic therapy. Finally, specify the Reason for Administration and whether the therapy was completed.

For the **Radiation Log (Form 18.1)**, complete the **Visit Data Details** and **Radiation Administration Details**. Complete the Visit No. and Start and Stop Date (if applicable). For this log, you need to specify the Mode, Dosage, Reason for Administration, and whether the therapy was completed. For neoadjuvant cancer therapies recorded at the Baseline Visit, specify Baseline for Visit No. and both the Start and End Date.

SYSTEMIC THERAPY LOG - FORM 17.1

#	Visit Date Details	Systemic Therapy Details	Therapy Administration Details
1	Visit No. '*Intervention Phase*': ☐ Baseline ☐ 3 Month ☐ 6 Month ☐ 9 Month ☐ 12 Month ☐ 15 Month ☐ 18 Month ☐ 21 Month ☐ 24 Month Visit No. '*Post-intervention Phase*': ☐ 30 Month ☐ 36 Month ☐ 42 Month ☐ 48 Month ☐ 54 Month ☐ 60 Month ☐ Check if Ongoing Start Date: DD MM YYYY ☐ Check if Stopped → Stop Date: DD MM YYYY	Type: ☐ Cytotoxic ☐ Targeted Biological ☐ Immunotherapy Name: ☐ Dacarbazine ☐ Gemcitabine ☐ Docetaxel ☐ Ifosphamide ☐ Doxorubicin ☐ Other (specify): _____ Number of cycles: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ >7	Reason for Administration: ☐ Local recurrence ☐ Systemic recurrence ☐ Other (specify): _____ Therapy Completed? ☐ Yes ☐ No → If *no*, specify why not: ☐ Patient preference ☐ Definitive management of recurrence ☐ Systemic toxicity ☐ Tumor growth ☐ Other (specify): _____

RADIATION LOG - FORM 18.1

#	Visit Date Details	Radiation Administration Details
1	Visit No. '*Intervention Phase*': ☐ Baseline ☐ 3 Month ☐ 6 Month ☐ 9 Month ☐ 12 Month ☐ 15 Month ☐ 18 Month ☐ 21 Month ☐ 24 Month Visit No. '*Post-intervention Phase*': ☐ 30 Month ☐ 36 Month ☐ 42 Month ☐ 48 Month ☐ 54 Month ☐ 60 Month ☐ Check if Ongoing Start Date: DD MM YYYY ☐ Check if Stopped → Stop Date: DD MM YYYY	Mode: ☐ Standard external beam ☐ IMRT Dosage: ☐☐☐ Gy Reason for Administration: ☐ Local recurrence ☐ Systemic recurrence ☐ Other (specify): _____ Therapy Completed? ☐ Yes ☐ No → If *no*, specify why not: ☐ Definitive management of recurrence ☐ Patient preference ☐ Systemic toxicity ☐ Tumor growth ☐ Other (specify): _____

Please continue to screen all eligible participants at your site and complete all required study initiation activities to become enrolment ready! If you have questions, please reach out to the Methods Centre!