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Version: v1 – PSSV/SIV (Trial Coordinators)
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This document is for Trial Coordinators.
It outlines the DLM's process and requirements should support be required

FOR RESEARCH / CLINICAL TRIALS

PRE-STUDY SITE VISITS (PSSV)

SITE INITIATION VISITS (SIV)

All requests and enquiries pertaining to support from the DLM for research/clinical trial Pre-Study Site Visits (PSSV) or Site Initiation Visits (SIV) should be directed to the DLM Research & Clinical Trials Business Administrator (DLM CTA) in the first instance.

PSSV/SIV Timescales:
Research Teams **must** provide the DLM adequate notice (i.e. a minimum of 2 weeks), if representation is required at a PSSV/SIV.

Note: Without sufficient notice, it may not be possible for the DLM to accommodate the visit.

The DLM CTA will require the following:

1. **Details of the Visit**
   - Date/time/venue of intended PSSV/SIV.
   - Confirmation of which lab e.g. biochemistry, haematology etc. input is required from

2. **Documentation** (or drafts)
   - A completed DLM Study Application/Agreement Form (Section 1)
   - Protocol
   - SSI
   - Lab Manual

   If these documents are not available, please state when the DLM CTA can expect to receive them.

   Note: If sufficient information is not available prior to the PSSV/SIV, the DLM may not be able to accommodate the visit.

3. **Visitor Requirements (what is expected from the DLM):**
   - Representation at the PSSV/SIV meeting / a visit to the labs / or both ?

   For Lab Visits, the DLM CTA will also require the following information:
   - number of non-lab personnel visiting (inc. names/titles/contact details)
   - details of the person who will escort visitors to, from and between labs
   - details of the equipment visitors want to see (if any)
   - details of documentation required in advance of the visit e.g. equipment specs / calibration details /Reference Ranges / CPA certs etc.

Note: Controlled documents will not be provided if the DLM has not received confirmation that CMFT will be a participating site. Further details pertaining to requests for controlled documents can be found via the following link:

http://labmed.staffnet.xcmmc.nhs.uk/clinical-trials.aspx
'Protocol for Requesting Laboratory Costs for Research/Clinical Trials'

The DLM CTA will:

1. **Obtain Authorisation from the Relevant Lab(s)**

- Provide labs with all available information and state what (if anything) is still outstanding / forthcoming

- Ascertain who can be available for the PSSV/SIV

(Note: If the date/time of the visit is unsuitable for Lab Staff, the DLM CTA will advise the Research Team accordingly and request alternative dates/times).

2. **Confirm Lab Representation**

- The CTA will contact the research team:
  - obtain outstanding documentation and pursue queries (if any).
  - confirm DLM Lab Staff availability

- A confirmation email will be sent to the labs once all of the above has been finalised

- Visitors will be provided with PPE on arrival to Central Specimen Reception

PLEASE DO NOT PRESENT TO CENTRAL SPECIMEN RECEPTION WITH YOUR VISITORS UNTIL THE DLM CTA HAS CONFIRMED APPROVAL FOR THE VISIT

NOTE:
Pre-Study Site Visit (PSSV)– As this will be conducted at the 'site selection stage', there are no clinical governance issues, ergo research office approval is not required. However the DLM will require details/requirements of the visit, as requested above.

Site Initiation Visits (SIV) – These should take place after R&D approval is in place. However, the Research Office will facilitates SIVs and allow them before R&D approval if everything is nearly in place e.g. if all R-PEAK tasks are completed and the only item outstanding is a signed contract which is getting authorized by the sponsor.

Please ensure you notify the Research Office, if a SIV is taking place prior to approval.