[*Trial Short Name*] – Satellite Site Training

Slide deck template

Orientation

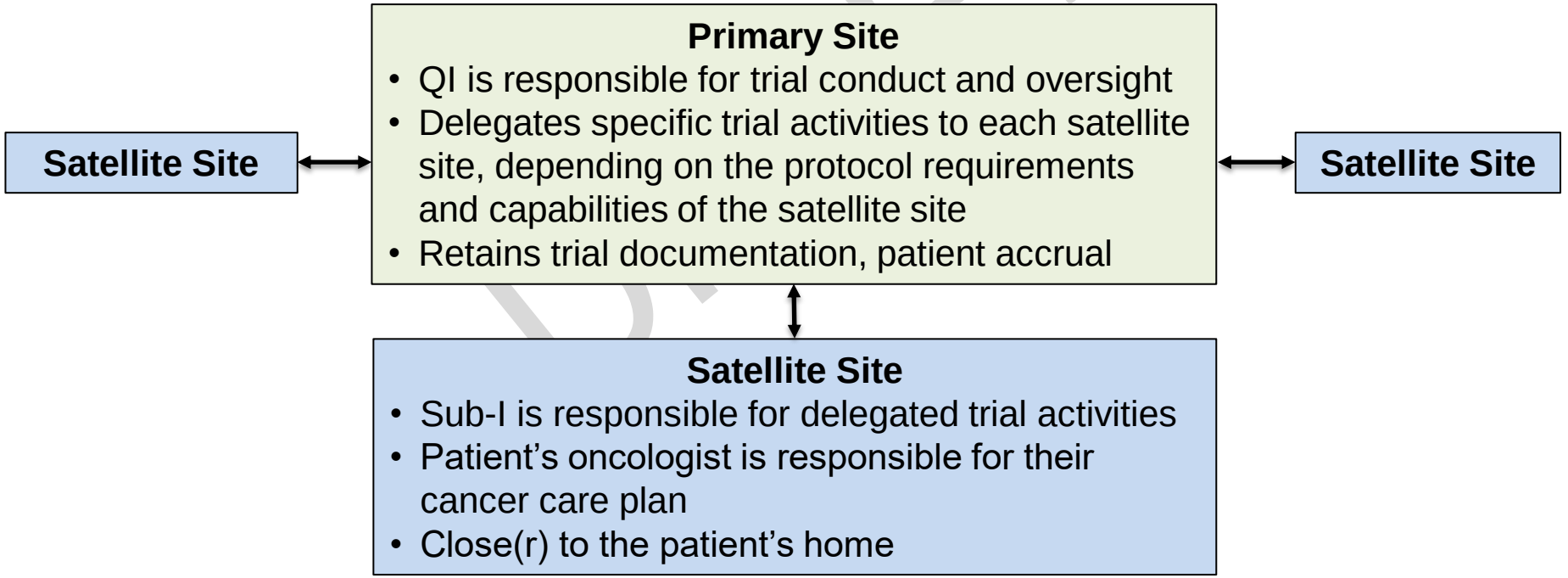
- Satellite A (name) Healthcare Centre is a satellite site to (primary site name) for the (trial name) trial.
  - *(Link to the full study protocol or instructions on how to access it)*

- The approach for this trial is based on the CRAFT (Canadian Remote Access Framework for clinical Trials) model. The Oncology Care Team at (satellite site Healthcare centre) retains responsibility for trial participant care and management. The Qualified investigator (name) from (Primary site name) is responsible for trial conduct and oversight.

- The purpose of this presentation is to provide training for all clinical team members who will perform delegated activities at (satellite site name). *The presentation can also be used to provide orientation to anyone at the satellite site who may be involved in the care of trial participants.*

CRAFT (Canadian Remote Access Framework for clinical Trials)

- A model for trial organization and delivery that allows for trial participation at satellite sites
- Developed by 3CTN[1] and its stakeholders, CRAFT is a Canadian adaptation of the Australasian Teletrials Model[2]
  - Trial clusters are formed on a trial-by-trial basis
  - Trial activities are managed based on agreements between the primary site and each satellite site



1. Canadian Cancer Clinical Trials Network https://3ctn.ca/for-researchers/craft/

2. https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf

About the Trial

Study Title *(insert full trial name)*

Trial Sponsor *(insert sponsor)*

Date trial opened: *(insert date - at the primary site)*

Last updated: *(date that this slide deck was updated)*

Principal Investigator: (*PI name*)

Trial Contact Person at (*primary site name*): *(Name, Contact details)*

Emergency Support: *(Name, Contact details)*

Protocol Objectives

Primary Objectives:

1. *(add)*
2. *(add any additional primary objectives)*

Secondary Objectives:

1. *(if applicable)*

Trial Endpoints and Clinical Outcomes

Primary Endpoints:

1. *(add)*
2. *(add any additional primary endpoints)*

Secondary Endpoints:

1. *(if applicable)*
2. *(add any additional secondary endpoints)*

Observational Outcomes:

1. *(if applicable)*

Patient Consent

Initial Consent

- Process outline, including roles & responsibilities of research personnel to be involved

- who can facilitate this? (must align with delegation log)

Ongoing Consent and Amendments

- Process outline, including roles & responsibilities

- who can facilitate this? (must align with delegation log)

Trial Schema

- *Copy from Trial Protocol. This may require multiple slides.*

Overview of Treatment Schedule

For participants at *(satellite site name),* the Trial activities are:

- *add description and schedule timing for each trial activity, clearly differentiating those visits and activities that are delegated to the satellite from any which may remain with the primary site*

Examples:

- cycle 1 (x weeks), cycle 2 (x weeks), cycle 3 (x weeks) ...
- assessment (*satellite site name*), radiology treatment (*primary site name*), follow-up (*satellite site name*)
- copy table/roadmap from the treatment protocol

Participant-Specific Variations in the Trial

Outline all treatment plans and unique interventions (e.g., drug dose and frequency)

Discuss the process for reviewing treatment plan with participants to ensure understanding and compliance with their roadmap (i.e., receives the correct trial intervention, instructions and follow-up at the correct location)

(if applicable, include possible variations here)

Study Management Plan

Responsibility	Person(s) Responsible	Description
Add each delegated trial responsibility from the Delegation Log		*Explain how each will be managed at our satellite site*
Add any additional monitoring or assessment activities as a result of the trial		
Include in the listing: *- Adverse Event Reporting* *- Source Documentation* *- Ongoing Consent/Amendments* *- Deviation Reporting* *- Provision of Standard of Care throughout the trial*		

Adverse Event (AE) Reporting Requirements

Clinical trial participants are closely monitored for adverse events to help determine the effectiveness and safety of the trial intervention.

- For (trial name), the (study sponsor) uses the (AE grading system name) grading system so that there is uniform reporting from all trial adverse events.
- AE's must be reported to (name, email/phone) at (primary site name) within (# hours) of the AE being identified.
- Report serious toxicities and side effects with (QI name, email/phone) at (primary site name) as soon as possible, even if they are not likely to be related to treatment.
- Some trials require that specific adverse events be reported. For the (trial name) trial, these are: (list)

Notification of changes during the clinical trial

For Urgent trial updates (*define 'urgent' for this trial*):
(name, role) at (primary site) will contact (name, role) at (satellite site) by email and phone. This will be followed by an email summarizing the update and required actions.

(name) will ensure this update is shared with (list names) by email and in person or by phone as much as possible.

For all other trial updates:
(name, role) at (primary site) will send a summary of the update and required actions to (name, role) at (satellite site name). (Name) will distribute the email update to (list names).

Key Contacts

(*Primary Site Name*)	(*Satellite Site Name*)
Qualified Investigator (QI): *Name* *Email* *Phone*	Sub-Investigator (sub-I): *Name* *Email* *Phone*
Trial Manager: *Name* *Email* *Phone*	Nurse, trial or supporting manager: *Name* *Email* *Phone*
(add any other important contacts for the trail)	*(add any other important contacts for the trail)*