SAFETY

Surveillance After Extremity Tumor Surgery

Case Report Form Completion Guidelines

Version 3.0

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Principal Investigator: Michelle Ghert, MD, FRCSC

Center for Evidence-Based Orthopaedics
McMaster University
Methods Center: 711 Concession Street
Lakeview Lodge | Level 3, Room 11
Hamilton, ON L8V 1C3

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Document History

Date (DD-MMM-YY)	Author(s)	Version No.	Description of Amendment(s)
02-JUN-20	Tricia Schneider & Victoria Giglio	1.0	Initial Version
09-JUL-21	Tess Hudson, Tricia Schneider, Victoria Giglio	2.0	• Addition of CRF header instructions • Updated questions to match SAFETY CRFs Version 4.0
11-JAN-22	Tess Hudson	3.0	• Updated questions to match SAFETY CRFs V6.0

1.0 Introduction

The purpose of this document is to provide guidance on the completion of the study case report forms (CRFs) for the **S**urveillance **AF**ter **E**xtremity **T**umor surger**Y** (SAFETY) trial. Clinical site personnel should review this document prior to beginning study recruitment and refer to it when questions arise. If clinical site personnel have questions regarding the completion of CRFs, they should contact the Project Manager at the Methods Center via email and / or telephone.

2.0 General Instructions

Case report forms (CRFs) for the SAFETY trial can be completed on paper CRFs and then entered into the trial electronic data capture (EDC) system, DataFax. Alternatively, data may be entered directly into the EDC system, provided you have source documentation in medical records to substantiate all data points. For instructions on how to use the DataFax system, please refer to *DataFax Manual and Data Submission Guidelines.*

Please note that these completion guidelines list the CRFs according to visit. Please refer to the Visit Schedule (TABLE 1) for the order of CRF completion (as required).

3.0 Form Header

The SAFETY CRF header consists of the Participant ID and Participant Initials. Clinical site personnel should complete this section on **every** form completed for the patient.

The Participant ID should be completed as described in the *Patient Screening and Eligibility Guidelines* and consists of a clinical site ID, classification of the patient, and sequential patient number.

In the Participant Initials, please indicate the first and last initials of the participant. If a clinical site does not have local research ethics approval to record participant's initials on the SAFETY CRFs, the filler initials of 'XX' should be used, as indicated in FIGURE 1.

Participant ID and Participant Initials will be auto-populated in iDataFax following entry on the **Screening Form (Form 1).**

Figure 1. Completing Participant Initials for sites without approval to use Patient initials

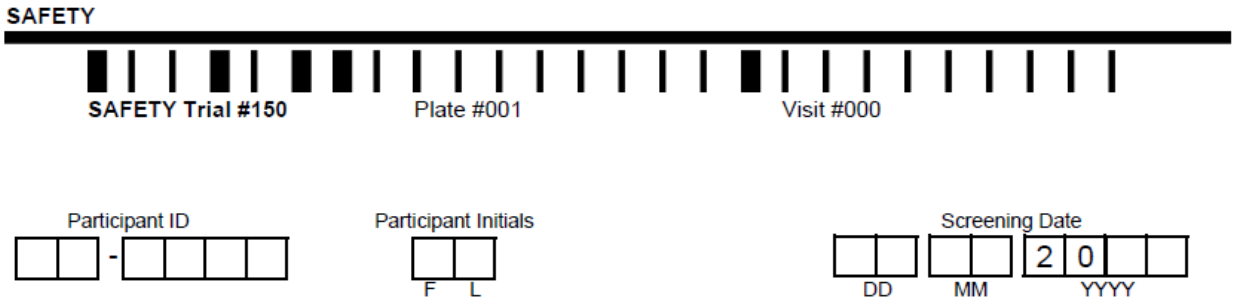

Table 1. Visit Data Collection Schedule

Data Collection	Baseline	*Intervention Phase Visits*								*Post-Intervention Phase Visits*						Early Withdrawal Visit
		3M Visit	6M Visit	9M Visit	12M Visit	15M Visit	18M Visit	21M Visit	24M Visit	30M Visit	36M Visit	42M Visit	48M Visit	54M Visit	60M Visit	
	Case Report Forms															
Patient Contact Form (Form 0)	✓															
Screening Form (Form 1)	✓															
Randomization Form (Form 2)	✓															
Baseline Characteristics Form (Form 3)	✓															
Baseline Tumor Pathology Report Form (Form 4)	✓															
Initial Surgical Report Form (Form 5)	✓															
Baseline Thoracic Imaging Report Form (Form 6)	✓															
Baseline Local Imaging Report Form (Form 7)	✓															
Intervention Phase Surveillance Visit Form (Form 8)		✓*	✓	✓*	✓	✓*	✓	✓*	✓							
PROMIS® Cancer-Anxiety Questionnaire (Form 20)	✓		✓		✓		✓		✓		✓		✓		✓	✦
PROMIS® Satisfaction with Social Roles and Activities Questionnaire (Form 21)	✓		✓		✓		✓		✓		✓		✓		✓	✦
EQ-5D™ Questionnaire (Form 22)	✓		✓		✓		✓		✓		✓		✓		✓	✦
Patient Cancer Care Cost Diary (Form 23)	✓	✓*	✓	✓*	✓	✓*	✓	✓*	✓		✓		✓		✓	✦
Post-Intervention Phase Surveillance Visit Form (Form 9)										✓	✓	✓	✓	✓	✓	
Missed Surveillance Visit Form (Form 10)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Unscheduled Clinic Visit Form (Form 11)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Local Recurrence Form (Form 12)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Systemic Recurrence Form (Form 13)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Unplanned Re-Operation Form (Form 14)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Other Surgical Intervention Form (Form 15)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Adverse Event Form (Form 16)		✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Systemic Therapy Log (Form 17)	✦	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Radiation Log (Form 18)	✦	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦	✦	✦	✦	✦	✦	✦
Protocol Deviation Form (Form 19)	✦	✦†	✦†	✦†	✦†	✦†	✦†	✦†	✦†							
Early Withdrawal Form (Form 20)																✓

✓ Required
✦ As Needed
* As Per Surveillance Frequency Allocation
† As Per Imaging Modality Allocation

4.0 Baseline Visit Forms

Once informed consent has been obtained, the following CRFs are to be completed by clinical site personnel for each participant at the baseline visit. Additional CRFs may be required as indicated in the in the baseline visit CRFs.

4.1 Patient Contact Form (Form 0)

Clinical site personnel should use this form to collect complete contact information for the participant, as well as up to three alternate contacts.

> **REMINDER:** Do not submit the **Patient Contact Form (Form 0)** to the Methods Center. Store this form separately from participant study binders.

4.2 Screening Form (Form 1)

Clinical site personnel should complete this form for **each** patient who presents to the clinical site who is 18 years of age or older with a soft-tissue sarcoma who has undergone surgical excision of the tumor with curative intent.

In Part A, please indicate whether the patient meets, or does not meet, all study inclusion criteria (Questions 1 – 5). For Question 4, if the patient has not received any neoadjuvant or adjuvant radiation and / or chemotherapy, please select "N / A." If you answered "NO" to any of Questions 1 – 5, the patient should be considered "Ineligible and EXCLUDED" in Part C.

In Part B, please indicate whether the patient meets, or does not meet, any of the study exclusion criteria (Questions 6 – 15). For Question 15, please provide the "Other" reason for excluding the patient. Please note that this 'Other' reason must be approved by the Methods Center. If you answered "YES" to any of Questions 6 – 15, the patient should be considered "Ineligible and EXCLUDED" in Part C.

Once Parts A and B have been completed, please complete Part C. For Question 16, if the patient did not provide informed consent, select "NO" and provide the rationale for why the patient did not provide informed consent. If informed consent was not obtained from the patient (e.g., for screened and ineligible patients or missed patients), select "N / A."

For Question 17, specify whether the patient was "Eligible and INCLUDED," "Ineligible and EXCLUDED," or "MISSED." For "Eligible and INCLUDED" patients, please complete Questions 17 – 19. For "Ineligible and EXCLUDED" or "MISSED" patients, please complete Question 17 and include any additional comments in Question 20.

If a patient has already commenced post-operative surveillance and was not screened prior to beginning post-operative surveillance (i.e., not approached for consent), this patient should be considered "MISSED." Please complete a screening form for this patient, completing Parts A and B and indicating the patient as "MISSED" on Question 17.

4.3 Randomization Form (Form 2)

Clinical site personnel should complete this form at the time of randomization.

1. **Peri-Operative Chemotherapy:** Please indicate whether the participant has received any peri-operative (neoadjuvant or adjuvant) chemotherapy.

REMINDER: Please complete this question prior to randomization as this information will be required to properly stratify the participant.

2. **Surveillance Arm:** Upon randomizing the participant in the randomization system, please indicate the surveillance arm to which the participant was randomized.
3. **Initials:** Please indicate the first and last initials of the individual who completed the randomization.
4. **Comments:** Please provide any other relevant comments, if applicable.

4.4 Baseline Characteristics Form (Form 3)

This form is divided into two sections: Patient-Administered Questions and Research Personnel-Administered Questions. Clinical site personnel should ensure all questions on this form are complete for each included participant at the baseline visit. Clinical research personnel should be mindful that the questions in Part A are not all readily available in a participant's medical records / chart and need to be completed by the participant (Questions 1-21).

0. **Date of Baseline Visit:** Please have the participant enter the date of their baseline visit in DD/MM/YYYY format.

Part A: PATIENT-ADMINISTERED QUESTIONS

1. **Date of Birth:** Please have the participant enter their date of birth in DD/MM/YYYY format.
2. **Date of Cancer Diagnosis:** Please have the participant enter their initial date of cancer diagnosis in DD/MM/YYYY format.
3. **Biological Sex:** Please have the participant indicate whether they are biologically male or female.
4. **Self-Reported Gender:** Please have the participant indicate the gender they identify with.
5. **Race / Ethnicity:** Please have the participant indicate the race or ethnicity with which they most identify (select one only). Please specify if either "Other" or "Mixed" are selected.
6. **Height:** Please have the participant enter their height and indicate the unit of measurement (inches [in] or centimeters [cm]).
7. **Weight:** Please have the participant enter their weight and indicate the unit of measurement (pounds [lbs] or kilograms [kg]).
8. **Employment Status:** Please have the participant indicate whether they are currently employed or not. If "Yes," have them list their current occupation.
9. **Education:** Please have the participant indicate the highest level of education they have received (select one only).
10. **Household Income:** Please have the participant select their yearly household income and indicate the appropriate currency (select one only). Alternatively, please have them indicate if they would prefer not to answer.
11. **Marital Status:** Please have the participant select their marital status or if they would prefer not to answer (select one only).

12. **Travel Time:** Please have the participant select how long it typically takes them to travel to the clinic for an appointment related to their soft-tissue sarcoma.
13. **Mode of Transportation:** Please have the participant select the mode of transportation they typically use to travel to the clinic for an appointment related to their soft-tissue sarcoma.
14. **Medical Insurance Coverage:** Please have the participant indicate whether they have medical insurance coverage. If "Yes," please specify the type of insurance the participant has.
15. **Medical Items Insured:** Please have the participant indicate which items are insured and the percentage of insured items that the insurance covers. Alternatively, please indicate if the participant would prefer not to answer the percentage the insurance covers.
16. **Medical History:** Please have the participant select all relevant disease of which they have a medical history.
17. **Tobacco Use:** Please have the participant indicate whether they use tobacco products. Please have them select "Yes, Current User" if they consider themself a regular user of tobacco products, as per their discretion. Please have them select "Yes, Former User" if applicable and specify the age they began using tobacco products regularly and the age they quit.
18. **Recreational Drug Use:** Please have the participant indicate whether they use recreational drugs. If "Yes," please have them specify the type of drug, as well as the frequency by entering the number of times and indicating the appropriate unit of measurement (per week or per month).
19. **Alcohol Consumption:** Please have the participant indicate whether they consume alcohol. If "Yes," please have them specify the frequency by entering the number of drinks and indicating the appropriate unit of measurement (per week or per month).
20. **Mental Health Support:** Please have the participant indicate whether they are receiving any mental health support (select all the apply). If "Medication," please have them specify the types of medication the participant currently uses.
21. **Medication Use:** Please have the participant indicate whether they are taking any of the listed medications (select all that apply).

Part B: RESEARCH PERSONNEL-ADMINISTERED QUESTIONS

22. **Biopsy Prior to Initial Surgery:** Please indicate whether a biopsy was performed prior to the participant's initial surgery. If "Yes," please specify the type of biopsy performed.
23. **Neoadjuvant Cancer Therapies:** Please indicate whether the participant has undergone any neoadjuvant cancer therapies. If they have undergone "Neoadjuvant Systemic Therapy," please complete a **Systemic Therapy Log (Form 17)**. If they have undergone "Neoadjuvant Radiation," please complete a **Radiation Log (Form 18)**.
24. **Adjuvant Cancer Therapies:** Please indicate whether the participant has undergone any adjuvant cancer therapies. If they have undergone "Adjuvant Systemic Therapy," please complete a **Systemic Therapy Log (Form 17)**. If they have undergone "Adjuvant Radiation," please complete a **Radiation Log (Form 18)**.
25. **Location of Tumor:** Please indicate the anatomical location of the participant's initial soft-tissue tumor. Specify both the Side and Position of the initial soft-tissue tumor.
26. **Completion of Patient Quality of Life Surveys:** Please indicate whether the patient quality of life surveys were completed at the baseline visit.

27. **Acceptable Visit Windows:** Please indicate whether the acceptable visit windows have been calculated using the *SAFETY Participant Visit Window Tracker*. If "No," please specify why this was not done.
28. **Educational Content:** Please indicate whether the patient was educated on how to self-examine for a local recurrence of their soft-tissue tumor. If "No," please specify why this was not done.
29. **Ad Hoc Clinic Visit:** Please indicate whether the participant was advised that they can schedule an ad hoc clinic visit anytime they are concerned with the status of their health. If "No," please specify why this was not done.
30. **Patient Cost Care Diary:** Please indicate whether the participant was provided with a **Patient Cancer Care Costs Diary (Form 23)** to bring home. If "No," please specify why this was not done.
31. **First Study 'Intervention Phase' Visit:** Please indicated whether the participant's first 'intervention phase' visit (either 3-Month or 6-Month) was scheduled at the time of the baseline visit. If "No," please specify why this was not done. If "Yes," please specify the date of the participant's first 'intervention phase' visit in DD/MM/YYYY format.
32. **Comments:** Please provide any other relevant comments, if applicable.

4.5 Baseline Tumor Pathology Form (Form 4)

Clinical site personnel should complete all questions on this form for each included participant at the baseline visit using the tumor pathology report that was issued following the participant's initial surgery to resect the tumor.

0. **Baseline Pathology Report Date:** Please enter the date of the issued tumor pathology report that was used to complete the remainder of this CRF in DD/MM/YYYY format.
1. **Name of Pathologist:** Please provide the name of the pathologist that issued the participant's tumor pathology report in 'First Name, Last Name' format. If there were multiple pathologists, please designate the most responsible pathologist.
2. **Pathological Diagnosis:** Please select the corresponding code for the pathological diagnosis as per the issued tumor pathology report. Further details of the pathological diagnosis can be left in the 'Diagnosis Description' text field. For pathological diagnoses that state "describe above," it is required that you provide further details in the 'Diagnosis Description' text field.
3. **Tumor Grade:** Please indicate the grade of the participant's soft-tissue tumor. If "Grade 1," please complete a **Protocol Deviation Form (Form 19)**.
4. **Tumor Stage:** Please indicate the stage of the participant's soft-tissue tumor. If "Stage IA," "Stage IB" or "Stage II," please complete a **Protocol Deviation Form (Form 19)**.
5. **Soft-Tissue Mass Dimensions:** Please indicate the width, length, and depth of the initial soft-tissue tumor in centimeters [cm].
6. **Location of Soft-Tissue Mass:** Please indicate the location(s) of the initial soft-tissue tumor (select all that apply).
7. **Number of Compartments:** Please indicate how many compartments were involved in the initial soft-tissue tumor.
8. **Overall Margins:** Please indicate whether the overall surgical margins of the initial soft-tissue tumor were negative, microscopically positive, or grossly positive.

9. **Closest Margin:** Please indicate the closest margin of the initial resected soft-tissue tumor in centimeters [cm].
10. **Bone Involvement:** Please indicate whether the initial soft-tissue tumor had bone involvement.
11. **Joint Involvement:** Please indicate whether the initial soft-tissue tumor had joint involvement.
12. **Skin Involvement:** Please indicate whether the initial soft-tissue tumor had skin involvement.
13. **Fascia Involvement:** Please indicate whether the initial soft-tissue tumor had fascia involvement.
14. **Muscle Involvement:** Please indicate whether the initial soft-tissue tumor had muscle involvement.
15. **Vascular Involvement:** Please indicate whether the initial soft-tissue tumor had vascular involvement that required vascular resection.
16. **Nerve Involvement:** Please indicate whether the initial soft-tissue tumor had nerve involvement that required nerve resection.
17. **Lymph Nodes Examined:** Please indicate whether the lymph nodes were examined. If "Yes," please specify the number of nodes and whether they were positive for malignancy.
18. **Comments:** Please provide any other relevant comments, if applicable.

4.6 Initial Surgical Report Form (Form 5)

Clinical site personnel should complete all questions on this form for each included participant at the baseline visit using the surgical report from the participant's initial surgery to resect the soft-tissue tumor.

0. **Date of Initial Surgery:** Please enter the date of the participant's initial surgery to resect the soft-tissue tumor in DD/MM/YYYY format.
1. **Name of Attending Surgeon:** Please indicate the name of the attending surgeon in 'First Name, Last Name' format. If there were multiple treating surgeons, please designate the most responsible surgeon.
2. **Performed Majority of Surgery:** Please indicate who performed the majority of the initial surgery to resect the soft-tissue tumor (select one only).
3. **Total Operative Time:** Please indicate the total operative time for the initial surgery to resect the soft-tissue tumor in hours and minutes.
4. **Procedure(s):** Please indicate which procedure(s) was / were conducted during the participant's initial surgery to resect the soft-tissue tumor. If "Wide resection + reconstruction," please specify whether the limb was reconstructed with an allograft or endoprosthesis. If "Amputation," please specify which limb was amputated. Please specify the type of procedure if "Other" is selected.
5. **Anesthesia:** Please indicate the anesthesia that was used during the participant's initial surgery. Please specify if "Other" is selected.
6. **Length of Incision:** Please indicate the total length of the incision in centimeters [cm] during the participant's initial surgery.
7. **Skin Excised:** Please indicate how much skin was excised during the participant's initial surgery.
8. **Muscle Excised:** Please indicate how much muscle was excised during the participant's initial surgery.

9. **Fascial Tissue Excised:** Please indicate how much fascial tissue was excised during the participant's initial surgery.
10. **Bone Excised:** Please indicate how much bone was excised during the participant's initial surgery.
11. **Tumor Intact on Excision:** Please indicate whether the tumor was intact upon excision during the participant's initial surgery. If "No," specify the type of gross breach.
12. **Surgical Wound Closure:** Please indicate the type(s) of surgical wound closure technique(s) that was / were used during the participant's initial surgery (select all that apply). Please specify if "Other" is selected.
13. **Date of Hospital Discharge:** Please enter the date of hospital discharge following the participant's initial surgery to resect the soft-tissue tumor in DD/MM/YYYY format.
14. **Planned Additional Procedures:** Please indicate whether any additional procedures are planned for the included soft-tissue tumor at the time of the baseline visit. If "Yes," please specify the additional procedure(s) that is / are planned and complete a **Protocol Deviation Form (Form 19)**.
15. **Comments:** Please provide any relevant comments from the surgeon's operative note.

4.7 Baseline Thoracic Imaging Form (Form 6)

Clinical site personnel should complete all questions on this form for each included participant at the baseline visit using the radiology report from the participant's baseline thoracic imaging prior to the participant's initial surgery to resect the soft-tissue tumor. If the participant underwent neoadjuvant chemotherapy or radiation, please complete this form using imaging obtained immediately prior to surgery, not at initial presentation.

0. **Date of Baseline Thoracic Imaging:** Please enter the date that the baseline thoracic imaging was obtained in DD/MM/YYYY format.
1. **Name of Radiologist:** Please provide the name of the radiologist that reviewed the participant's baseline thoracic imaging in 'First Name, Last Name' format. If there were multiple radiologists, please designate the most responsible radiologist.
2. **Type of Thoracic Imaging:** Please indicate the type of thoracic imaging that was conducted.
3. **Initial Indeterminate Nodules:** Please indicate whether any indeterminate nodules were found on the baseline thoracic imaging report. If "Yes," please specify the number of indeterminate nodules and whether they were followed and determined to be stable. If "No," the nodules were not determined stable, please complete a **Protocol Deviation Form (Form 19)**.
4. **Comments:** Please provide any relevant comments from the radiologist's baseline thoracic imaging report.

4.8 Baseline Local Imaging Form (Form 7)

Clinical site personnel should complete all questions on this form for each included participant at the baseline visit using the radiology report from the participant's baseline local imaging prior to the participant's initial surgery to resect the soft-tissue tumor. If the participant underwent neoadjuvant chemotherapy or radiation, please complete this form using imaging obtained immediately prior to surgery, not at initial presentation.

0. **Date of Baseline Local Imaging:** Please enter the date that the baseline local imaging was obtained in DD/MM/YYYY format.
1. **Name of Radiologist:** Please provide the name of the radiologist that reviewed the participant's baseline local imaging in 'First Name, Last Name' format. If there were multiple radiologists, please designate the most responsible radiologist.
2. **Type of Local Imaging:** Please indicate the type of local imaging that was conducted.
3. **Comments:** Please provide any relevant comments from the radiologist's baseline local imaging report.

5.0 Intervention Phase Visit Forms

At minimum, the **Intervention Phase Surveillance Visit Form (Form 8)** should be completed by clinical site personnel for each participant at their 'intervention phase' visit. Each participant should also be provided with a new **Patient Cancer Care Costs Diary (Form 23)** at each 'intervention phase' visit. At the 6-Month, 12-Month, 18-Month and 24-Month 'intervention phase' visits, each participant should also complete the three participant questionnaires.

5.1 Intervention Phase Surveillance Visit Form (Form 8)

Clinical site personnel should complete all questions on this form for each included participant at each 'intervention phase' study visit. The appropriate 'intervention phase' surveillance visit being reported should be recorded in the upper right-hand corner on *each* **Intervention Phase Surveillance Visit Form (Form 8)** page. Clinical research personnel should be mindful that not all answers to questions are readily available in a participant's medical records / chart and may need to be directly asked to the participant (Questions 10, 11).

0. **Date of 'Intervention Phase' Visit:** Please enter the date of the participant's 'intervention phase' visit being reported in DD/MM/YYYY format.
1. **Visit Conducted:** Please indicate how the 'intervention phase' visit being reported was conducted / how the participant's information was collected.
2. **Acceptable Visit Window:** Please indicate whether the study visit falls within the acceptable visit window. If "No," please specify why not.
3. **Completion of Patient Quality of Life Surveys:** Please indicate whether the patient quality-of-life surveys were completed at the 'intervention phase' visit. For participants randomized to 'intervention phase' visits every three months, please select "Not Applicable" if reporting on the 3-Month, 9-Month, 15-Month or 21-Month visits.
4. **Patient Cost Care Diary:** Please indicate whether the participant returned the completed **Patient Cancer Care Costs Diary (Form 23)** that was given to them at their previous visit.
5. **Visit Status:** Please indicate whether the study visit is complete (i.e., if the **Intervention Phase Surveillance Visit Form (Form 8)** is complete as well as any relevant patient questionnaires).
6. **Additional Orthopaedic Oncology Visits Since Last Study Visit:** Please indicate if the participant has attended sarcoma clinic to follow-up with the orthopaedic oncologist since the last study visit. If "Yes," please record the total number of additional follow-up visits since the last study visit and complete both an **Unscheduled Clinic Visit Form (Form 11)** and a **Protocol Deviation Form (Form 19)**.

7. **Additional Thoracic Imaging Since Last Study Visit:** Please indicate whether the participant has obtained any additional thoracic imaging (in addition to what is required for the study) since the last study visit. If "Yes," please complete a **Protocol Deviation Form (Form 19)**.
8. **Appropriate Thoracic Imaging Conducted Since Last Study Visit:** Please indicate whether the appropriate thoracic imaging (the thoracic imaging according to the randomized surveillance arm) has been obtained for the participant since the last study visit. If "Yes," please specify the date of the most recent thoracic imaging in DD/MM/YYYY format, as well as the type of thoracic imaging obtained and where the thoracic imaging was conducted. If "No," please specify why this was not done and complete a **Protocol Deviation Form (Form 19).**
9. **Local Imaging Conducted Since Last Study Visit:** Please indicate whether any local imaging of the initial soft-tissue sarcoma has been obtained for the participant since the last study visit. If "Yes," please specify the date of the most recent local imaging in DD/MM/YYYY format, as well as the type of local imaging obtained and where the local imaging was conducted. If "No," please specify why this was not done.
10. **Return to Pre-Cancer Level of Work:** Please indicate whether the participant had returned to their pre-cancer level of work. If "Yes," please specify the date that the participant returned to their pre-cancer level of work in DD/MM/YYYY format. Please select "Previously Reported" if the participant had returned to their pre-cancer level of work at a previous study visit.

REMINDER: You cannot select "Previously Reported" if it is the participant's first 'intervention phase' visit.

11. **Return to Pre-Cancer Level of Activity:** Please indicate whether the participant had returned to their pre-cancer level of activity. If "Yes," please specify the date that the participant returned to their pre-cancer level of activity in DD/MM/YYYY format. Please select "Previously Reported" if the participant had returned to their pre-cancer level of activity at a previous study visit.

REMINDER: You cannot select "Previously Reported" if it is the participant's first 'intervention phase' visit.

12. **New Local Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any <u>new</u> local recurrences related to the primary soft-tissue sarcoma since the last study visit. If "Yes," please specify the number of new local recurrences since the last study visit and complete a **Local Recurrence Form (Form 12)** for each new local recurrence.
13. **New Systemic Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any <u>new</u> systemic recurrences (metastases) related to the primary soft-tissue sarcoma since the last study visit. If "Yes," please specify the number of new systemic recurrences since the last study visit and complete a **Systemic Recurrence Form (Form 13)** for each new systemic recurrence.
14. **Unplanned Re-Operations Since Last Study Visit:** Please indicate whether the participant has undergone any unplanned re-operations and / or additional procedures at the initial tumor

site since the last study visit. If "Yes," please specify the number of unplanned re-operations / additional procedures since the last study visit and complete an **Unplanned Re-Operations Form (Form 14)** for each new procedure.

15. **Other Surgical Interventions Since Last Study Visit:** Please indicate whether the participant has undergone any other surgical interventions outside of the initial tumor site but related to the initial cancer since the last study visit. If "Yes," please specify the number of other surgical interventions since the last study visit and complete an **Other Surgical Interventions Form (Form 15)** for each new procedure.
16. **New Adverse Events Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any new adverse events since the last study visit. If "Yes," please specify the number of new adverse events since the last study visit and complete an **Adverse Event Form (Form 16)** for each new event.
17. **Pain Medication**: Please indicate whether the patient is currently taking any pain medication. If "Yes," please specify all that apply.
18. **Educational Content:** Please indicate whether the patient was reminded of how to self-examine for a local recurrence of their soft-tissue tumor. If "No," please specify why this was not done.
19. **Ad Hoc Clinic Visit:** Please indicate whether the participant was reminded that they can schedule an ad hoc clinic visit anytime they are concerned with the status of their health. If "No," please specify why this was not done.
20. **Patient Cost Care Diary:** Please indicate whether the participant was provided with a **Patient Cancer Care Costs Diary (Form 23)** to bring home. If "No," please specify why this was not done.
21. **Next Study Visit:** Please indicated whether the participant's next study visit was scheduled at the time of this 'intervention phase' visit. If "No," please specify why this was not done. If "Yes," please specify the date of the participant's next study visit in DD/MM/YYYY format.
22. **Comments:** Please provide any other relevant comments, if applicable.

5.2 Participant Questionnaires

It is preferred that all participant questionnaires are self-administered (i.e., completed individually by the participant). However, instances may arise that require clinical site personnel to administer the questionnaires, such as at times when a participant is unable to record their responses. For interviewer-administered questionnaires, clinical research personnel should directly read the questionnaire questions to the participant. The participant's responses can then be recorded on the relevant participant questionnaire.

REMINDER: A family member or friend cannot provide responses on behalf of the participant or prompt them with respect to question responses.

Properly administering a questionnaire can be surprisingly difficult. Many of the approaches clinical site personnel might intuitively take can cause methodological concerns. The following tips may help clinical site personnel develop some techniques to avoid causing methodological or data quality issues:

- **Never Help a Participant Develop an Answer:** There are no right or wrong answers. Participants are simply asked to answer the questions as they understand them, and to pick

the option they believe best expresses their opinion. Participants may ask if their given response is correct. It may be instinctual to be helpful and reply 'Yes, that is correct.' However, this would compromise the validity of their responses. It must be made known to participants that it is their choice, and that whatever they choose is appropriate. A suitable answer to a participant asking if their response is correct would be 'There is no right or wrong response – we are interested in what you think so we ask that you pick the response that you believe best describes your opinion.'

- **Be Neutral:** Maintain a neutral composure when reviewing or responding to a participant's questionnaire responses. Be careful to ensure that nothing in your words or mannerisms implies surprise, sympathy, approval, or disapproval towards the participant's responses.
- **Never Explain, Elaborate or Paraphrase Questionnaire Items:** Do not rephrase a question if a participant asks for clarification. Instead, inform the participant that the meaning of the question is whatever they understand it to be.
- **Watch for Inconsistencies:** If some of a participant's responses contradict each other, verify the responses by asking the participant to confirm that they are correct.

5.2.1 PROMIS® Cancer Anxiety Questionnaire (Form 20)

The **PROMIS® Cancer Anxiety Questionnaire (Form 20)** is a validated, 22-item questionnaire that assesses patient self-reported fear (fearfulness, panic), anxious misery (worry, dread), hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart, dizziness). The questionnaire is to be independently completed by each participant at the following study visits: Baseline, 6-Month, 12-Month, 18-Month, 24-Month, 36-Month, 48-Month and 60-Month study visits.

5.2.2 PROMIS® Satisfaction with Social Roles & Activities Questionnaire (Form 21)

The **PROMIS® Satisfaction with Social Roles & Activities Questionnaire Short Form 8A (Form 21)** is a validated, eight-item questionnaire that assesses patient overall satisfaction with performing one's usual social roles and activities. The questionnaire is to be independently completed by each participant at the following study visits: Baseline, 6-Month, 12-Month, 18-Month, 24-Month, 36-Month, 48-Month and 60-Month study visits.

5.2.2 EQ-5D™Questionnaire (Form 22)

The **EQ-5D™ Questionnaire (Form 22)** is a validated, 6-item questionnaire that assesses patient quality of life and overall health status across five dimensions (mobility, self-care, usual activities, pain / discomfort, and anxiety / depression). The questionnaire is to be independently completed by each participant at the following study visits: Baseline, 6-Month, 12-Month, 18-Month, 24-Month, 36-Month, 48-Month and 60-Month study visits.

5.3 Patient Cancer Care Costs Diary (Form 23)

The **Patient Cancer Care Costs Diary (Form 23)** evaluates costs associated with health services as a result of or related to the participant's sarcoma care. Clinical research personnel should provide the participant with a new diary at each visit for them to complete at home and return at their next visit (irrespective of whether the participant was randomized to every three months or every six months visits). Please indicate the appropriate surveillance visit the diary is being returned at in the upper right-hand corner on *each* **Patient Cancer Care Costs Diary (Form 23)** page.

0. **Date of Completion:** Please enter the date the participant was given the diary in DD/MM/YYYY format.
1. **Unable to Perform Usual Household Activities:** Please have the participant indicate the number of days they were unable to perform their usual household activities since their last study visit.
2. **Unable to Perform Usual Leisure Activities:** Please have the participant indicate the number of days they were unable to perform their usual leisure activities since their last study visit.
3. **Change in Employment Status:** Please have the participant indicate whether there has been any change in employment status (either restarted work or stopped work) since their last study visit. If "Yes," please have the participant specify the change in their employment status.
4. **Missed Work Since Last Study Visit:** Please have the participant indicate whether they have missed any work since their last study visit. If the participant is not currently employed, the participant should select "Not Applicable" and can skip to Question 6. If "Yes," please have the participant specify how many days of work they have missed.
5. **Worked at Partial Duties Since Last Study Visit:** Please have the participant indicate whether they have worked at only partial duties since their last study visit. If "Yes," please have the participant specify how many days of work they have worked at only partial duties, as well as estimate the percentage of the participant's regular duties that they performed.
6. **Visit to Family Physician Since Last Study Visit:** Please have the participant indicate whether they visited the family physician for health services required as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each visit to the family physician as a separate visit entry:
    a. **Date of Visit:** Please have the participant enter the date of the visit to the family physician in DD/MM/YYYY format.
    b. **Reason for Visit:** Please have the participant indicate the reason for the visit to the family physician. If "Other," please have the participant specify.
    c. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost the participant may have incurred as a result of the visit to the family physician, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.
7. **Visit to Emergency Room / Urgent Care Since Last Study Visit:** Please have the participant indicate whether they visited the emergency room or urgent care center for health services required as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each visit to the emergency room / urgent care center as a separate visit entry:
    a. **Date of Visit:** Please have the participant enter the date of the visit to the emergency room / urgent care center in DD/MM/YYYY format.
    b. **Reason for Visit:** Please have the participant indicate the reason for the visit to the emergency room / urgent care center. If "Other," please have the participant specify.
    c. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost they have incurred as a result of the visit to the emergency room / urgent care center, as well as indicate the currency in which the cost was incurred. If there were no out of

pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.

8. **Visit to Medical Oncologist Since Last Study Visit:** Please have the participant indicate whether they visited the medical oncologist for health services required as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each visit to the medical oncologist as a separate visit entry:
    a. **Date of Visit:** Please have the participant enter the date of the visit to the medical oncologist in DD/MM/YYYY format.
    b. **Reason for Visit:** Please have the participant indicate the reason for the visit to the medical oncologist. If "Other," please have the participant specify.
    c. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost they have incurred as a result of the visit to the medical oncologist, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.
9. **Visit to Radiation Oncologist Since Last Study Visit:** Please have the participant indicate whether they visited the radiation oncologist for health services required as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each visit to the radiation oncologist as a separate visit entry:
    a. **Date of Visit:** Please have the participant enter the date of the visit to the radiation oncologist in DD/MM/YYYY format.
    b. **Reason for Visit:** Please have the participant indicate the reason for the visit to the radiation oncologist. If "Other," please have the participant specify.
    c. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost they have incurred as a result of the visit to the radiation oncologist, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.
10. **Visit to Surgical Oncologist Since Last Study Visit:** Please have the participant indicate whether they visited a surgical oncologist (other than the orthopaedic oncologist) for health services required as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each visit to the surgical oncologist as a separate visit entry:
    a. **Date of Visit:** Please have the participant enter the date of the visit to the surgical oncologist in DD/MM/YYYY format.
    b. **Field of Surgical Specialization:** Please have the participant enter the surgical oncologist's field of specialization.
    c. **Reason for Visit:** Please have the participant indicate the reason for the visit to the surgical oncologist. If "Other," please have the participant specify.
    d. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost they may have incurred as a result of the visit to the surgical oncologist, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.
11. **Visit to Other Specialist Since Last Study Visit:** Please have the participant indicate whether they visited the any other specialist for health services required as a result of or

related to their cancer care since their last study visit. If "Yes," please have the participant enter each visit to any other specialist as a separate visit entry:

a. **Date of Visit:** Please have the participant enter the date of the visit to any other specialist in DD/MM/YYYY format.
b. **Field of Specialization:** Please have the participant enter the specialist's field of specialization.
c. **Reason for Visit:** Please have the participant indicate the reason for the visit to the other specialist.
d. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost they may have incurred as a result of the visit to any other specialist, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.

12. **Prescriptions Filled / Purchased Since Last Study Visit:** Please have the participant indicate whether they had any prescriptions for medications or purchased over-the-counter medications as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each prescription / medication as a separate entry:
    a. **Medication Name:** Please have the participant enter the name of the medication.
    b. **Dosage:** Please have the participant enter the medication dosage, as well as indicate the dosage unit (grams [g] or micrograms [mg]).
    c. **Daily Frequency:** Please have the participant enter the daily frequency of the medication (i.e., how many times per day the participant takes the medication).
    d. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost the participant may have incurred as a result of filling the prescription or purchasing the over-the-counter medication, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.
13. **Assistance at Home Since Last Study Visit:** Please have the participant indicate whether they obtained any assistance at home (such as paid nursing / caregiver) as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each type of assistance as a separate entry:
    a. **Type of Assistance:** Please have the participant indicate the type of home assistance obtained. If "Other," please have the participant specify.
    b. **Duties Performed:** Please have the participant indicate the duties performed. If "Other," please have the participant specify.
    c. **No. of Hours:** Please have the participant enter the number of hours of home assistance.
    d. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost the participant may have incurred as a result of obtaining any assistance at home, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.
14. **Other Expenses Incurred Since Last Study Visit:** Please have the participant indicate whether they incurred any other expenses (such as transportation, accommodations, or meal expenses) as a result of or related to their cancer care since their last study visit. If "Yes," please have the participant enter each type of expense incurred as a separate entry:

a. **Type of Other Expense:** Please have the participant indicate the type of expense incurred. If "Other," please have the participant specify.
b. **Out of Pocket Cost:** Please have the participant enter any out-of-pocket cost they may have incurred as a result of any other expense, as well as indicate the currency in which the cost was incurred. If there were no out of pocket costs (e.g., if costs were covered by insurance), have the participant write zero here.

6.0 Post-Intervention Phase Visit Forms

The **Post-Intervention Phase Surveillance Visit Form (Form 9)** should be completed by clinical site personnel for each participant at their 'post-intervention phase' visit. Each participant should also be provided with a new **Patient Cancer Care Costs Diary (Form 23)** at each 'post-intervention phase' visit. At the 36-Month, 48-Month and 60-Month 'post-intervention phase' visits, each participant should also complete the three participant questionnaires.

6.1 Post-Intervention Phase Surveillance Visit Form (Form 9)

Clinical site personnel should complete all questions on this form for each included participant at each 'post-intervention phase' study visit. The appropriate 'post-intervention phase' surveillance visit being reported should be recorded in the upper right-hand corner on *each* **Post-Intervention Phase Surveillance Visit Form (Form 9)** page. Clinical research personnel should be mindful that not all answers to questions are readily available in a participant's medical records / chart and may need to be directly asked to the participant (Questions 10, 11).

0. **Date of 'Post-Intervention Phase' Visit:** Please enter the date of the participant's 'post-intervention phase' visit being reported in DD/MM/YYYY format.
1. **Visit Conducted:** Please indicate how the 'post-intervention phase' visit being reported was conducted / how the participant's information was collected.
2. **Acceptable Visit Window:** Please indicate whether the study visit falls within the acceptable visit window. If "No," please specify why not.
3. **Completion of Patient Quality of Life Surveys:** Please indicate whether the patient quality-of-life surveys were completed at the 'post-intervention phase' visit. Please select "Not Applicable" if reporting on the 30-Month, 42-Month or 54-Month visits.
4. **Patient Cost Care Diary:** Please indicate whether the participant returned the completed **Patient Cancer Care Costs Diary (Form 23)** that was given to them at their previous visit.
5. **Visit Status:** Please indicate whether the study visit is complete (i.e., if the **Post-Intervention Phase Surveillance Visit Form (Form 9)** is complete as well as any relevant patient questionnaires).
6. **Additional Orthopaedic Oncology Visits Since Last Study Visit:** Please indicate if the participant has attended sarcoma clinic to follow-up with the orthopaedic oncologist since the last study visit. If "Yes," please record the total number of additional follow-up visits since the last study visit and complete an **Unscheduled Clinic Visit Form (Form 11)** for each visit.
7. **Thoracic Imaging Since Last Study Visit:** Please indicate whether the participant has obtained any additional thoracic imaging (in addition to what is required for the study) since the last study visit. If "No," please specify why not. If "Yes," please indicate the date of the most recent thoracic imaging in DD/MM/YYYY format, as well as the type of thoracic imaging obtained and where the thoracic imaging was conducted.

8. **Additional Thoracic Imaging Since Last Study Visit:** Please indicate if the participant has obtained additional thoracic imaging since the last study visit that results in their thoracic imaging being more frequent than every six (6) months. If "Yes," please specify why this occurred.
9. **Local Imaging Conducted Since Last Study Visit:** Please indicate whether any local imaging of the initial soft-tissue sarcoma has been obtained for the participant since the last study visit. If "No," please specify why not. If "Yes," please indicate the date of most recent local imaging in DD/MM/YYYY format, as well as the type of local imaging obtained and where the local imaging was conducted.
10. **Return to Pre-Cancer Level of Work:** Please indicate whether the participant had returned to their pre-cancer level of work. If "Yes," please specify the date that the participant returned to their pre-cancer level of work in DD/MM/YYYY format. Please select "Previously Reported" if the participant had returned to their pre-cancer level of work at a previous study visit.
11. **Return to Pre-Cancer Level of Activity:** Please indicate whether the participant had returned to their pre-cancer level of activity. If "Yes," please specify the date that the participant returned to their pre-cancer level of activity in DD/MM/YYYY format. Please select "Previously Reported" if the participant had returned to their pre-cancer level of activity at a previous study visit.
12. **New Local Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any new local recurrences related to the primary soft-tissue sarcoma since the last study visit. If "Yes," please specify the number of new local recurrences since the last study visit and complete a **Local Recurrence Form (Form 12)** for each new local recurrence.
13. **New Systemic Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any new systemic recurrences (metastases) related to the primary soft-tissue sarcoma since the last study visit. If "Yes," please specify the number of new systemic recurrences since the last study visit and complete a **Systemic Recurrence Form (Form 13)** for each new systemic recurrence.
14. **Unplanned Re-Operations Since Last Study Visit:** Please indicate whether the participant has undergone any unplanned re-operations and / or additional procedures at the initial tumor site since the last study visit. If "Yes," please specify the number of unplanned re-operations / additional procedures since the last study visit and complete an **Unplanned Re-Operations Form (Form 14)** for each new procedure.
15. **Other Surgical Interventions Since Last Study Visit:** Please indicate whether the participant has undergone any other surgical interventions outside of the initial tumor site but related to the initial cancer since the last study visit. If "Yes," please specify the number of other surgical interventions since the last study visit and complete an **Other Surgical Interventions Form (Form 15)** for each new procedure.
16. **New Adverse Events Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any new adverse events since the last study visit. If "Yes," please specify the number of new adverse events since the last study visit and complete an **Adverse Event Form (Form 16)** for each new event.
17. **Pain Medication**: Please indicate whether the patient is currently taking any pain medication. If "Yes," please specify all that apply.

18. **Patient Cost Care Diary:** Please indicate whether the participant was provided with a **Patient Cancer Care Costs Diary (Form 23)** to bring home. If "No," please specify why this was not done.
19. **Next Study Visit:** Please indicated whether the participant's next study visit was scheduled at the time of this 'intervention phase' visit. If "No," please specify why this was not done. If "Yes," please specify the date of the participant's next study visit in DD/MM/YYYY format. Please select "Not Applicable" if reporting on the 60-Month visit.
20. **Comments:** Please provide any other relevant comments, if applicable.
21. **Planned Re-Operations:** Please indicate whether any re-operations and / or additional procedures at the initial tumor site have been planned for the participant after the 60-month post-intervention phase surveillance visit. If "Yes," please specify whether the re-operations are to operatively manage a local recurrence at the initial tumor site.

REMINDER: Please answer this question only if it is the participant's 60-Month 'post-intervention phase' study visit.

22. **Planned Other Surgical Interventions:** Please indicate whether any other surgical interventions have been planned for the participant 60-month after the post-intervention phase surveillance visit. If "Yes," please specify whether the surgical interventions are to operatively manage a systemic recurrence of the patient's soft-tissue tumor.

REMINDER: Please answer this question only if it is the participant's 60-Month 'post-intervention phase' study visit.

7.0 As Needed Forms

Clinical site personnel should only complete the following forms if required, as described below.

7.1 Missed Surveillance Visit Form (Form 10)

Clinical site personnel should complete this form only after all measures have been exhausted to contact the participant or one of their alternate contacts during the study visit's acceptable window. The surveillance visit that was missed should be recorded in the upper right-hand corner on *each* **Missed Surveillance Visit Form (Form 10)** page.

0. **Date of Form Completion:** Please enter the date of the form was completed in DD/MM/YYYY format.
1. **Reason for Missed Visit:** Please provide a reason for the missed study visit.
2. **Confirmation of Attempts to Contact Participant:** Please indicate how the clinical site personnel attempted to contact the participant to conduct the study visit prior to marking the study visit as missed (select all that apply). If "Other," please specify.
3. **Thoracic Imaging Conducted:** Please indicate whether the appropriate thoracic imaging was still conducted even if the participant missed the study visit. If "No," and the missed study visit falls within the 'intervention phase', please specify why not and complete a **Protocol Deviation Form (Form 19)**. If "Yes," please indicate the date of the most recent thoracic imaging in DD/MM/YYYY format, as well as the type of thoracic imaging obtained and where the thoracic imaging was conducted.

4. **Local Imaging Conducted:** Please indicate whether the appropriate local imaging was still conducted even if the participant missed the study visit. If "No," please specify why not. If "Yes," please indicate the date of the most recent local imaging in DD/MM/YYYY format, as well as the type of local imaging obtained and where the local imaging was conducted.
5. **Comments:** Please provide any other relevant comments on the missed visit or the patient's current status.

7.2 Unscheduled Clinic Visit Form (Form 11)

Clinical site personnel should complete this form only if the participant attends clinic for an additional visit that does not follow the appropriate surveillance clinic visit follow-up schedule determined at randomization. The next scheduled surveillance should be recorded in the upper right-hand corner on *each* **Unscheduled Clinic Visit Form (Form 11)** page.

0. **Date of Unscheduled Clinic Visit:** Please enter the date of the unscheduled clinic visit in DD/MM/YYYY format.
1. **Reason for Unscheduled Visit:** Please indicate why the unscheduled clinic visit occurred. If "Other," please specify.
2. **Unscheduled Thoracic Imaging Obtained:** Please indicate whether unscheduled thoracic imaging was also obtained at the unscheduled clinic visit. If "Yes," and the unscheduled clinic visit falls within the 'intervention phase', please complete a **Protocol Deviation Form (Form 19)**.
3. **Change to Patient's Current Status:** Please indicate if there has been any change to the patient's current status, including local or systemic recurrences, surgical procedures, or adverse events. If "Yes," complete questions 5-9 and provide any additional comments in 4. If "No," please provide any additional comments in 4 and then form is complete.
4. **Comments:** Please provide any other relevant comments, if applicable.
5. **New Local Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any new local recurrences related to the primary soft-tissue sarcoma since the last study visit. If "Yes," please complete a **Local Recurrence Form (Form 12)** for each new local recurrence and ensure that each new local recurrence is counted towards the total number of new local recurrences on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.
6. **New Systemic Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any new systemic recurrences (metastases) related to the primary soft-tissue sarcoma since the last study visit. If "Yes," please complete a **Systemic Recurrence Form (Form 13)** for each new systemic recurrence and ensure that each new systemic recurrence is counted towards the total number of new systemic recurrences on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.
7. **Unplanned Re-Operations Since Last Study Visit:** Please indicate whether the participant has undergone any unplanned re-operations and / or additional procedures at the initial tumor site since the last study visit. If "Yes," please complete an **Unplanned Re-Operations Form (Form 14)** for each new procedure and ensure that each re-operation and / or additional procedure is counted towards the total number of new procedures on the next **Intervention**

Phase Surveillance Visit Form (Form 8) or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.

8. **Other Surgical Interventions Since Last Study Visit:** Please indicate whether the participant has undergone any other surgical interventions outside of the initial tumor site but related to the initial cancer since the last study visit. If "Yes," please complete an **Other Surgical Interventions Form (Form 15)** for each new procedure and ensure that each surgical intervention is counted towards the total number of new procedures on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.
9. **New Adverse Events Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any <u>new</u> adverse events since the last study visit. If "Yes," please complete an **Adverse Event Form (Form 16)** for each new event and ensure that each event is counted towards the total number of new adverse events on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.

7.3 Local Recurrence Form (Form 12)

Clinical site personnel should complete this form if the participant is diagnosed with a local recurrence. The next scheduled surveillance should be recorded in the upper right-hand corner on *each* **Local Recurrence Form (Form 12)** page.

0. **Date of Local Recurrence Confirmation:** Please enter the date that the local recurrence being reported was confirmed in DD/MM/YYYY format.
1. **First Identification of Local Recurrence:** Please indicate the method by which the local recurrence was first identified. If "Other," please specify.
2. **Biopsy Performed:** Please indicate whether a biopsy was performed.
3. **Confirmation of Local Recurrence:** Please indicate how the local recurrence was confirmed. If "Other," please specify.
4. **Local Recurrence palpability:** Please indicate if the local recurrence is palpable.
5. **Comments:** Please provide any other relevant comments, if applicable.
6. **Local Recurrence Treatment:** Please indicate how this local recurrence was treated. If "Radiation," please complete a **Radiation Log (Form 18)**. If "Systemic Therapy," please complete a **Systemic Therapy Log (Form 17)**. If "Other medical / supportive therapies," please specify. If "Operative management," please complete **Part F** of this form and an **Unplanned Re-Operation Form (Form 14).** If "Other," please specify.

REMINDER: You cannot select both "No active treatment" and any of the other response options.

7. **Re-Hospitalization for Local Recurrence:** Please indicate whether the participant was re-hospitalized for the local recurrence being reported. If "Yes," please enter the dates of hospital re-admission and discharge in DD/MM/YYYY format. If the participant was already re-hospitalized when the local recurrence being reported occurred, please select "Not applicable." Please note, if the patient died while re-hospitalized for this local recurrence, the date of death should be entered as the date of hospital discharge.

8. **Relatedness to Study Treatment Arm:** Please indicated whether the study investigator believes that the local recurrence being reported is related to the study treatment arm (i.e., the frequency of follow-up and / or imaging modality). If "possibly / probably / definitely related," please specify if this event was unexpected.

REMINDER: Adverse events related to disease recurrence (local or systemic), as well as complications resulting from treatment for disease recurrence, should be considered at least possibly related to the study treatment arm.

9. **Outcome of Local Recurrence:** Please indicate the outcome of the local recurrence. If "Ongoing," please remember to update once the outcome is known. If "Fatal," please complete an **Early Withdrawal Form (Form 24)**. If "Resolved," please specify the degree of impairment, as well as enter the date that the local recurrence resolved in DD/MM/YYYY format. If "Unresolved," please specify whether the local recurrence was unresolved at the time of "Study exit" or "Death."

REMINDER: Only one study event should have a fatal outcome. All other events should be considered unresolved at the time of the participant's death.

10. **Local Recurrence Considered Serious Adverse Event:** Please indicate if the local recurrence meets the criteria for a serious adverse event. If "No," skip to Part E (Question 10). If "Yes," please specify why it is considered a serious adverse event. If "Other," please specify.

REMINDER: A serious adverse event is any event that is fatal, immediately life threatening, requires or prolongs a hospital stay, results in persistent or significant disability / incapacity, a congenital anomaly / birth defect, or is an important medical event.

11. **Reporting of Local Recurrence to Local Ethics Committee:** Please indicate if the serious adverse event was reported to the appropriate local ethics committee. If the serious adverse event does not mee the local ethics committee's requirements for reporting, please select "Not Applicable." If "Yes," please specify the date the serious adverse event was reported in DD/MM/YYYY format, and whether any actions are required by the local ethics committee.
12. **Additional Pertinent Information:** Please provide any other information on the serious adverse event, if applicable.
13. **Imaging Taken as Part of Local Recurrence Work-Up:** Please indicate if any imaging was performed on this local recurrence. If "No," specify why not. If "Yes," please upload all relevant de-identified image(s).

REMINDER: Please refer to the *Submission of Adjudication Materials Guidelines* on how to upload adjudication materials.

14. **Clinical Notes Detailing the Diagnosis / Management of Local Recurrence:** Please indicate if any clinical notes were recorded detailing this local recurrence. If "No," specify why not. If "Yes," please upload all relevant de-identified clinic note(s).
15. **Operative Notes Detailing the Surgical Management of Local Recurrence:** Please indicate if operative notes were recorded detailing the surgical management of this local

recurrence. If the local recurrence was not treated operatively, please select "Not Applicable." If "No," specify why not. If "Yes," please complete either an **Unplanned Re-Operation Form (Form 14)** or **Other Surgical Intervention Form (Form 15)** and upload all relevant de-identified image(s).

16. **Date of Tumor Pathology Report:** Please enter the date of the issued tumor pathology report that was used to complete the remainder of this CRF is DD/MM/YYY format.
17. **Name of Pathologist:** Please provide the name of the pathologist that issued the participant's tumor pathology report in 'First Name, Last Name' format. If there were multiple pathologists, please designate the most responsible pathologist.
18. **Pathological Diagnosis:** Please select the corresponding code for the pathological diagnosis as per the issued tumor pathology report. Further details of the pathological diagnosis can be left in the 'Diagnosis Description' text field. For pathological diagnoses that state "describe above," it is required that you provide further details in the 'Diagnosis Description' text field.
19. **Tumor Grade:** Please indicate the grade of the participant's local recurrence.
20. **Tumor Stage:** Please indicate the stage of the participant's local recurrence.
21. **Location of Local Recurrence:** Please indicate the location(s) of the local recurrence (select all that apply).
22. **Dimensions of Local Recurrence:** Please indicate the width, length, and depth of the local recurrence in centimeters [cm].
23. **Number of Compartments:** Please indicate how many compartments were involved in the local recurrence.
24. **Overall Margins:** Please indicate whether the overall surgical margins of the local recurrence were negative, microscopically positive or grossly positive.
25. **Closest Margin:** Please indicate the closest margin of the local recurrence in centimeters [cm].
26. **Bone Involvement:** Please indicate whether the local recurrence had bone involvement.
27. **Joint Involvement:** Please indicate whether the local recurrence had joint involvement.
28. **Skin Involvement:** Please indicate whether the local recurrence had skin involvement.
29. **Fascia Involvement:** Please indicate whether the local recurrence had fascia involvement.
30. **Muscle Involvement:** Please indicate whether the local recurrence had muscle involvement.
31. **Vascular Involvement:** Please indicate whether the local recurrence had vascular involvement that required vascular resection.
32. **Nerve Involvement:** Please indicate whether the local recurrence had nerve involvement that required nerve resection.
33. **Lymph Nodes Examined:** Please indicate whether the lymph nodes were examined. If "Yes," please specify the number of nodes and whether they were positive for malignancy.

7.4 Systemic Recurrence Form (Form 13)

Clinical site personnel should complete this form if the participant is diagnosed with a systemic recurrence. The next scheduled surveillance should be recorded in the upper right-hand corner on *each* **Systemic Recurrence Form (Form 13)** page.

0. **Date of Systemic Recurrence Confirmation:** Please enter the date that the systemic recurrence being reported was confirmed in DD/MM/YYYY format.
1. **Location of Metastases:** Please indicate the location of metastases.

2. **First Identification of Systemic Recurrence:** Please indicate the method by which this systemic recurrence was first identified. If "Other," please specify.
3. **Biopsy Performed:** Please indicate whether a biopsy was performed.
4. **Confirmation of Systemic Recurrence:** Please indicate how the systemic recurrence was confirmed. If "Other," please specify.
5. **Comments:** Please provide any other relevant comments, if applicable.
6. **Systemic Recurrence Treatment:** Please indicate how this systemic recurrence was treated. If "Radiation," please complete a **Radiation Log (Form 18)**. If "Systemic Therapy," please complete a **Systemic Therapy Log (Form 17)**. If "Other medical / supportive therapies," please specify. If "Operative management," please complete **Part F** of this form and an **Other Surgical Intervention Form (Form 15).** If "Other," please specify.

REMINDER: You cannot select both "No active treatment" and any of the other response options.

7. **Re-Hospitalization for Systemic Recurrence:** Please indicate whether the participant was re-hospitalized for the systemic recurrence being reported. If "Yes," please enter the dates of hospital re-admission and discharge in DD/MM/YYYY format. If the participant was already re-hospitalized when the systemic recurrence being reported occurred, please select "Not applicable." Please note, if the patient died while re-hospitalized for this local recurrence, the date of death should be entered as the date of hospital discharge.
8. **Relatedness to Study Treatment Arm:** Please indicated whether the study investigator believes that the systemic recurrence being reported is related to the study treatment arm

REMINDER: Adverse events related to disease recurrence (local or systemic), as well as complications resulting from treatment for disease recurrence, should be considered at least possibly related to the study treatment arm.

(i.e., the frequency of follow-up and / or imaging modality). If "possibly / probably / definitely related," please specify if this event was unexpected.

9. **Outcome of Systemic Recurrence:** Please indicate the outcome of the systemic recurrence. If "Ongoing," please remember to update once the outcome is known. If "Fatal," please complete an **Early Withdrawal Form (Form 24)**. If "Resolved," please specify the degree of impairment, as well as enter the date that the systemic recurrence resolved in DD/MM/YYYY format. If "Unresolved," please specify whether the adverse event was unresolved at the time of "Study Exit" or "Death."

REMINDER: Only one study event should have a fatal outcome. All other events should be considered unresolved at the time of the participant's death.

10. **Systemic Recurrence Considered Serious Adverse Event:** Please indicate if the systemic recurrence meets the criteria for a serious adverse event. If "No," skip to Part E (Question

REMINDER: A serious adverse event is any event that is fatal, immediately life threatening, requires or prolongs a hospital stay, results in persistent or significant disability / incapacity, a congenital anomaly / birth defect, or is an important medical event.

10). If "Yes," please specify why it is considered a serious adverse event. If "Other," please specify.

11. **Reporting of Systemic Recurrence to Local Ethics Committee:** Please indicate if the serious adverse event was reported to the appropriate local ethics committee. If the serious adverse event does not mee the local ethics committee's requirements for reporting, please select "Not Applicable." If "Yes," please specify the date the serious adverse event was reported in DD/MM/YYYY format, and whether any actions are required by the local ethics committee.
12. **Additional Pertinent Information:** Please provide any other information on the serious adverse event, if applicable.
13. **Imaging Taken as Part of Systemic Recurrence Work-Up:** Please indicate if any imaging was performed on this systemic recurrence. If "No," specify why not. If "Yes," please upload all relevant de-identified image(s).

REMINDER: Please refer to the *Submission of Adjudication Materials Guidelines* on how to upload adjudication materials.

14. **Clinical Notes Detailing the Diagnosis / Management of Systemic Recurrence:** Please indicate if any clinical notes were recorded detailing this systemic recurrence. If "No," specify why not. If "Yes," please upload all relevant de-identified clinic note(s).
15. **Operative Notes Detailing the Surgical Management of Systemic Recurrence:** Please operative notes were recorded detailing the surgical management of this systemic recurrence. If the systemic recurrence was not treated operatively, please select "Not Applicable." If "No," specify why not. If "Yes," please complete either an **Unplanned Re-Operation Form (Form 14)** or **Other Surgical Intervention Form (Form 15)** and upload all relevant de-identified image(s).
16. **Date of Tumor Pathology Report:** Please enter the date of the issued tumor pathology report that was used to complete the remainder of this CRF is DD/MM/YYY format.
17. **Name of Pathologist:** Please provide the name of the pathologist that issued the participant's tumor pathology report in 'First Name, Last Name' format. If there were multiple pathologists, please designate the most responsible pathologist.
18. **Pathological Diagnosis:** Please select the corresponding code for the pathological diagnosis as per the issued tumor pathology report. Further details of the pathological diagnosis can be left in the 'Diagnosis Description' text field. For pathological diagnoses that state "describe above," it is required that you provide further details in the 'Diagnosis Description' text field.
19. **Tumor Grade:** Please indicate the grade of the participant's systemic recurrence.
20. **Tumor Stage:** Please indicate the stage of the participant's systemic recurrence.
21. **Number of Nodules / Metastatic Lesions:** Please indicate the number of nodules / metastatic lesions of the participant's systemic recurrence.
22. **Dimensions of Systemic Recurrence:** Please indicate the width, length and depth of the systemic recurrence in centimeters [cm].
23. **Number of Compartments:** Please indicate how many compartments were involved in the systemic recurrence.
24. **Overall Margins:** Please indicate whether the overall surgical margins of the systemic recurrence were negative, microscopically positive or grossly positive.

25. **Closest Margin:** Please indicate the closest margin of the systemic recurrence in centimeters [cm].
26. **Lymph Nodes Examined:** Please indicate whether the lymph nodes were examined. If "Yes," please specify the number of nodes and whether they were positive for malignancy.

7.5 Unplanned Re-Operation Form (Form 14)

Clinical site personnel should complete this form if the participant undergoes an unplanned re-operation at the initial tumor site. The next scheduled surveillance should be recorded in the upper right-hand corner on *each* **Unplanned Re-Operation Form (Form 14)** page.

0. **Date of Unplanned Re-Operation:** Please enter the date of the participant's unplanned re-operation in DD/MM/YYYY format.
1. **Name of Attending Surgeon:** Please indicate the name of the attending surgeon in 'First Name, Last Name' format. If there were multiple treating surgeons, please designate the most responsible surgeon.
2. **Total Operative Time:** Please indicate the total operative time for the unplanned re-operation in hours and minutes.
3. **Type of Additional Procedure(s):** Please indicate which procedure(s) was / were conducted during this unplanned re-operation. If "Amputation," please specify which limb was amputated. Please specify the type of procedure if "Other" is selected.
4. **Reason for Re-Operation:** Please indicate the reason(s) why the re-operation was / were conducted. If "Hardware failure," please specify the type of hardware failure. If "Other," please specify.
5. **Anesthesia:** Please indicate the anesthesia that was used during the unplanned re-operation. Please specify if "Other" is selected.
6. **Length of Incision:** Please indicate the total length of the incision in centimeters [cm] during the unplanned re-operation.
7. **Skin Excised:** Please indicate how much skin was excised during the participant's unplanned re-operation**.**
8. **Muscle Excised:** Please indicate how much muscle was excised during the participant's unplanned re-operation**.**
9. **Fascial Tissue Excised:** Please indicate how much fascial tissue was excised during the participant's unplanned re-operation.
10. **Bone Excised:** Please indicate how much bone was excised during the participant's unplanned re-operation**.**
11. **Surgical Wound Closure Techniques Used:** Please indicate the type(s) of surgical wound closure technique(s) that was / were used during the participant's unplanned re-operation (select all that apply). Please specify if "Other" is selected.
12. **Any Intra-Operative Adverse Events:** Please indicate if any intra-operative adverse events occurred during this unplanned re-operation. If "Yes," please complete an **Adverse Event Form (Form 16)** and ensure this adverse event is counted towards the total number of new adverse events on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.

13. **Re-Operation a Treatment for an Adverse Event:** Please indicate if this unplanned re-operation occurred as a treatment for an adverse event (including a local recurrence). If "Yes," ensure that an **Adverse Event Form (Form 16) (or Local Recurrence Form [Form 12])** has been completed and ensure this event is counted towards the total number of new adverse events (or local recurrences) on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.
14. **Re-Hospitalization for Re-Operation:** Please indicate whether the participant was re-hospitalized for the re-operation being reported. If "Yes," please enter the dates of hospital re-admission and discharge in DD/MM/YYYY format. If the participant was already re-hospitalized when the re-operation being reported occurred, please select "Not applicable." Please note, if the patient died while re-hospitalized for this unplanned re-operation, the date of death should be entered as the date of hospital discharge.
15. **Planned Additional Procedures:** Please indicate if there are any other additional procedures planned for the soft-tissue tumor. If "Yes," please specify.
16. **Comments:** Please provide any other relevant comments, if applicable.
17. **Relatedness to Study Treatment Arm:** Please indicated whether the study investigator believes that the re-operation being reported is related to the study treatment arm (i.e., the

REMINDER: Re-operations related to disease recurrence (local or systemic), should be considered at least possibly related to the study treatment arm.

frequency of follow-up and / or imaging modality). If "possibly / probably / definitely related," please specify if this event was unexpected.
18. **Operative Notes Detailing the Re-Operation:** Please indicate if operative notes were recorded detailing this unplanned re-operation. If "No," specify why not. If "Yes," please upload all relevant de-identified image(s).

REMINDER: Please refer to the *Submission of Adjudication Materials Guidelines* on how to upload adjudication.

7.6 Other Surgical Intervention Form (Form 15)

Clinical site personnel should complete this form if the participant undergoes any surgical intervention pertaining to systemic disease recurrence of the initial soft-tissue tumor. The next scheduled surveillance should be recorded in the upper right-hand corner on *each* **Other Surgical Intervention Form (Form 15)** page.

0. **Date of Other Surgical Intervention:** Please enter the date of the participant's other surgical intervention in DD/MM/YYYY format.
1. **Name of Attending Surgeon:** Please indicate the name of the attending surgeon in 'First Name, Last Name' format. If there were multiple treating surgeons, please designate the most responsible surgeon.

2. **Type of Surgical Intervention:** Please indicate which procedure(s) was / were conducted during this surgical intervention. Please specify the type of procedure if any "Other" option is selected.
3. **Total Operative Time:** Please indicate the total operative time for this surgical intervention in hours and minutes.
4. **Reason for Surgical Intervention:** Please indicate the reason why this surgical intervention was conducted. If "Other," please specify.
5. **Anesthesia Used:** Please indicate the anesthesia that was used during this surgical intervention. Please specify if "Other" is selected.
6. **No. of Metastatic Lesions Resected:** Please indicate how many metastatic lesions were resected during this surgical intervention.
7. **Any Intra-Operative Adverse Events:** Please indicate if any intra-operative adverse events occurred during this surgical intervention. If "Yes," please complete an **Adverse Event Form (Form 16)** and ensure this adverse event is counted towards the total number of new adverse events on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.
8. **Surgical Intervention a Treatment for an Adverse Event:** Please indicate if this surgical intervention occurred as a treatment for an adverse event (including a systemic recurrence). If "Yes," ensure that an **Adverse Event Form (Form 16) (or Local Recurrence Form [Form 12])** has been completed and ensure this event is counted towards the total number of new adverse events (or systemic recurrences) on the next **Intervention Phase Surveillance Visit Form (Form 8)** or the **Post-Intervention Phase Surveillance Visit Form (Form 9),** as appropriate.
9. **Re-Hospitalization for Surgical Intervention:** Please indicate whether the participant was re-hospitalized for the surgical intervention being reported. If "Yes," please enter the dates of hospital re-admission and discharge in DD/MM/YYYY format. If the participant was already re-hospitalized when the surgical intervention being reported occurred, please select "Not applicable." Please note, if the patient died while re-hospitalized for this surgical intervention, the date of death should be entered as the date of hospital discharge.
10. **Planned Additional Procedures:** Please indicate if there are any other additional procedures planned that are related to this surgical intervention. If "Yes," please specify.
11. **Comments:** Please provide any other relevant comments, if applicable.
12. **Relatedness to Study Treatment Arm:** Please indicated whether the study investigator believes that the surgical intervention being reported is related to the study treatment arm (i.e., the frequency of follow-up and / or imaging modality). If "possibly / probably / definitely related," please specify if this event was unexpected.

REMINDER: Surgical interventions related to disease recurrence (local or systemic), should be considered at least possibly related to the study treatment arm.

13. **Operative Notes Detailing the Surgical Intervention:** Please indicate if operative notes were recorded detailing this surgical intervention. If "No," specify why not. If "Yes," please upload all relevant de-identified image(s).

7.7 Adverse Event Form (Form 16)

Clinical site personnel should complete this form if the participant is diagnosed with an adverse event. All adverse events codes that are listed on the **Adverse Event Form (Form 16)** should be reported. For any adverse event that is not listed on the **Adverse Event Form (Form 16),** please contact the Methods Centre for guidance on reporting. The next scheduled surveillance should be recorded in the upper right-hand corner on *each* **Adverse Event Form (Form 16)** page.

REMINDER: Please refer to the *Submission of Adjudication Materials Guidelines* on how to upload adjudication.

0. **Date of Adverse Event Diagnosis:** Please enter the date that the adverse event being reported was diagnosed in DD/MM/YYYY format.
1. **Adverse Event Description:** Please select the code that best fits the adverse event diagnosis. Further details of the adverse event diagnosis can be left in the 'Diagnosis Description' or the 'Anatomic Location' text fields. For adverse events that state, "describe above," it is required that you provide further details in the 'Diagnosis Description' text field. For adverse events that state, "specify location," it is required that you provide further details in the 'Anatomic Location' text field.
2. **Treatment of Adverse Event:** Please indicate how the adverse event was treated. Please specify if "Medical / supportive therapies," "Operative management" and / or "Other" were selected.

REMINDER: You cannot select both "No active treatment" and any of the other response options.

3. **Additional Information:** Please provide any other relevant comments pertaining to the actions taken in response to the adverse event, if applicable.
4. **Re-Hospitalization for Adverse Event:** Please indicate whether the participant was re-hospitalized for the adverse event being reported. If "Yes," please enter the dates of hospital re-admission and discharge in DD/MM/YYYY format. If the participant was already re-hospitalized when the adverse event being reported occurred, please select "Not applicable."
5. **Relatedness to Study Treatment Arm:** Please indicate whether the study investigator believes that the adverse event being reported is related to the study treatment arm.

REMINDER: Adverse events related to disease recurrence (local or systemic), as well as complications resulting from treatment for disease recurrence, should be considered at least possibly related to the study treatment arm.

6. **Outcome of Adverse Event:** Please indicate the outcome of the adverse event. If "Ongoing," please remember to update once the outcome is known. If "Fatal," please complete an **Early Withdrawal Form (Form 24)**. If "Resolved," please specify the degree of impairment, as well as enter the date that the adverse event resolved in DD/MM/YYYY format. If "Unresolved," please specify whether the adverse event was unresolved at the time of "Study exit" or "Death."
7. **Adverse Event Considered Serious Adverse Event:** Please indicate if the adverse event meets the criteria for a serious adverse event. If "No," skip to Part E (Question 10). If "Yes," please specify why it is considered a serious adverse event. If "Other," please specify.
8. **Reporting of Adverse Event to Local Ethics Committee:** Please indicate if the serious

REMINDER: Only one study event should have a fatal outcome. All other events should be considered unresolved at the time of the participant's death.

REMINDER: A serious adverse event is any event that is fatal, immediately life threatening, requires or prolongs a hospital stay, results in persistent or significant disability / incapacity, a congenital anomaly / birth defect, or is an important medical event.

adverse event was reported to the appropriate local ethics committee. If the serious adverse event does not mee the local ethics committee's requirements for reporting, please select "Not Applicable." If "Yes," please specify the date the serious adverse event was reported in DD/MM/YYYY format, and whether any actions are required by the local ethics committee.

9. **Additional Pertinent Information:** Please provide any other information on the serious adverse event, if applicable.
10. **Imaging Taken as Part of Adverse Event Work-Up:** Please indicate if any imaging was performed on as part of the work-up for the adverse event. If imaging is not relevant to this type of adverse event, please select "Not Applicable." If "No," specify why not. If "Yes," please upload all relevant de-identified image(s).
11. **Clinical Notes Detailing the Diagnosis / Management of Adverse Event:** Please indicate if any clinical notes were recorded detailing the adverse event. If clinical notes are not relevant to this type of adverse event, please select "Not Applicable." If "No," specify why not. If "Yes," please upload all relevant de-identified clinic note(s).
12. **Operative Notes Detailing the Surgical Management of Adverse Event:** Please indicate if operative notes were recorded detailing the surgical management of the adverse event. If the adverse event was not treated operatively, please select "Not Applicable." If "No," specify why not. If "Yes," please complete either an **Unplanned Re-Operation Form (Form 14)** or **Other Surgical Intervention Form (Form 15)** and upload all relevant de-identified image(s).

REMINDER: Please refer to the *Submission of Adjudication Materials Guidelines* on how to upload adjudication materials.

7.8 Systemic Therapy Log (Form 17)

Clinical site personnel should complete all questions on this form for each included participant that has undergone any systemic cancer therapy. This log should be continually updated as the participant undergoes any additional systemic cancer therapy treatments.

1. **Visit Date Details:** Please indicate the visit number that the systemic therapy is being reported for.
2. **Start Date:** Please indicate the start date of the systemic therapy in DD/MM/YYYY format.
3. **Stop Date:** Please indicate the start date of the systemic therapy in DD/MM/YYYY format. Please note, this date is only required if the therapy has been marked as "Stopped."
4. **Type of Systemic Therapy:** Please indicate the type of systemic therapy the participant received.
5. **Name of Systemic Therapy:** Please indicate the name of the systemic therapy the participant received. If "Other," please specify.
6. **No. of Cycles:** Please indicate the number of cycles of systemic therapy the participant underwent.
7. **Reason for Administration:** Please indicate the reason the systemic therapy was administered. If "Other," please specify.
8. **Therapy Completed:** Please indicate if all planned systemic therapy was completed. If "No," specify was it was not completed.

7.9 Radiation Log (Form 18)

Clinical site personnel should complete all questions on this form for each included participant that has undergone any radiation therapy. This log should be continually updated as the participant undergoes any additional radiation therapy treatments.

1. **Visit Date Details:** Please indicate the visit number that the radiation therapy is being reported for.
2. **Start Date:** Please indicate the start date of the radiation therapy in DD/MM/YYYY format.
3. **Stop Date:** Please indicate the start date of the radiation therapy in DD/MM/YYYY format. Please note, this date is only required if the therapy has been marked as "Stopped."
4. **Mode of Radiation:** Please indicate the mode of radiation therapy.
5. **Dosage of Radiation:** Please indicate the dosage of radiation therapy in Gy.
6. **Reason for Administration:** Please indicate the reason the radiation therapy was administered. If "Other," please specify.
7. **Therapy Completed:** Please indicate if all planned radiation therapy was completed. If "No," specify was it was not completed.

7.10 Protocol Deviation Form (Form 19)

Clinical site personnel should complete all questions on this form if a protocol deviation occurs. A separate form should be completed for each visit a protocol deviation occurs at. The surveillance visit the protocol deviation occurred at should be recorded in the upper right-hand corner on *each* **Protocol Deviation Form (Form 19)** page.

1. **Ineligible Patient Included in Study:** Please indicate if an ineligible participant was included in the study. If "Yes," please specify why the participant is ineligible and the date at which the ineligible participant was first identified in DD/MM/YYYY format.

> **REMINDER:** As per the intention-to-treat principle, **all** ineligible participants should continue to be followed in the study.

2. **Improper Thoracic Imaging Modality Utilized:** Please indicate whether the improper thoracic imaging was utilized. If "Yes," please specify why, the date of the improper thoracic imaging in DD/MM/YYYY format, as well as the type of thoracic imaging obtained and where the thoracic imaging was conducted.
3. **Appropriate Thoracic Imaging Missed:** Please indicate if the appropriate thoracic imaging was missed. If "Yes," please specify why.
4. **Scheduled Clinic Visit Missed:** Please indicate if a scheduled clinic visit was missed. If "Yes," please specify why.
5. **Unscheduled Clinic Visit:** Please indicate if the participant was seen in clinic for an unscheduled clinic visit. If "Yes," please specify why, and the date of the unscheduled clinic visit in DD/MM/YYYY format.
6. **Unscheduled Thoracic Imaging:** Please indicate if the participant obtained additional, unscheduled thoracic imaging. If "Yes," please specify why, the date of the unscheduled thoracic imaging in DD/MM/YYYY format, as well as the type of thoracic imaging obtained and where the thoracic imaging was conducted.

7.11 Early Withdrawal Form (Form 24)

Clinical site personnel should complete an **Early Withdrawal Form (Form 24)** if the outcome of an adverse event is fatal, a participant is unable to be located or if the participant chooses to withdraw from the study before its completion.

> **REMINDER:** A participant is considered 'unable to locate' only after all resources to find the participant have been exhausted.

0. **Date of Early Withdrawal:** Please enter the date the participant withdrew from the SAFETY trial in DD/MM/YYYY format. If a participant has a fatal outcome to an adverse event, the date of early withdrawal should be the participant's date of death.
1. **Reason for Study Withdrawal:** Please indicate the reason that the participant was withdrawn from the study.
    a. If the participant died, please specify on which form a fatal event has been reported: **Local Recurrence Form (Form 12)**, **Systemic Recurrence Form (Form 13)**, or **Adverse Event Form (Form 16)**. Please specify the follow-up visit in which the fatal event has been reported.
    b. A participant should be considered unable to locate only after the 60-month 'post-intervention phase' visit has passed and all reasonable attempts have been made to contact the participant, including contacting the alternate contacts that the participant listed on their **Patient Contact Form (Form 0)**.
    c. If the participant withdrew consent, please indicate the reason for withdrawing consent (select only one).

d. Please indicate if the Adjudication Committee has deemed the participant ineligible.

REMINDER: If your site enrolls a participant who is determined to be ineligible, you must continue to follow the participant. Only the Adjudication Committee may withdraw a participant due to ineligibility.

2. **Clinic Visit and / or Contact with Participant Since Last Study Visit:** Please indicate whether the participant has been to clinic or has been contacted since their last study visit prior to early withdrawal. If "Yes," please answer Questions 3 – 15 by referring to the participant's medical records / charts. If "No," the form is complete.
3. **Date of Last Clinic Visit:** Please enter the date of the participant's last clinic visit in DD/MM/YYYY format.
4. **Thoracic Imaging Since Last Study Visit:** Please indicate whether any thoracic imaging has been obtained for the participant since the last study visit prior to early withdrawal. If "Yes," please specify the date of the thoracic imaging in DD/MM/YYYY format, as well as the type of thoracic imaging obtained and where the thoracic imaging was conducted. If the participant is still in the 'intervention phase,' please confirm if the proper thoracic imaging modality was utilized. If "No," please complete **a Protocol Deviation Form (Form 19).**
5. **Local Imaging Since Last Study Visit:** Please indicate whether any local imaging of the initial soft-tissue sarcoma has been obtained for the participant since the last study visit prior to early withdrawal. If "Yes," please specify the date of the local imaging in DD/MM/YYYY format, as well as the type of local imaging obtained and where the local imaging was conducted.
6. **Return to Pre-Cancer Level of Work:** Please indicate whether the participant had returned to their pre-cancer level of work since the last visit prior to early withdrawal. If "Yes," please specify the date that the participant returned to their pre-cancer level of work in DD/MM/YYYY format. Please select "Previously Reported" if the participant had returned to their pre-cancer level of work at a previous study visit.
7. **Return to Pre-Cancer Level of Activity:** Please indicate whether the participant had returned to their pre-cancer level of activity since the last study visit prior to early withdrawal. If "Yes," please specify the date that the participant returned to their pre-cancer level of activity in DD/MM/YYYY format. Please select "Previously Reported" if the participant had returned to their pre-cancer level of activity at a previous study visit.
8. **New Local Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any <u>new</u> local recurrences related to the primary soft-tissue sarcoma since the last study visit prior to early withdrawal. If "Yes," please specify the number of new local recurrences since the last study visit and complete a **Local Recurrence Form (Form 12)** for each new local recurrence.
9. **New Systemic Recurrences Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any <u>new</u> systemic recurrences (metastases) related to the primary soft-tissue sarcoma since the last study visit prior to early withdrawal. If "Yes," please specify the number of new systemic recurrences since the last study visit and complete a **Systemic Recurrence Form (Form 13)** for each new systemic recurrence.
10. **Unplanned Re-Operations Since Last Study Visit:** Please indicate whether the participant has undergone any unplanned re-operations and / or additional procedures at the initial tumor

site since the last study visit prior to early withdrawal. If “Yes,” please specify the number of unplanned re-operations / additional procedures since the last study visit and complete an **Unplanned Re-Operations Form (Form 14)** for each new procedure.

11. **Other Surgical Interventions Since Last Study Visit:** Please indicate whether the participant has undergone any other surgical interventions outside of the initial tumor site but related to the initial cancer since the last study visit prior to early withdrawal. If “Yes,” please specify the number of other surgical interventions since the last study visit and complete an **Other Surgical Interventions Form (Form 15)** for each new procedure.
12. **New Adverse Events Since Last Study Visit:** Please indicate whether the participant has been diagnosed with any <u>new</u> adverse events since the last study visit prior to early withdrawal. If “Yes,” please specify the number of adverse events since the last study visit and complete an **Adverse Event Form (Form 16)** for each new event.
13. **Planned Re-Operations:** Please indicate whether any re-operations and / or additional procedures at the initial tumor site have been planned for the participant since the last study visit prior to early withdrawal. If “Yes,” please specify whether the re-operations are to operatively manage a local recurrence at the initial tumor site.
14. **Planned Other Surgical Interventions:** Please indicate whether any other surgical interventions have been planned for the participant since the last study visit prior to early withdrawal. If “Yes,” please specify whether the surgical interventions are to operatively manage a systemic recurrence of the patient’s soft-tissue tumor.
15. **Comments:** Please provide any other relevant comments, if applicable.