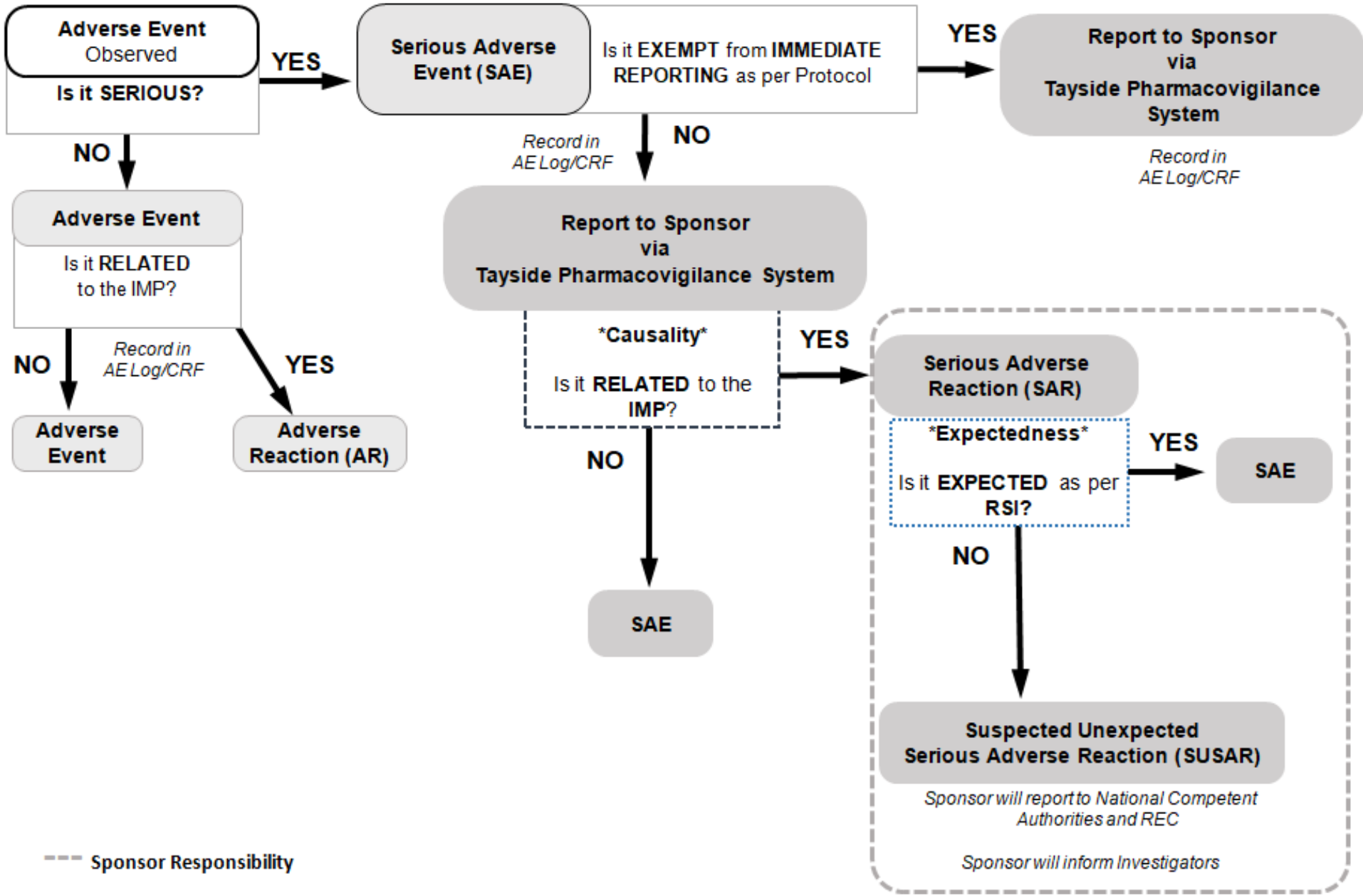
Basic User & Principal Investigator
Tayside Pharmacovigilance System User Guide

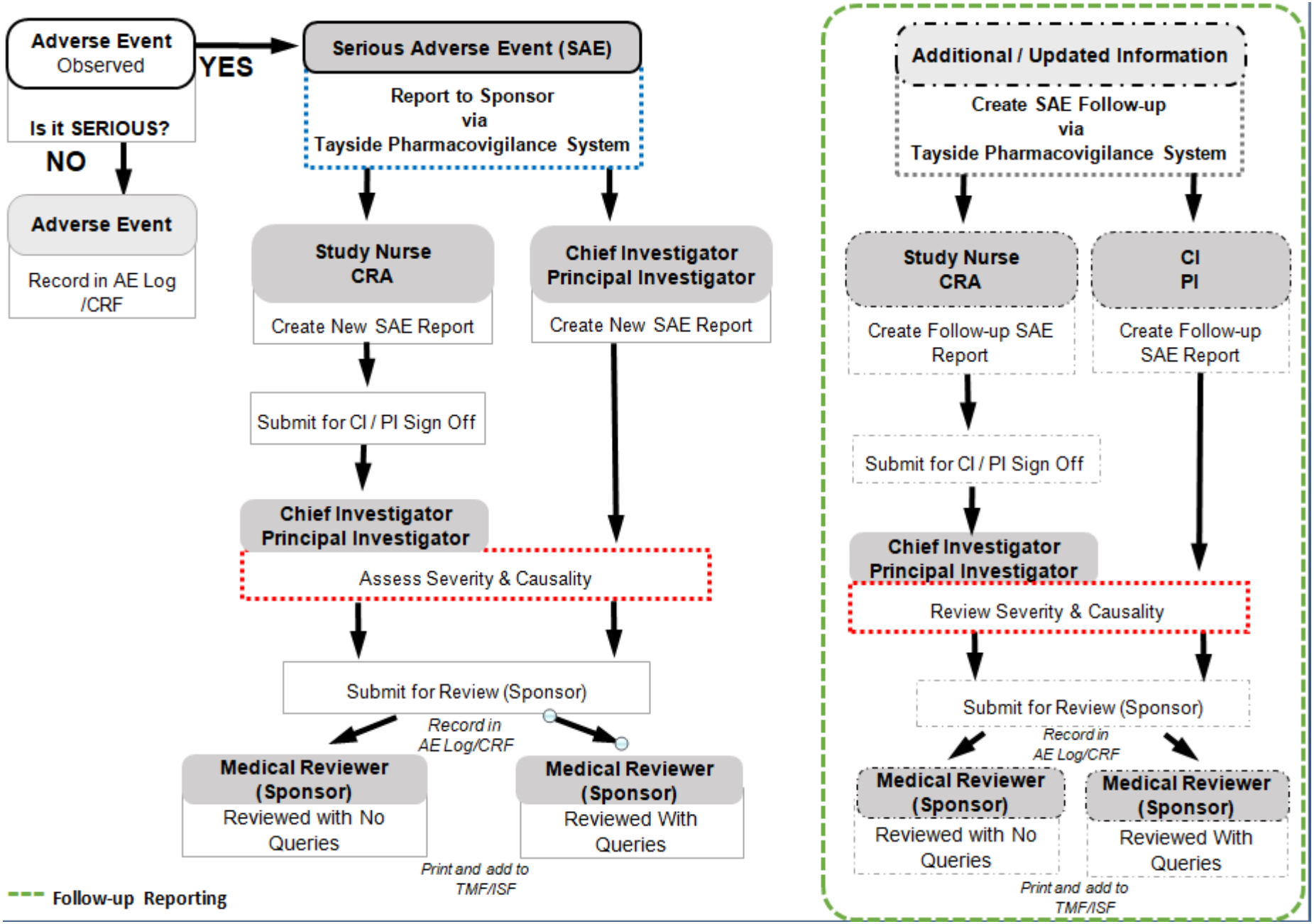
Tayside Pharmacovigilance

Contents

Serious Adverse Event Assessment Flow Chart



Tayside Pharmacovigilance System Reporting Flow Chart



1. Introduction

The Tayside Pharmacovigilance (PV) System will be an online database to report Serious Adverse Events to Sponsor and will replace the email notification of the SAE forms.

The Tayside PV system will enable reporting SAEs by filling the on-line form, allowing the following features:
- Initial SAE Data entry
- SAE follow ups
- PI/ CI review and Sign off
- Medical Review (Sponsor) and Expectedness assessment
- Pharmacovigilance monitoring (Sponsor)

2. Getting started

Access to the PV system can be made via the link: https://pharmacovigilance.hicservices.dundee.ac.uk and TASC website under www.dundee.ac.uk/tasc/policies-sops-templates.

2.1. Home page

The above link will take Users directly to the Welcome Page.

2.2. Account types

Currently there are 4 types of accounts:
- Basic User
- PIs (Investigators)
- Medical Reviewers (Sponsor)
- Pharmacovigilance Monitor (Sponsor)

Basic Users will have access to studies they are currently working on at their relevant site. They will be able to create new SAE forms, and create follow-up forms. Access will be granted and removed to this user type depending on the delegation log for that study.

Principal Investigators (PI) will have access to sites/studies on which they are currently working. They will be able to create new SAE forms, add additional information, create a follow-up, change data (provided there is a reason for change) and provide sign off for Review.

If required a PI can also have Medical Reviewer rights for studies in which they are not involved.

Medical Reviewers will be able to review signed off SAEs, enter expectedness (as per TASC SOP11) and raise queries.

3. Login & Change Password

To start using the Tayside PV system, Users will get their account created by TASC Pharmacovigilance Monitor.

Once the account is activated, Users will be able to log into the PV system on https://pharmacovigilance.hicservices.dundee.ac.uk.

3.1. Login

1. Go to top of the Homepage and add your details.

2. Once logged on click on 'here' at the bottom left of the homepage to access reports.

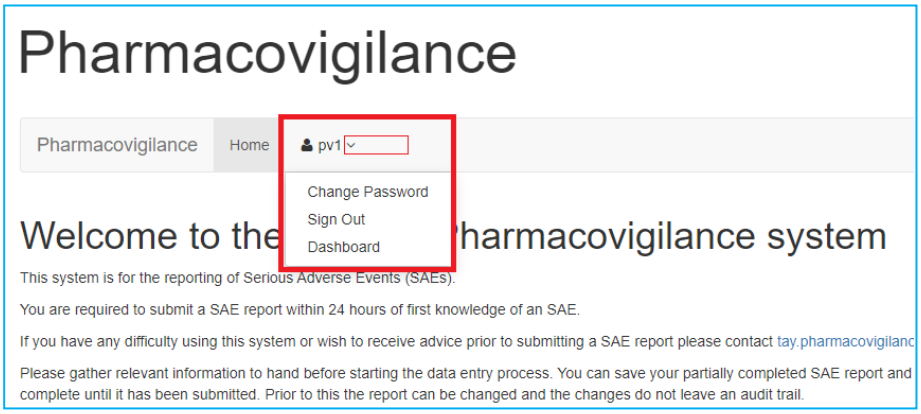
3.2. Password Change or Recovery

We recommend users change their password after they log in.

1. Go to top of the Homepage, select Sign In and add your details.

2. Once logged on click on your user name (v) at the top of the homepage to find Change Password option.

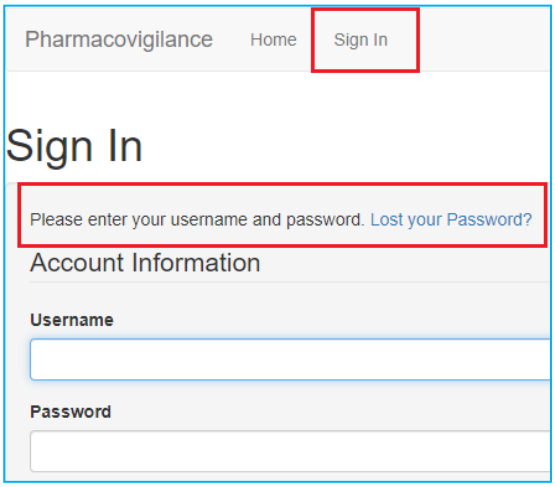
3. Use the form to change your password.



If the user has lost their password, this can be recovered directly on the homepage.

1. Go to top of the Homepage, select Sign In.

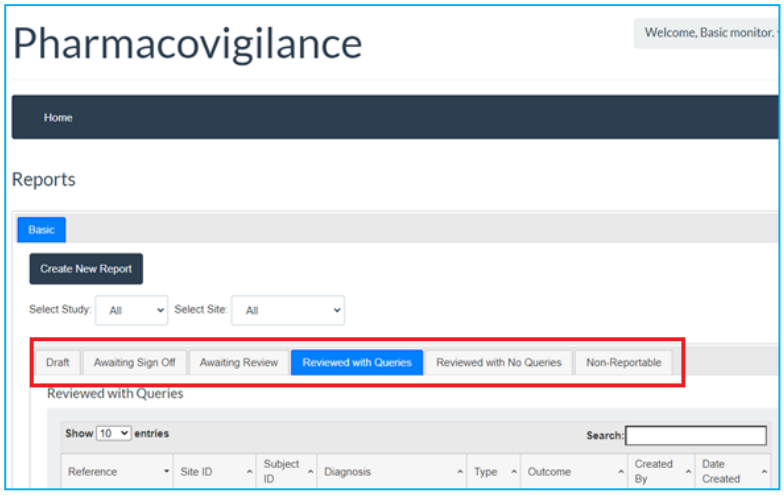
2. Select Lost your Password? And complete the required information.



4. SAE Data Entry & Basic User Reports

4.1. Home page

The Home Page is the same for all Users, what changes are the available **Report** tabs.

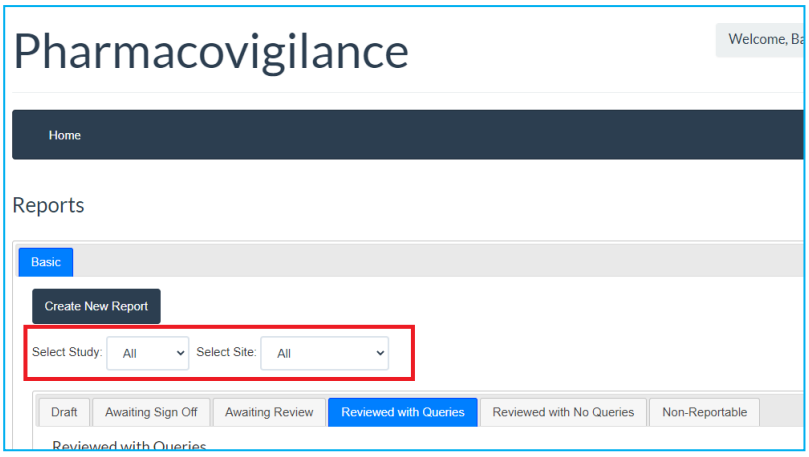


4.2. Reports

Reports available for Basic Users:

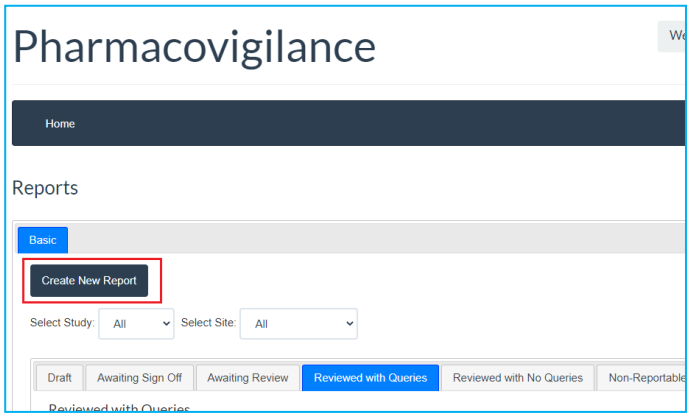
- **Draft**: SAE forms in draft.
- **Awaiting Sign Off:** SAEs completed and waiting PI/CI sign off.
- **Awaiting Review:** SAEs waiting for Medical review and Expectedness assessment.
- **Reviewed with Queries:** SAEs that have been reviewed but Medical Reviewer has raised queries that need to be answered.
- **Reviewed with No Queries:** SAEs that have been reviewed by Medical Reviewer.
- **Non-Reportable SAEs**

Users are able to filter reports using 'Select Study' and 'Select Site' tabs.



4.3. Creating an SAE Report

To create a new SAE form, follow the instructions below:

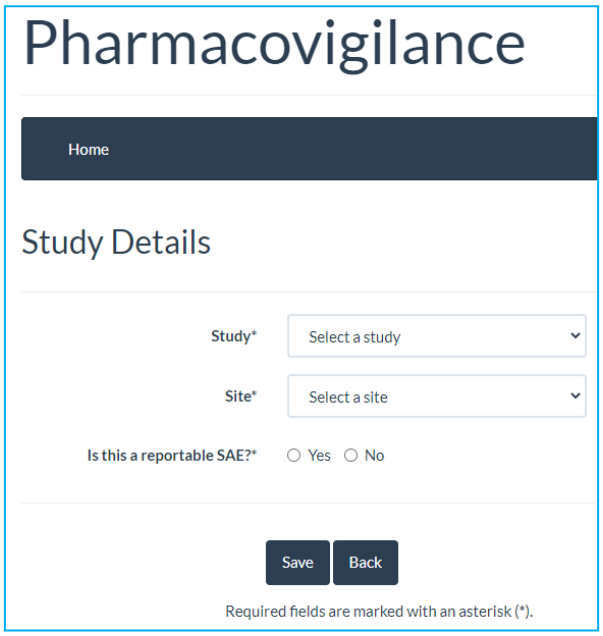


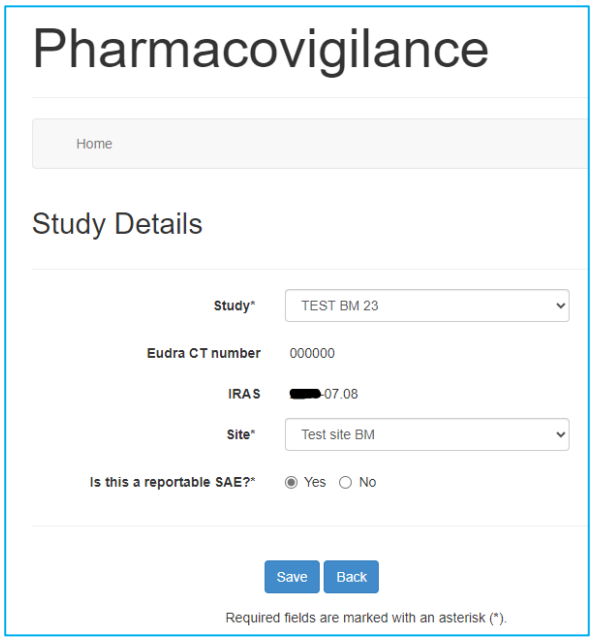
4.3.1 Study Details

1. Clink on **Create a New Report**.

2. The **Study Details** page will show up giving Users choice to select the **Study** and the **Site**. Users need to confirm if SAE is **reportable.**

3. After selecting **Study** and **Site**, User will be able to see the study **EudraCT number** and **R&D number**.





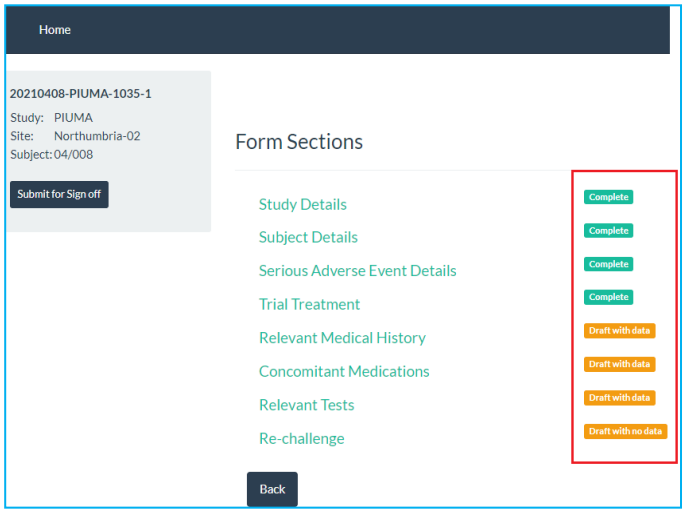
4. After clicking on 'Save', the **Study Details** section becomes complete (see below the green box-complete tag)

The **Form Sections** is divided in sections, and each section has a tag that changes colour based on the level data entry completion.

Complete – all fields completed

Draft with data – additional fields available for completion

Draft with no data – no data

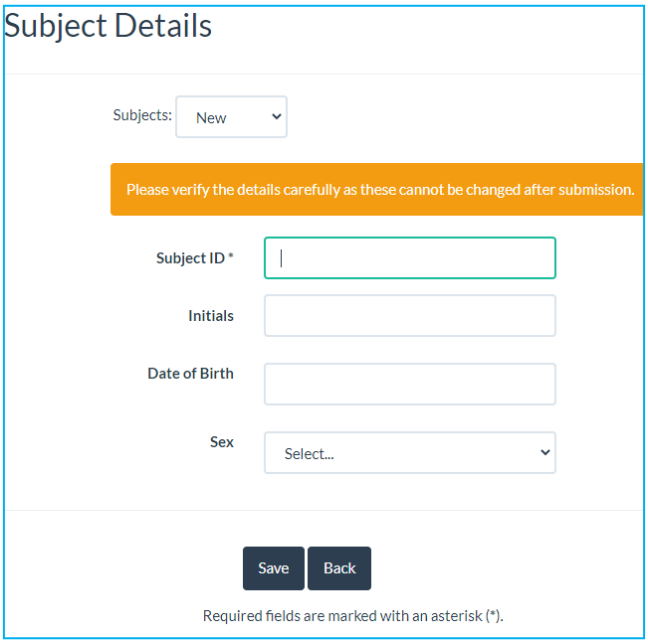


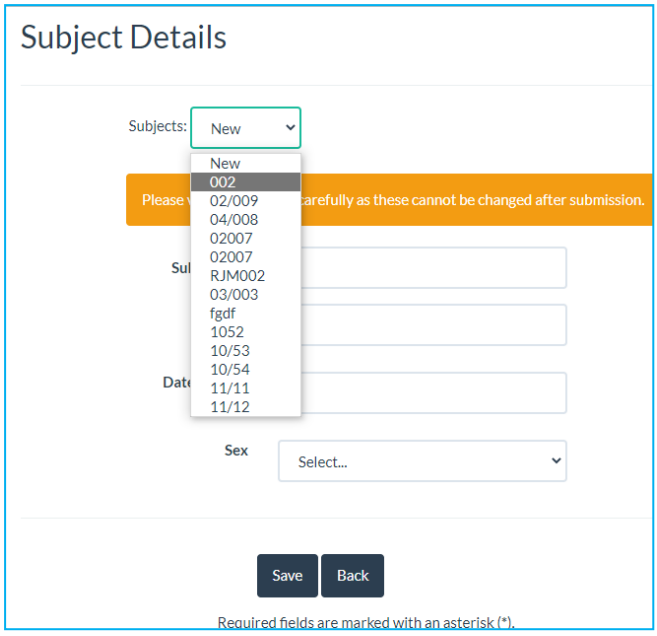
4.3.2 Subject Details

Users can enter details for an existing participant, or add a new participant. Users will be able to view all existing **Subject Ids** in dropdown.

1. Select **Subject Details** and enter all available subject information.
2. Selecting a pre-existing **Subject** will auto-populate the **Subject Details** fields.
3. If you are entering a new **Subject** click **New** and complete all mandatory fields.
4. Click **Save** if you wish to proceed.

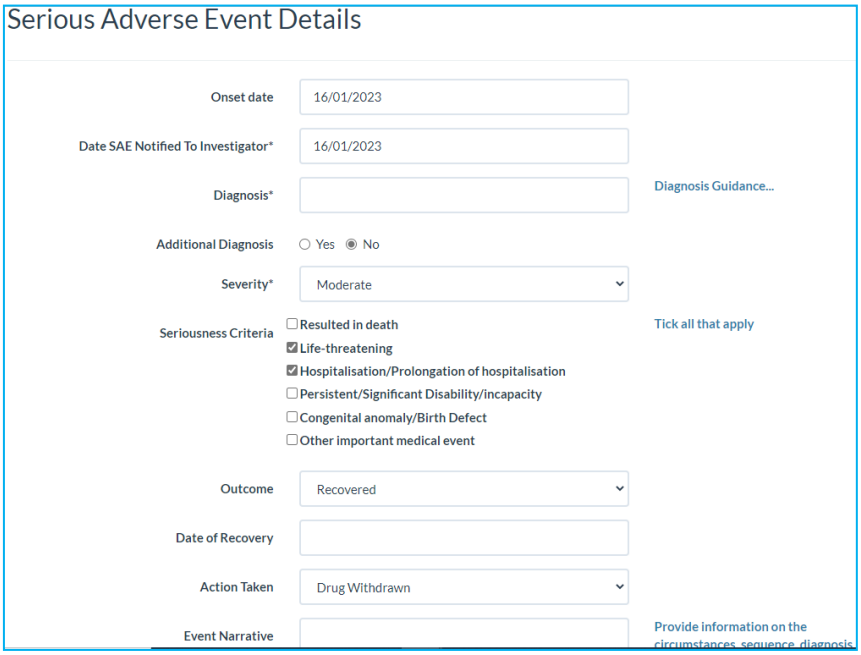
Note: Please verify details are carefully entered as these cannot be changed after submission.





4.3.3 Serious Adverse Event Details

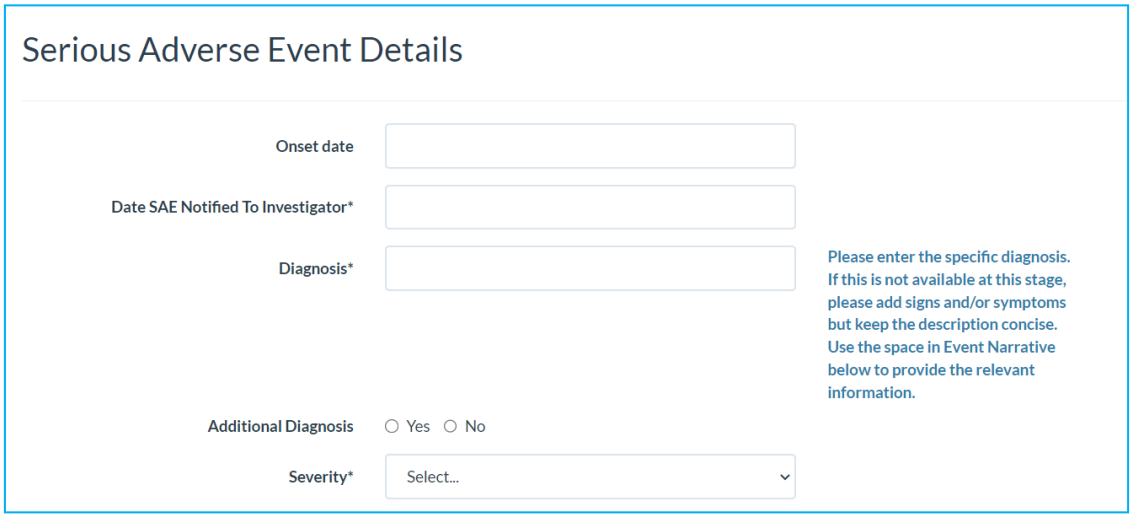
1. Select **Serious Adverse Events Details** and complete all mandatory fields.



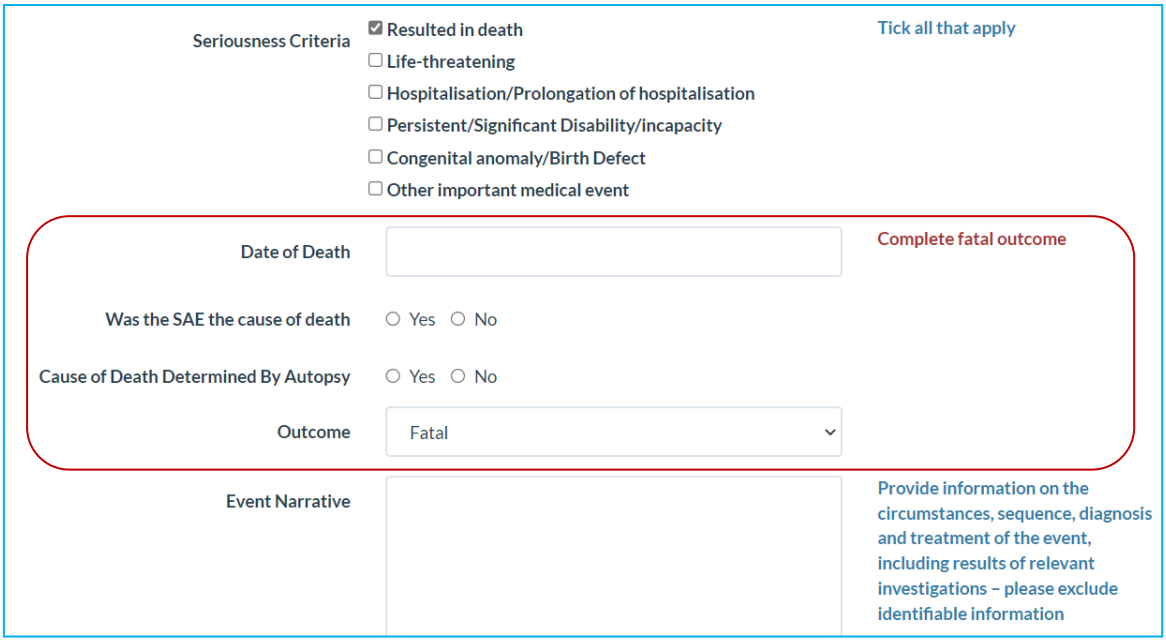
Note: Users will only be allowed to save if all required fields are complete.

The features of the **Serious Adverse Events Details** section are:

- Drop-down calendars for dates;
- Alert if **Date Notified to Investigator** is out with 24 hours of report being submitted;
- Alert to fill another SAE form in case of **Additional Diagnosis**;
- **Severity** is not a mandatory field for Basic Users;
- **Seriousness** is not a mandatory field for Basic Users;
- Alert to ensure Follow-up report is submitted in case **Outcome** is Recovering/Not Recovered/Unknown;
- **Date of Recovery** if **Outcome** is Recovered/Recovered with Sequelea



If the **Seriousness Criteria** is 'Resulted in death', **Outcome** will automatically be 'Fatal', and the form layout will look different.

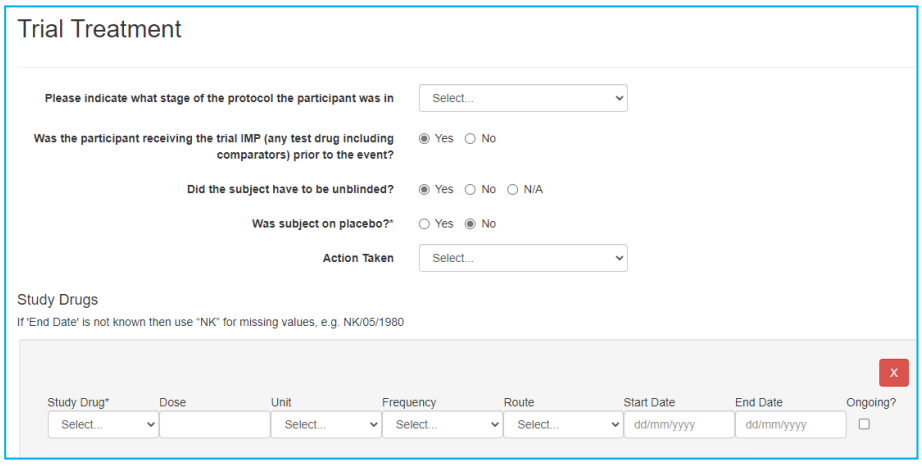


2. Click **Save** if you wish to proceed.

4.3.4 Trial Treatment

This section includes information on subject trial treatment stage, unblinding, study drug and causality.

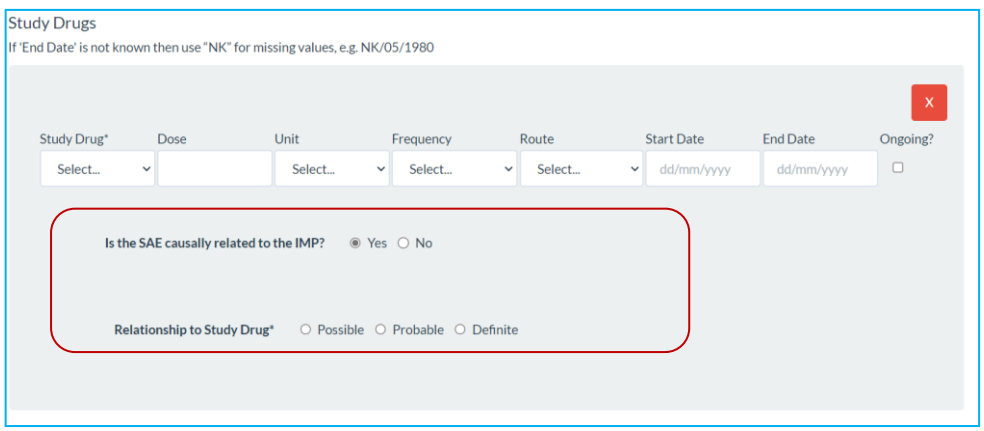
1. Select the **Trial Treatment** and complete all mandatory fields.



The features of the **Trial Treatment** section are:

- **Causality** question is not mandatory for Basic Users.

2. Click **Save** if you wish to proceed.



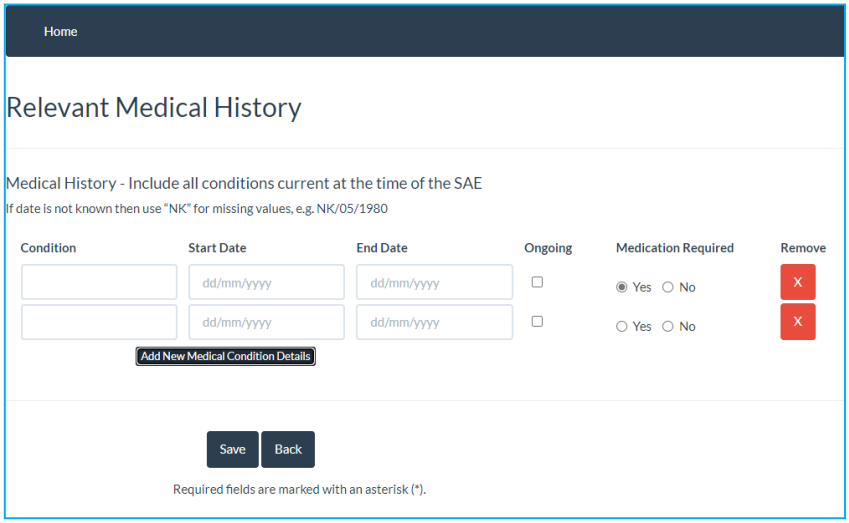
Note: Users will only be allowed to save if all required fields are complete.

4.3.5 Relevant Medical History

All relevant medical conditions need to be added in this section.

1. Add as many **New Medical Conditions** as necessary.

2. Click **Save** if you wish to proceed.



4.3.6. Concomitant Medications

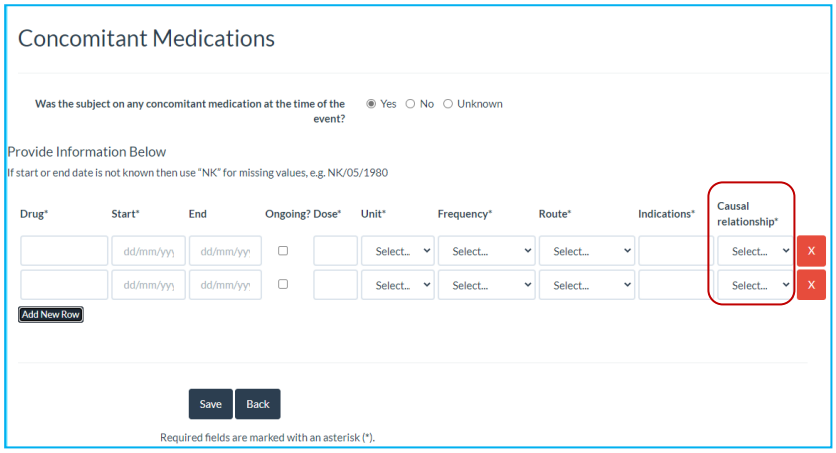
All relevant concomitant medications should be added in this section.

The feature of the **Concomitant Medications** section is:

- **Causal Relationship** field is not mandatory for Basic Users.

1. Add as many **New Rows** as necessary.

2. Click **Save** if you wish to proceed.

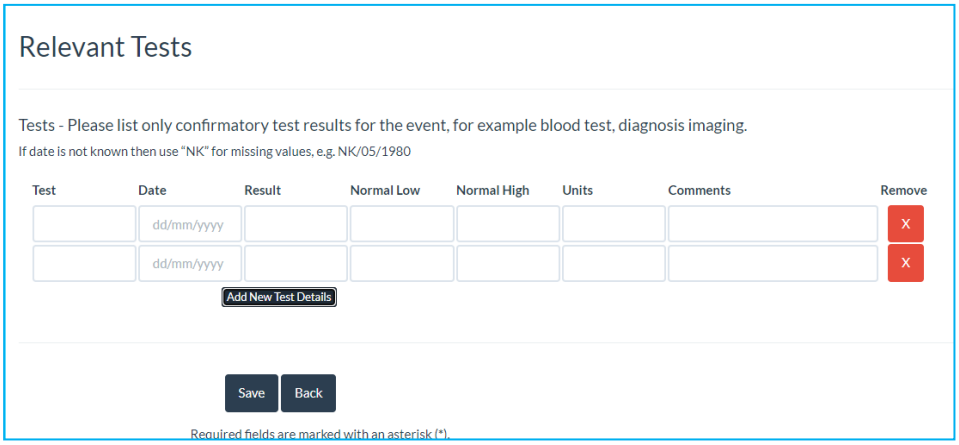


4.3.7. Relevant Tests

Users should list only confirmatory test results for the event, ie. blood test, diagnosis imaging.

1. Add as many **New Test Details** as necessary.

2. Click **Save** if you wish to proceed.

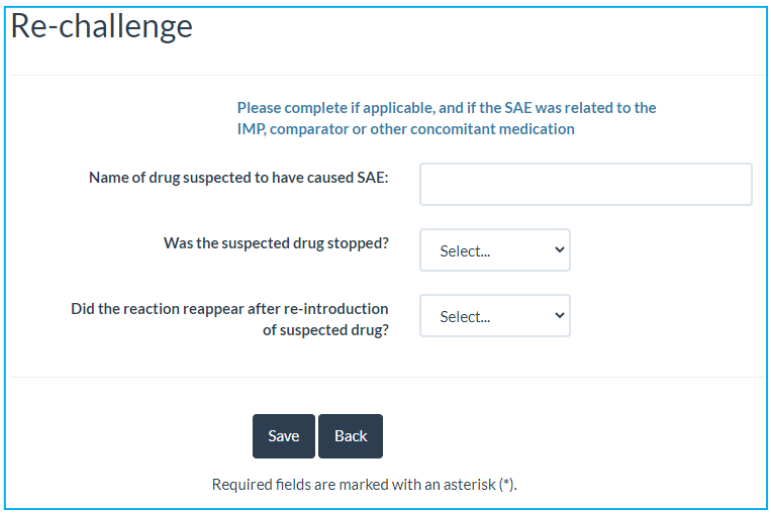


4.3.8. Re-challenge

Please complete if applicable, and if the SAE is related to the IMP, comparator or other concomitant medication.

1. Complete all fields.

2. Click **Save** if you wish to proceed.

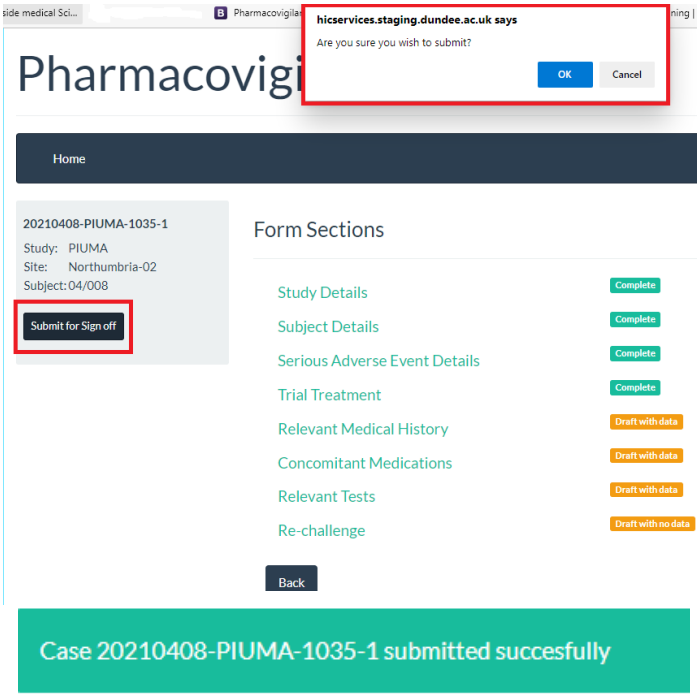


4.4. Submit a Report

Once the User has added all relevant and mandatory information, the SAE Report can be submitted for PI sign off.

1. Click on **Submit for Sign off** tab on left hand side of the screen. The User will be prompted to confirm if they want to submit the SAE report.

2. When the submission is done, the User will be redirected to the homepage and a green message will appear to confirm the submission, with a case number.



The SAE case number is composed as follows:

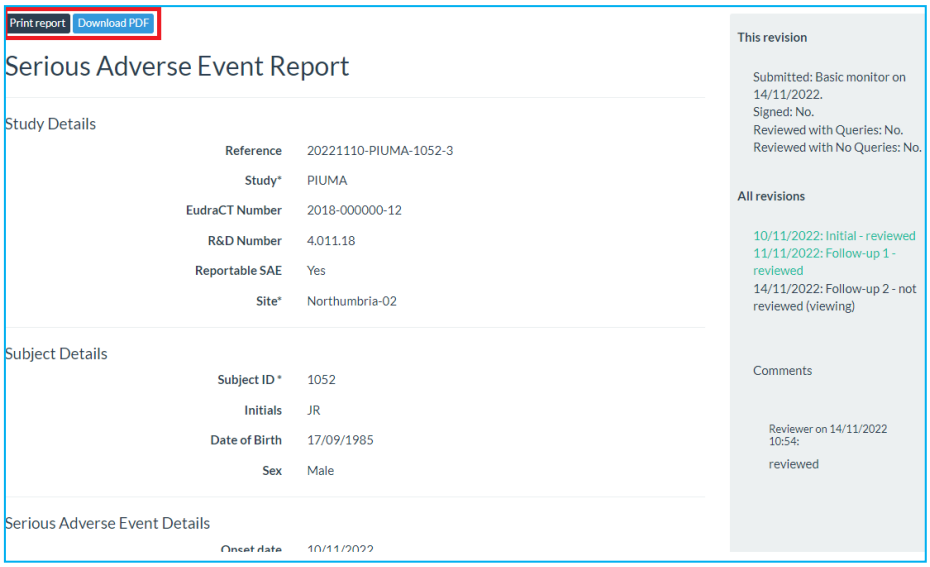
- Date submitted
- Study name
- Incremental ID
- Number of submissions (e.g. 1 for initial, 2 for first follow-up etc.).

4.5 Viewing Submitted SAEs

To view submitted SAEs Awaiting Sign off, the User should return to Reports page (Section 4.2).

1. Click on the relevant study to access the submitted SAEs.

The entire SAE form can be reviewed, printed or downloaded.



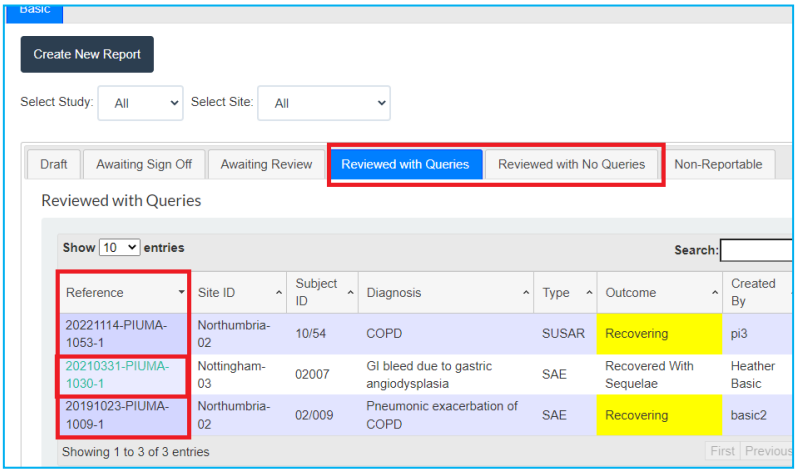
5. Create a Follow-up report

In some instances a follow-up SAE form will be required. This can be created on the PV system after the SAE form has been **Signed off** and **Reviewed**.

To create a Follow-up report log into the PV system (Section 3).

1. Find your original SAE report under the tabs Reviewed with Queries/Review with No Queries and click on your SAE Reference.

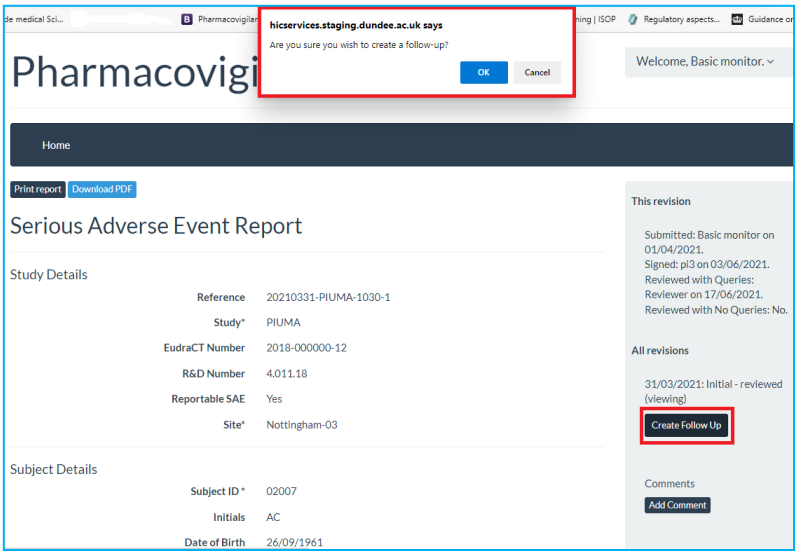
This will open your previously completed Serious Adverse Event Report.



2. Click on ‘Create Follow Up’, this will prompt the user to confirm if they wish to create a follow-up. Click ‘OK’ if you wish to proceed.

Most previously completed sections will be available for update, but Users will need to provide a Reason for Change.

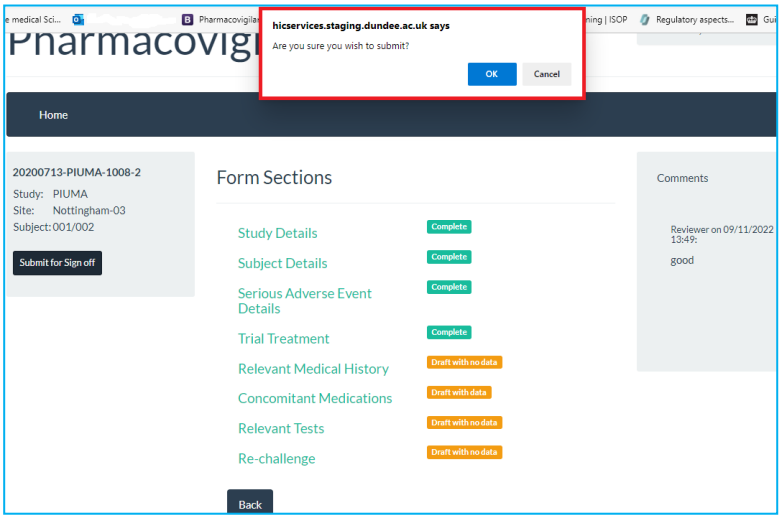
After changes are made, the form can be submitted.



3. Click on ‘Submit for Sign off’. This will prompt the user to confirm if they wish to submit. Click ‘OK’ if you wish to proceed.

When the submission is done User will be redirected to **Reports** and a green message will appear to confirm the submission, with the update case number (e.g. 1 for initial, 2 for first follow-up etc.).

Case 20200713-PIUMA-1008-2 submitted succesfully

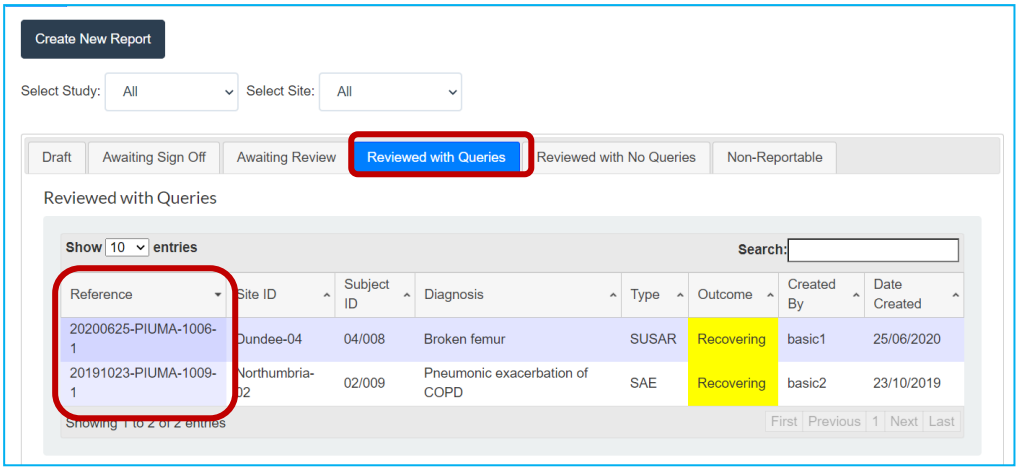


6. Answering Queries

Users will receive email alerts to notify them of any queries raised by the Medical Reviewer/ Pharmacovigilance Monitor regarding the submitted SAE report. The email will provide a link to access the system.

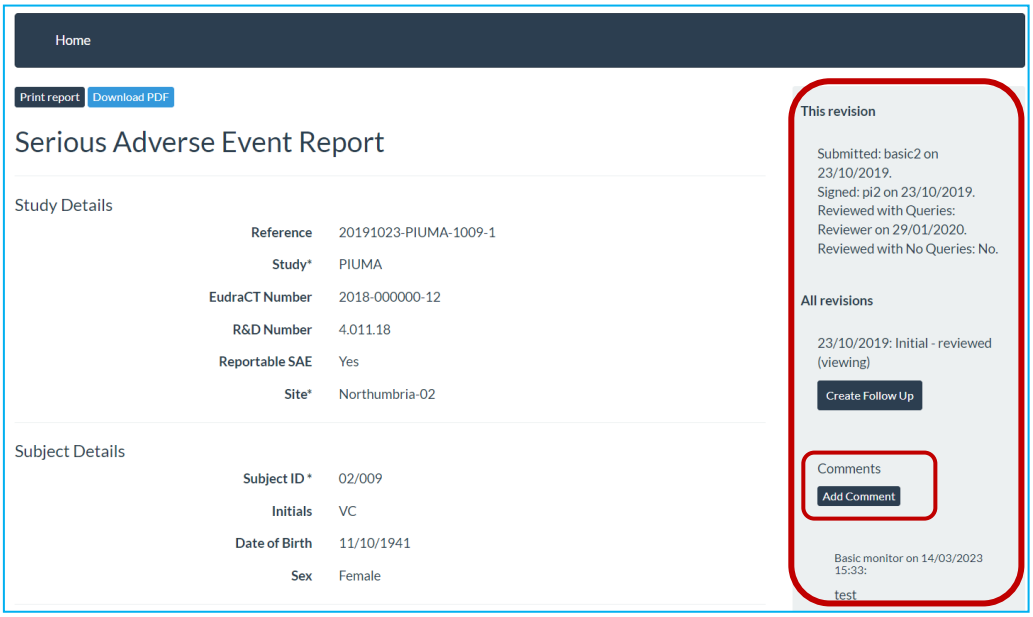
1. After signing into the PV system, the user should select the tab **Reviewed with Queries.**

2. Select the relevant SAE by clicking the report 'Reference'.



3. An overview of the SAE report will come up.

4. The query will appear on the right hand side of the SAE overview and an answer can be provided by selecting **Comments** and clicking 'Save'.



7. PI SAE Sign off and Reports

7.1. Homepage

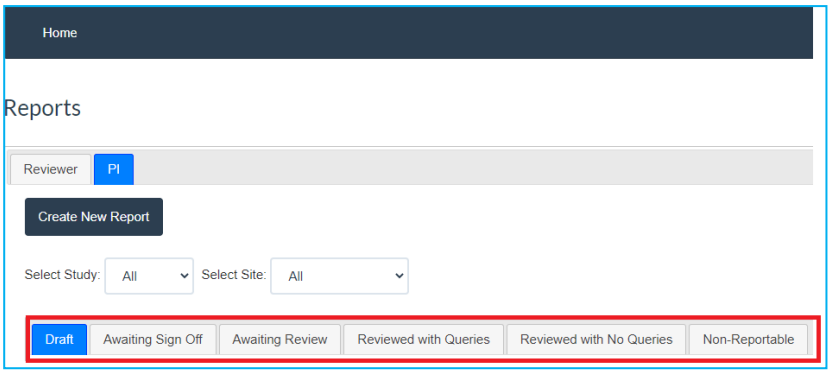
The **Home Page** is the same for all the users, what changes are the **Report** tabs.

To **Log In** as a PI please see Section 2 and 3.

7.2. PI Reports

Investigators have access to SAEs for studies and sites on which they are working.

If required they will also have access to **Reviewer** tab for studies in which they are not involved.



Note: Users are also able to filter the reports by using 'Select Study' and 'Select Site' Tab.

Reports available for Investigators:

- **Draft**: SAE forms in draft
- **Awaiting Sign Off:** SAEs completed and waiting PI/CI sign off
- **Awaiting Review:** signed off SAEs
- **Reviewed with Queries:** signed off SAEs that have been reviewed but Medical reviewer has raised query that needs to be answered.
- **Reviewed with No Queries:** signed off SAEs that have been reviewed by Medical reviewer with no queries.
- **Non-Reportable SAEs**

7.3. PI SAE Sign Off

PIs will receive email alerts to notify them of any Serious Adverse Events entered for their study. The email will provide a link to access the system and alert that a review, assessment of severity and causality need to be submitted within 24 hours from initial SAE data entry.

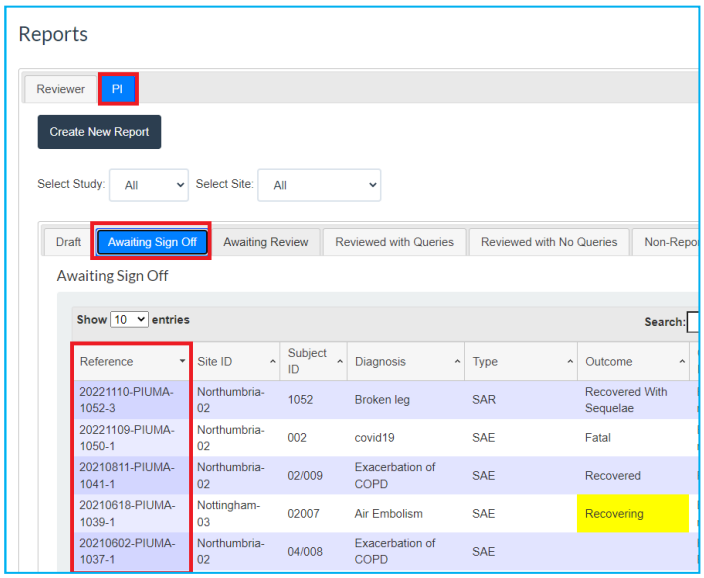
Access to PV system is available through the email link or website address.

7.3.1. Signing off SAE Report

1. After signing into the PV system, PIs should select the PI tab.

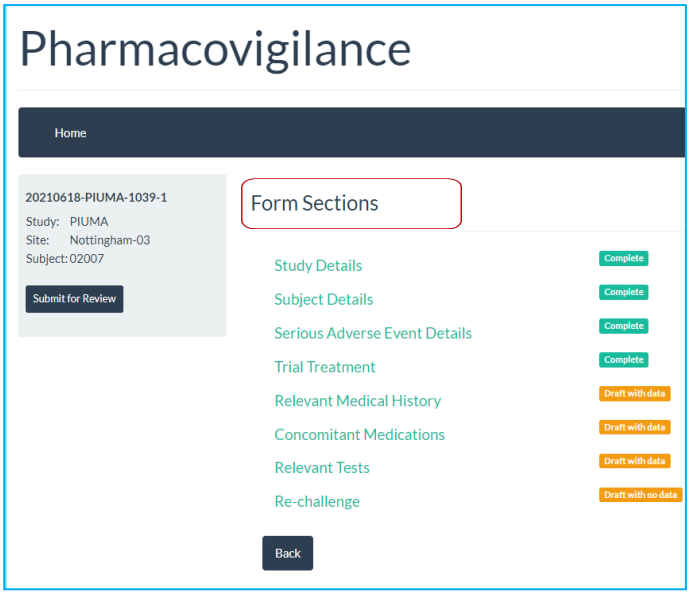
2. Click the 'Awaiting Sign off' tab to view all SAE's from the relevant site/study.

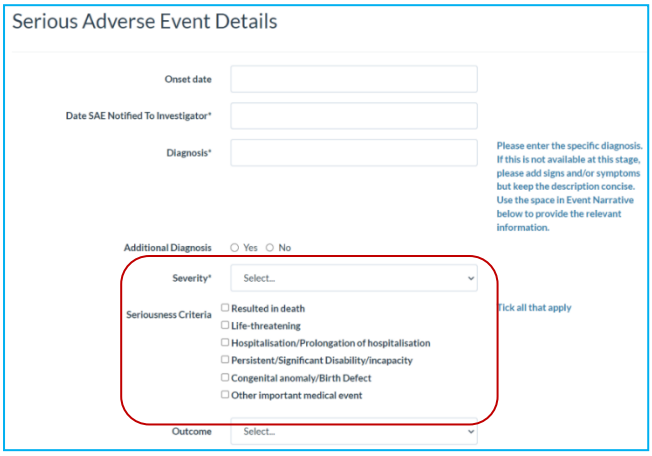
3. Access the report by clicking the report 'Reference'.



The **Form Sections** page will show up for PI to review and amend/add any information to the existing SAE report.

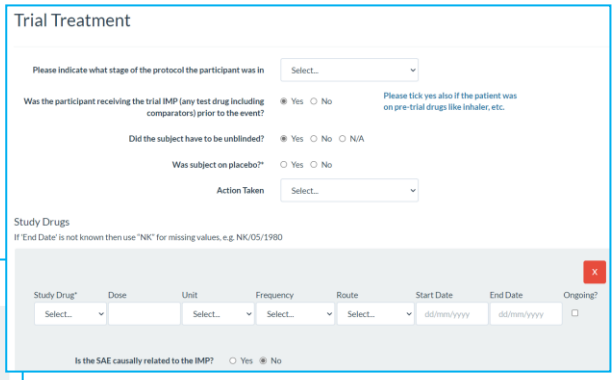
4. To review/add **'Severity Criteria and Seriousness Criteria'**, please select **Serious Adverse Event Details**. Tick all that apply and Save.

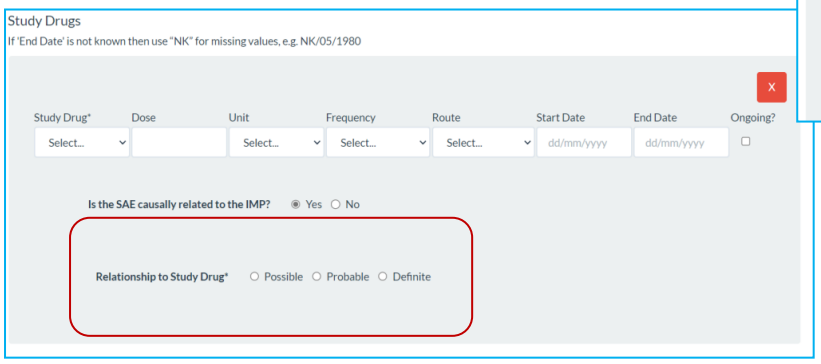




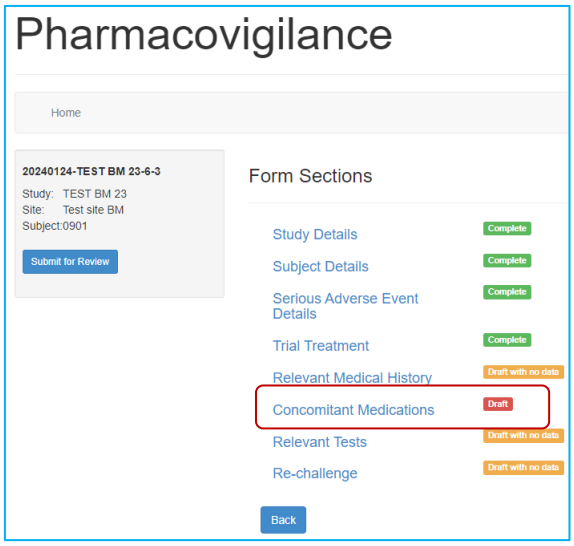
5. To review/add '**Causality'**, please select **Trial Treatment**. Please complete '*Is the SAE causally related to the IMP?*' and '*Relationship to Study Drug'*.

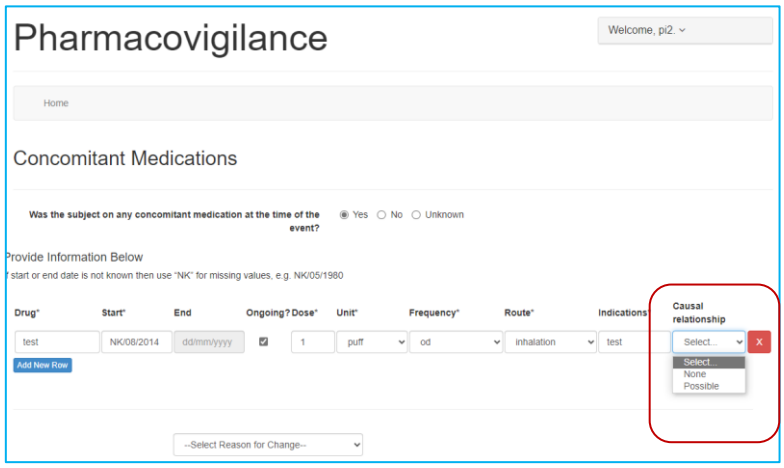
Information should have been entered regarding Trial IMP and Study Drug details.





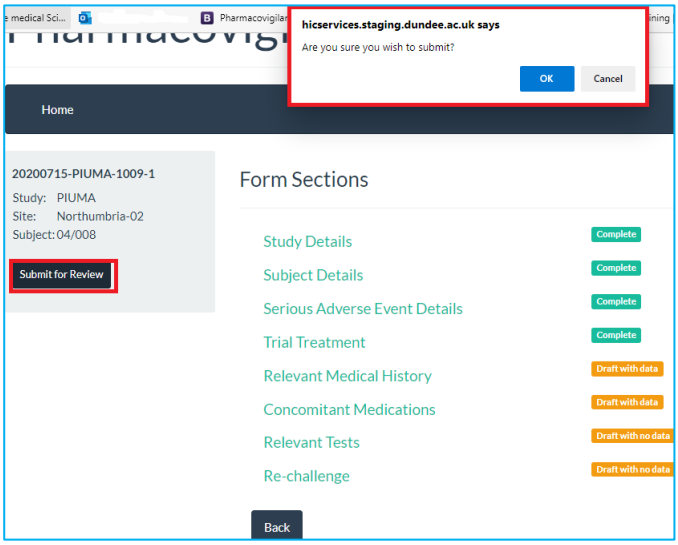
6. To add missing information under **Concomitant Medications.** Please review information as required and provide **Causal Relationship**.





Once happy with the form PI should submit for Medical Review

7. Click on 'Submit for Review' on top left side of **Forms Sections**. This will prompt the user to confirm if they wish to submit. Click 'OK' if you wish to proceed.



Note: If any changes are to be made before sign off these can be done by going into any Section and providing a 'Reason for Change'.