



TASC

Tayside Medical Sciences Centre

SOPHIST

Site Initiation Visit

Investigator Responsibilities

Investigator responsibilities

ICH GCP section 4 details the investigator responsibilities.

<http://ichgcp.net/4-investigator>

Investigator responsibilities

- Investigator and site staff qualifications
 - Site agreements
 - Adequate resources to conduct the study
 - Medical care of trial participants
 - Compliance with the protocol
 - Knowledge of the Investigational Medicinal Product including the Reference Safety Information
 - Randomisation Procedures and Unblinding
 - Informed consent of trial participants
 - Records and Reports
 - Safety Reporting
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SOPHIST
Site Initiation Visit
Monitoring

Purpose of Monitoring

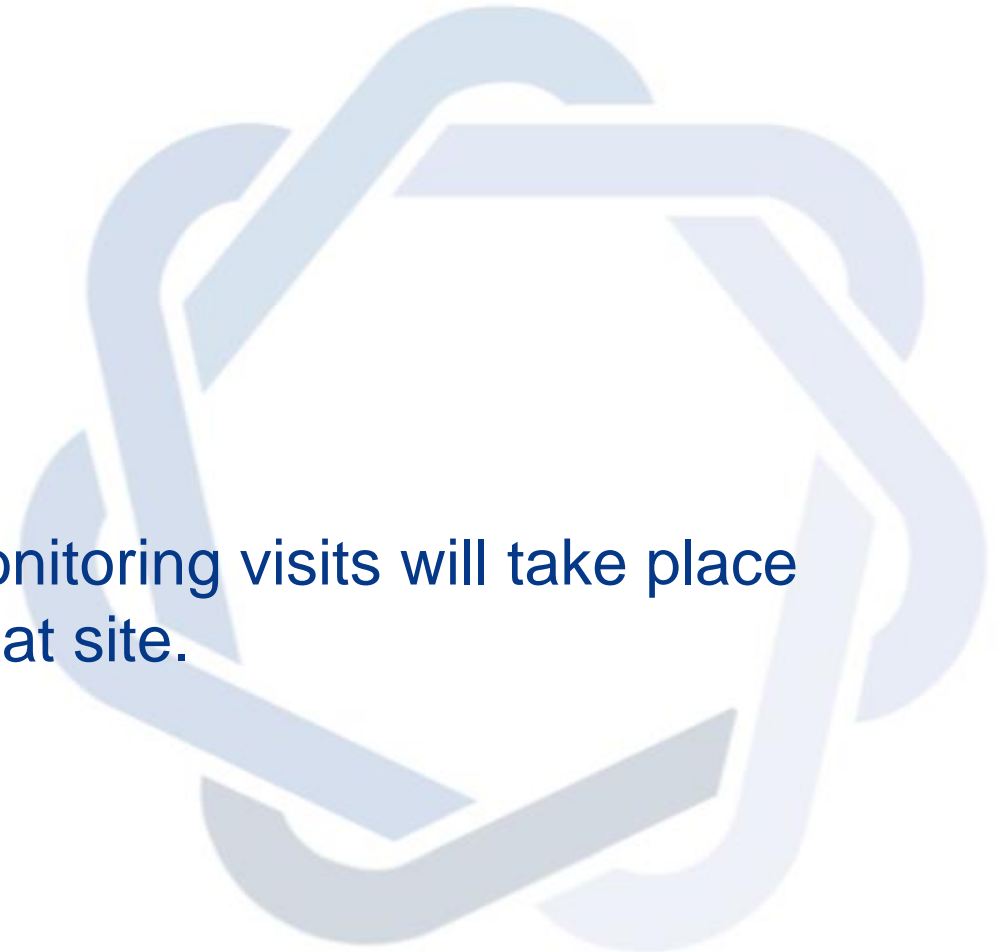
- To verify that the rights and well-being of participants are protected.
- To ensure that reported trial data is accurate, complete and verifiable from source data.
- To ensure that the trial is compliant with the protocol, Good Clinical Practice (GCP), SOPs and regulatory requirements.

Monitoring Schedule

The monitoring schedule is detailed in the monitoring plan located in the site file.

Visits are as follows:

- Site initiation.
- FPFV
- On-site or Remote monitoring visits will take place depending on activity at site.
- Close out visit.

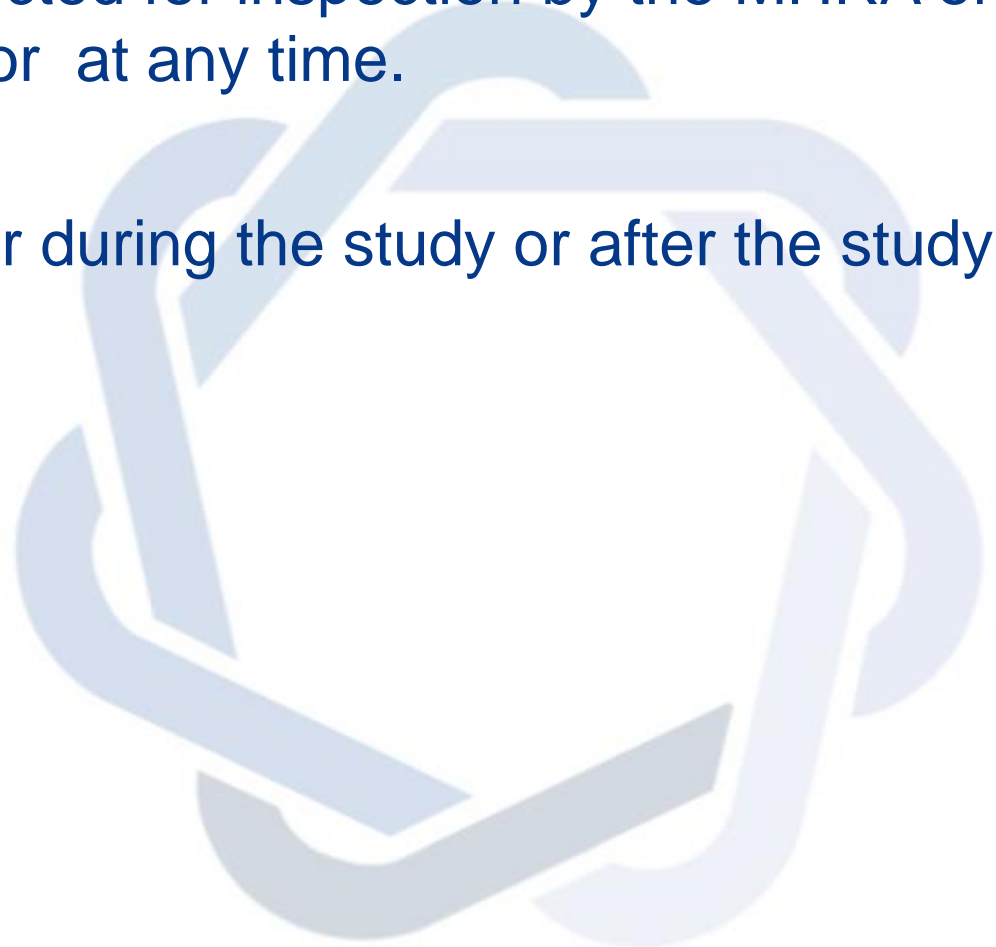


Monitoring visits

- Prior to a monitoring visit the monitor will email the site contact to arrange a visit date and request information to be provided ahead of the visit.
- **During a visit, the monitor will require access to:**
 - medical notes, eCRF and source data
 - ISF/PSF
 - Screening logs and informed consent forms
 - Sample storage and temperature logs
- Post visit the monitor will issue a monitoring visit report. This will document the visit and the actions to be completed.
- Actions are to be completed and returned to the monitor.

Audit and Inspection

- The study can be selected for inspection by the MHRA or audit by the Sponsor or at any time.
- This could occur either during the study or after the study is closed.



Monitor Questions

- Essential documents
- Study equipment
- Emergency medication
- Lab equipment
- Sample storage
- Source data





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Informed consent

Who can take consent in the SOPHIST study?

- The PI, Research nurse or delegate can take consent at each site.
- The person taking consent should be suitably trained and qualified and have sufficient knowledge of the study.
- The person taking consent must be recorded on the signature and delegation log.

Important Things to Remember

- ☑ Use most recently approved version of Informed consent form and participant information sheet on headed paper.
- ☑ Ensure the participant is fully informed of the study.
- ☑ Ensure the participant has received all the approved documentation and had adequate time to read it (usually at least 24 hours).
- ☑ Ensure the participant has had the opportunity to ask questions.
- ☑ Consent should be taken before any trial specific procedures are carried out.
- ☑ Ensure that the participant has initialled all boxes.
- ☑ The consent form should be signed by the participant and by the person taking consent on the same day.
- ☑ Any corrections should be scored through and initialled and dated.
- ☑ A copy of the signed consent should be given to the participant, a copy in the medical notes, and the original in the Investigator Site file.



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SOPHIST

Site Initiation Visit

Pharmacovigilance

Pharmacovigilance

Login ▾

[Home](#)

Welcome to the Tayside Pharmacovigilance system

This system is for the reporting of Serious Adverse Events (SAEs).
You are required to submit a SAE report within 24 hours of first knowledge of an SAE.
If you have any difficulty using this system or wish to receive advice prior to submitting a SAE report please contact tay.pharmacovigilance@nhs.scot for help.
Please gather relevant information to hand before starting the data entry process. You can save your partially completed SAE report and come back to it later if you wish. A report is not complete until it has been submitted. Prior to this the report can be changed and the changes do not leave an audit trail.
You can use the information tabs to obtain further information and clarification of what is being asked for, during the data entry process.
After completion the report will need to be signed off as complete by the PI, otherwise it is not considered to be a valid report.
Partial data entry is possible but you will be required to provide outstanding information and supply it in a follow up report.

Please make sure that you have checked your protocol as for some trials some types of SAE are considered to be non-reportable and are not required to be notified to the Pharmacovigilance department.

[Click here to access the system.](#)

Reports

Select Study: Select Site:

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-
-
-
-
-

Draft

Show entries

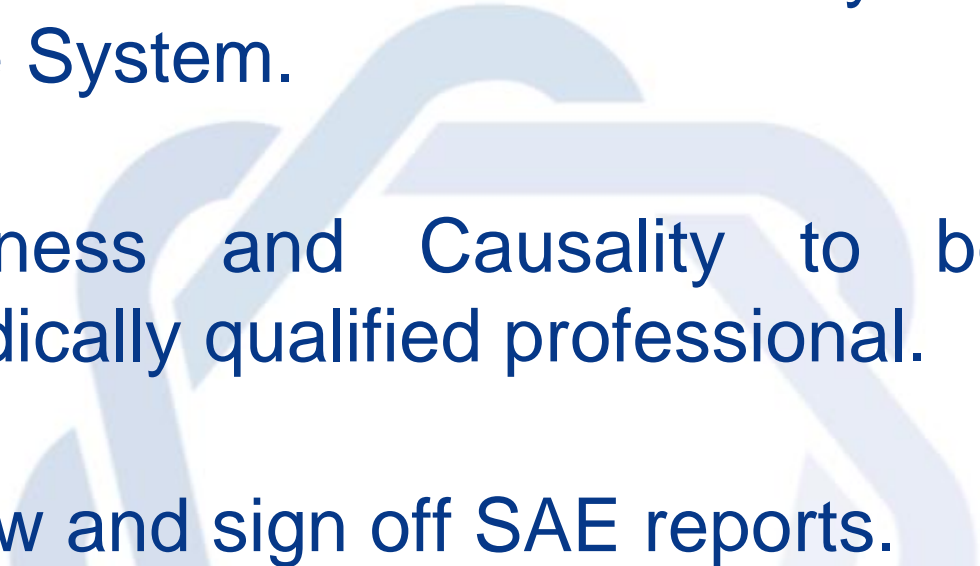
Search:

Reference	Site ID	Subject ID	Diagnosis	Type	Outcome	Created By	Date Created
20230116-PIUMA-1055-1	Northumbria-02			SAE		Basic monitor	16/01/2023
20221116-PIUMA-1055-1	Northumbria-02	11/11	test	SAR	Recovering	Basic monitor	16/11/2022

Form Sections

- [Study Details](#)
- [Subject Details](#)
- [Serious Adverse Event Details](#)
- [Trial Treatment](#)
- [Relevant Medical History](#)
- [Concomitant Medications](#)
- [Relevant Tests](#)
- [Re-challenge](#)

Serious Adverse Events

- Submit SAE report within 24 hrs on Tayside Pharmacovigilance System.
 - Severity, Seriousness and Causality to be assessed by a medically qualified professional.
 - PI or CI must review and sign off SAE reports.
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Expectedness

- Expectedness is assessed by Sponsor.

Pregnancy reporting

- Pregnancy forms are available on the TASC website:

<https://www.dundee.ac.uk/tasc/researchers/policies-sops-templates/sops-templates/pv-imp/>

- Pregnancy notification form must be completed and reported via email within 14 days:

Tay.pharmacovigilance@nhs.scot