Common Monitoring Findings

Common findings	Recommendation:
Informed consent: It is often noted that: - Use of superseded documents when participants were consented - Dates of signatures on consent form do not match up - Not all fields completed, such as PIS version in consent statements or particular statement that needs to be deleted - Statements completed with ticks instead of initials - Statements missed out - Person taking consent is not delegated this responsibility on the trial delegation log	Check the correct version of consent documents are used before they are completed, this includes the interval between participants receiving the information and the actual consent date. Both participants and the person taking consent must sign the consent form on the same day, if participants signed it ahead of consent visit, please ask them to re-sign and date it. Check all fields have been completed correctly. Errors, including those made by the participant, must be corrected in a GCP compliant manner. Ensure person taking consent has been delegated this task on the trial delegation log.
Participant Identifiable Data: It is sometimes noted that: - Participants' identifiable information, such as full name and hospital number are present on the CRFs. - Source documents such as lab reports sent to the coordinating team or with SAE reports contained participants' identifiable information.	These should never be present on the CRFs; participants must be identified only by their date of birth and their unique trial ID. All Trial documents with the exception of consent and subject ID log must remain anonymised. Ensure source documents are checked through before sending them on to the coordinating team or to outside of site team. Coordinating team members should review any source documents received for participant identifiable data and anonymised before forwarding or filing.
Trial-specific laboratory requests: It is often noted that: – Analysis parameters necessary for the trial are missing - Trial samples are being analysed for parameters that are not required according to the protocol	Create trial and visit specific templates in EPIC to remind nurses and practitioners of tests needed. For trials not using EPIC, set up trial-specific request forms with the labs.
Documentation pertinent to research samples collection and retention: It has been noted that: - Logs are not always fully completed - There is in general a lack of information on samples collected - Insufficient information about the transfer of samples - Samples not collected or processed according to protocol or trial specific lab manual - Contracts for sample transfer and laboratory are missing	Logs used for the trial should be fit for purpose, capturing minimally: - Trial ID - participant trial ID - Sample ID - Collection date/time - Processing date/time - Storage date/time - Personnel who handled the sample. Transfer of samples and analysis of samples must be covered with suitable agreements.

Common findings	Recommendation:
- Sample long term storage is different form REC approval	Any long term storage location must be consistent with that specified in protocol and REC form. Sample logs should be regularly checked for compliance to protocol and lab manual.
Delegation Log: Trial activities are completed by staff not listed on the delegation log. This is mostly observed in relation to consent documents and CRF completion.	It is CI/PI's responsibility to ensure responsibilities are delegated and a new team member has received sufficient training, including GCP training and trial-specific training in order to carry out his/her delegated responsibilities: - CI/PI countersignature on the delegation log should be completed as soon as staff is added to the delegation log - Each new member of staff starting on the trial must receive Trial-specific training, please refer to CCTU/GD010 Trial specific training guidance document - Trial-specific training must be documented, please refer to CCTU/FRM051 Trial specific training record - CI/PI must ensure that end date is noted on the log for staff who is leaving -
TMF and ISF maintenance It is often noted that: - Documents are filed in the wrong sections or in the wrong sequence - File notes are missing to explain where certain documents can be found if not filed in the appropriate section - No file note present in case a certain section is not needed - Key documents are not filed in a timely manner - Emails filed without structure or are incompletely filed.	Documents should be filed in sections as indicated by the index. If a section is not applicable, or the documents filed separately from the main file, this should be noted in a file note or on the trial/site file index. Consider creating sub-sections relevant to the trial. Sub-sections should be clearly added to the index. Develop the good practice of filing key documents as they are approved Emails relating to a particular subject should be filed together and in chronological order. Avoid filing repeated email chains.
Completion of monitoring findings It is often noted that: – Long delays between findings raised with the trial team and completion of the monitoring findings.	Monitoring findings should be addressed within 4 - 6 weeks of the date of the follow up letter. If trials team require a longer period of time this must be justified and confirmed with the CCTU Monitor.
IMP Administration: A date and time of IMP Administration is not always verifiable from the source, such as medical notes.	Please note that pharmacy records only confirm date and time of preparation and dispensing, but not necessarily date and time of dose administration – if the dosing time is essential this must be recorded. When recording in medical notes, please record date and time of IMP administration if IMP is administered at clinical site. If participants are given instruction on when to take IMP, that should also be recorded in the medical notes.

Common findings	Recommendation:
Documenting Trial Activities in medical notes: It is often noted that medical notes do not always sufficiently record: - Participants' eligibility review - Consent process - Trial-specific assessments - Review of AEs and related information It is sometimes noted that: - Trial visits are documented long after the visit has taken place - Trial data are inconsistent or inaccurate (such as dates of AEs and Concomitant medications) - On EPIC, trial activities are recorded in the 'research' tab only -	These records in the medical notes are essential as source data. When using EPIC, ensure that documentation of consent and any trial activities are recorded in the main patient notes section, and not only in the 'research' tab which is solely accessible to the trials team and not to Monitors/Auditors/Inspectors. See our separate document called "source data top tips" for more details.
Amendments not carried out in GCP compliant manner: It is often noted that: – Amendments to source records and CRFs are not GCP compliant or are lacking a clear audit trail – On paper documents, some amendments are not initialled and dated by the person carrying out the amendment. This also applies to patient questionnaires, patient diaries and patient's section on consent forms.	Ensure all amendments are GCP compliant, that is, initialled **and** dated, and brief comment added. Ensure patient questionnaires, diaries and consent forms are checked through at a patient's visit so that any non-GCP compliant amendments can be addressed at the visit.