Incorporating Patient-Centric Sampling in Clinical Trials – Lab Manual Template Text

Guidance for use of this document

When including patient centric sampling in a clinical study, the following suggested template text can be incorporated into the study lab manual. The sections of the lab manual are indicated as CAPITALISED HEADINGS and the suggested wording is set out for each. Text in brackets [] indicates where appropriate insertions/deletions are to be made. Instructions and guidance text appear in green font. This document is not intended to be exhaustive.

BLOOD SAMPLE COLLECTION AND PROCESSING

Overview Blood Collection

Blood collections should follow the schedule of activities (SoA) found in the Protocol.

- The following blood samples for PK and biomarkers will be collected at the time points indicated in Schedule of Activities in the protocol at all sites:
    - Blood for [analysis type] analysis ([tube type])
    - Blood for [analysis type] analysis ([tube type])
    - Plasma for [analysis type] analysis ([tube type])
- At all sites,[number] [blood sampler] patient-centric sampling devices are to be collected in clinic at the timepoints indicated in the SoA of the protocol.
- At the study visit prior to the [blood sampler] home collections, the site is to provide the participants with [number] [blood sampler] kits (including [blood sampler] device, instructions on use of devices, [central lab] requisition form, and labels).

[BLOOD SAMPLER] (SITE) SPECIMEN COLLECTION PROCEDURE

Specimen Collection Notes

NOTE: Refer to the protocol flow chart for scheduled collection time points.

NOTE Training:

1. All individuals who collect samples must perform the following steps prior to working on clinical samples:
    a. Read this [central lab] Manual to gain familiarity with the collection process (Sponsor training).

b. Gain familiarity with the provided [blood sampler] training devices by physically handling the training device.

It is recommended that training of clinical site personnel be conducted close to actual sample processing. If a large time lapse (e.g., >6 months) occurs between training and [blood sampler] collection, it is recommended that the personnel re-read the [central lab] Manual.

Supplies and Materials (per participant, per time point)

Provided to the Institution:

- Central lab requisition form (included in the [central lab] visit kit)
- Central lab labels
  - Foil return bag label(s) (included in [central lab] visit kit)
- Non-sterile gauze
- [number] Complete [blood sampler] sample collection kits
  Kit contains:
  - Instructions for use
  - [blood sampler] blood collection device in a sterile pouch
  - Warming pack
  - Alcohol wipe
  - Bandage
  - Foil return bag with absorbent pad

[include photograph of supplies kit]

Required Equipment

- Timer

Precautions

NOTE: Use while seated, as fainting may occur with any blood sampling procedure.

Wear institution required safety equipment (for example disposable gloves, safety glasses or goggles, a laboratory coat) and follow standard laboratory safety procedures while working with these samples.

Labelling

The [blood sampler] foil bag should not be labelled until immediately prior to use. The device must remain in the original [sterile] packaging until use.

[number] [blood sampler] devices will be used at every time point outlined in the SoA. For each collection, there are two labels, found in the [central lab] kit, one for each foil bag (A and B). Each foil bag will have a unique barcode label (A and B) in which each / the device must be placed.

Preparation

Use one of the following paragraphs if single, or multiple devices are used for sampling at the same time;

A single device will be used per collection timepoint. For collection, participants can decide which arm to place the device on.

or

Two individual devices will be used per collection timepoint. For collection, participants can decide to place both devices on one arm or place one device on each arm. If putting two devices on one arm, the two devices should be placed near each other.

If multiple timepoint samples are being collected, use the following paragraph:

For collection of subsequent timepoints, it is recommended that multiple sampling locations on the body are used.

If a venous draw is being completed at the exact same time as the [blood sampler] device(s), please collect the [blood sampler] sample(s) on the arm opposite to the venous draw. Any [blood sampler] collection should occur as close in time of the venous blood draw as possible, not exceeding 15 minutes.

[include text and photographs from blood sampler provider, as appropriate]

Specimen Collection

[include text and photographs from blood sampler provider, as appropriate]

Specimen Processing and Handling

[include text and photographs from blood sampler provider, as appropriate]

Storage

The [blood sampler] samples that were sealed in the foil bags with absorbent packets and stored at [temperature] temperature ([temperature range]) for [time period] hours should then be stored at [temperature] until shipping to the central lab.

Packaging and Shipping

1. It is the responsibility of the primary investigator to ensure that all staff personnel who will be handling, packaging, and/or shipping clinical specimens are trained and certified as required by national and international regulations and that they ship materials in accordance with all current regulations relating to the handling and shipping of hazardous goods.

NOTE: The packaging and shipping instructions provided by the central lab and/or shipping company are not considered nor are they intended to be formal dangerous goods training.

2. Follow packing and shipping instructions for DRY ICE shipments.

3. **Shipping schedule** – Select overnight or priority delivery and ensure that shipments are received at the destination vendor Monday through Thursday, except on [holidays].

Contact the vendor if you are uncertain about the shipping or receiving schedule.

NOTE: International shipments may require additional shipping paperwork. Consult the appropriate [central lab] Manual.

[BLOOD SAMPLER] (HOME) SPECIMEN COLLECTION PROCEDURE

Specimen Collection Notes

Preparation of [blood sampler] kit for participant use:

1. Clinic staff are to prepare [number] [blood sampler] kits for participant's home collection.
2. Gather the appropriate home labels and requestion form found in the [central lab] kit as well as the participant's instructions for use. Note: Discard the [central lab] kit box and biohazard bag that is included in the [central lab] kit as the [blood sampler] kit boxes will be used.
3. Clinic staff to pre-populate the [central lab] requisition form for participant's home collection found in the [central lab] kit.
4. Open the [blood sampler] device kits. Firmly affix the foil bag labels (found in the [central lab] kit) (see image below) on the foil bags. Do not open the foil bags. Put the unopened labelled foil bag back into each.

[include text and photographs from blood sampler provider, as appropriate]

5. Place the appropriate participant instructions for use in the [blood sampler] kits.
6. Place the appropriate contact details for if real-time questions arise during remote sample collection, in the [blood sampler] kits.
7. Place the requisition form in one of the [blood sampler] kits. Note: The courier will provide a shipping box.

Supplies and Materials (per participant, per time point)

Provided to the Participant:

- Central lab requisition forms (included in PPD visit kit)
- Central lab labels
  - Foil return bag labels (included in [central lab] visit kit)
- [number] Complete [blood sampler] blood collection kits
- Kits contains:
  - Instructions for use
  - Contact details
  - [blood sampler] blood collection device in a sterile pouch
  - Warming pack
  - Alcohol wipe
  - Bandage
  - Foil sample return bag with absorbent pad

[include photograph of supplies kit]

Required Equipment (advise participant)

- Timer
- [Mirror]

Precautions (advise participant)

NOTE:

- Use while seated as fainting may occur with any blood sampling procedure.
- Gloves are not required.

Preparation (review with participant)

NOTE:

Inform the participant that full instructions for home use will be provided and should be followed while performing the collection at home

[include text and photographs from blood sampler provider, as appropriate]

Specimen Collection

[include text and photographs from blood sampler provider, as appropriate]

Specimen Processing and Handling

[include text and photographs from blood sampler provider, as appropriate]

Packaging and Shipping

1. The Study Coordinator (or designee) will request the patient to provide a date when they will complete the [blood sampler] blood collections and can be picked up by [courier(s]).

2. The Study Coordinator (or designee) will call [courier(s] to schedule a pickup for these samples and provide the courier with the patient's address.

3. When scheduling a pickup, the site will need to check the [courier(s] starter pack to determine how long transit time is to ensure the samples do not arrive at [central lab] on a Sunday.

4. If the patient has a need to change their pickup date, they will need to coordinate this via their Investigator's Site.

5. The courier will provide a shipping box for [blood sampler] kit boxes.

6. The site will call the patient to ensure the samples were collected and shipped.