TASC

Tayside Medical Sciences Centre

GREAT-2

Site Initiation Visit

Investigator responsibilities

NHS Tayside

University of Dundee

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 subjects
- Compliance with the protocol
- Knowledge of the Investigational Medicinal Product including the Reference Safety Information
- Randomisation Procedures and Unblinding
- Informed consent of trial subjects
- Records and Reports
- Safety Reporting

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Site Initiation Visit

Monitoring

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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:
  - patient 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

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Who can take consent in the GREAT-2 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 patient 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 subject 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 patient notes, and the original in the Investigator Site file.

TASC

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GREAT-2

Site Initiation Visit

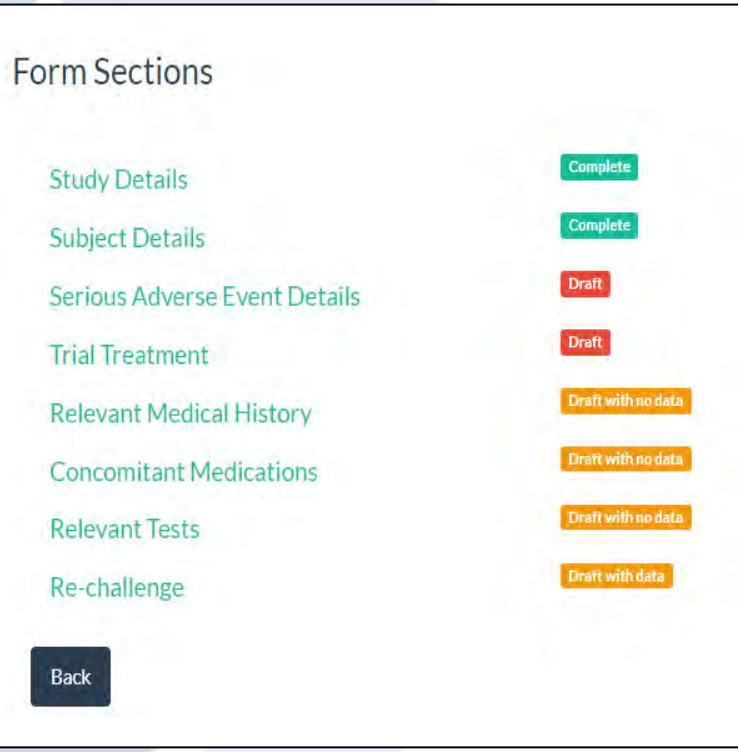
Pharmacovigilance

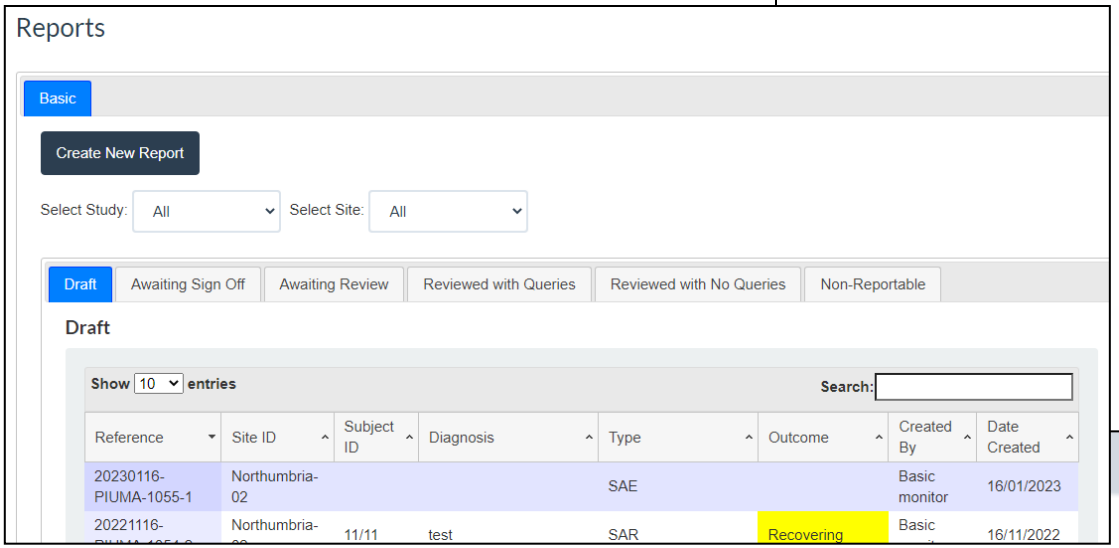
NHS Tayside

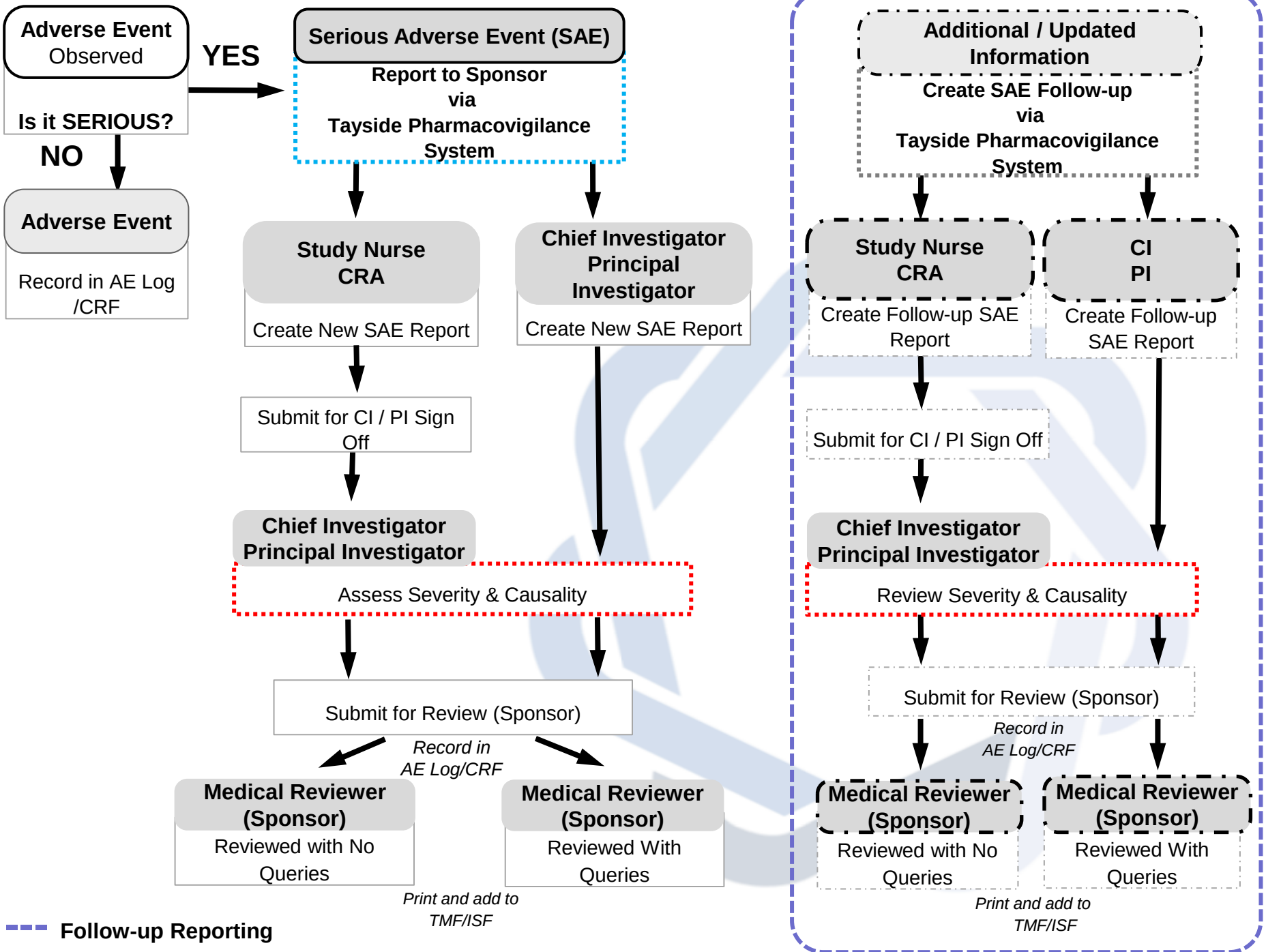
University of Dundee


Pharmacovigilance
Login
Username
Password
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 24hours 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.


Submit for Sign off


Form Sections
Study Details
Complete
Subject Details
Complete
Serious Adverse Event Details
Draft
Trial Treatment
Draft
Relevant Medical History
Draft with no data
Concomitant Medications
Draft with no data
Relevant Tests
Draft with no data
Re-challenge
Draft with data
Back


Reports
Basic
Create New Report
Select Study: All
Select Site: All
Draft
Awaiting Sign Off
Awaiting Review
Reviewed with Queries
Reviewed with No Queries
Non-Reportable
Draft
Show 10 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-
Northumbria-
11/11
test
SAR
Recovering
Basic
16/11/2022


Adverse Event Observed
Is it SERIOUS?
YES
NO
Adverse Event
Record in AE Log /CRF
Serious Adverse Event (SAE)
Report to Sponsor via Tayside Pharmacovigilance System
Study Nurse CRA
Create New SAE Report
Chief Investigator Principal Investigator
Create New SAE Report
Submit for CI / PI Sign Off
Chief Investigator Principal Investigator
Assess Severity & Causality
Submit for Review (Sponsor)
Record in AE Log/CRF
Medical Reviewer (Sponsor)
Reviewed with No Queries
Medical Reviewer (Sponsor)
Reviewed With Queries
Print and add to TMF/ISF
Additional / Updated Information
Create SAE Follow-up via Tayside Pharmacovigilance System
Study Nurse CRA
Create Follow-up SAE Report
CI PI
Create Follow-up SAE Report
Submit for CI / PI Sign Off
Chief Investigator Principal Investigator
Review Severity & Causality
Submit for Review (Sponsor)
Record in AE Log/CRF
Medical Reviewer (Sponsor)
Reviewed with No Queries
Medical Reviewer (Sponsor)
Reviewed With Queries
Print and add to TMF/ISF
Follow-up Reporting

Serious Adverse Events

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

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