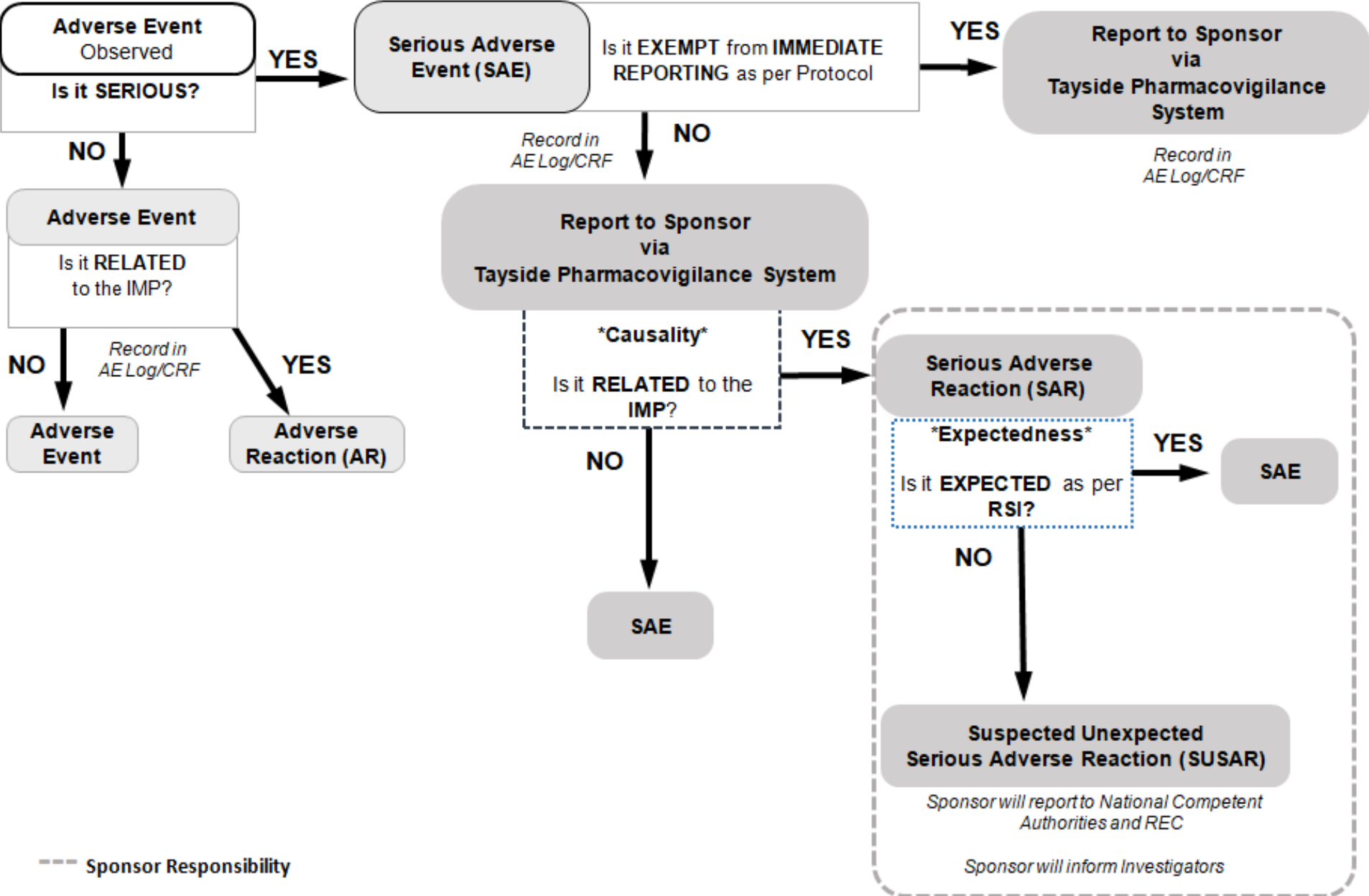


Basic User & Principal Investigator
Tayside Pharmacovigilance System User Guide
Tayside Pharmacovigilance

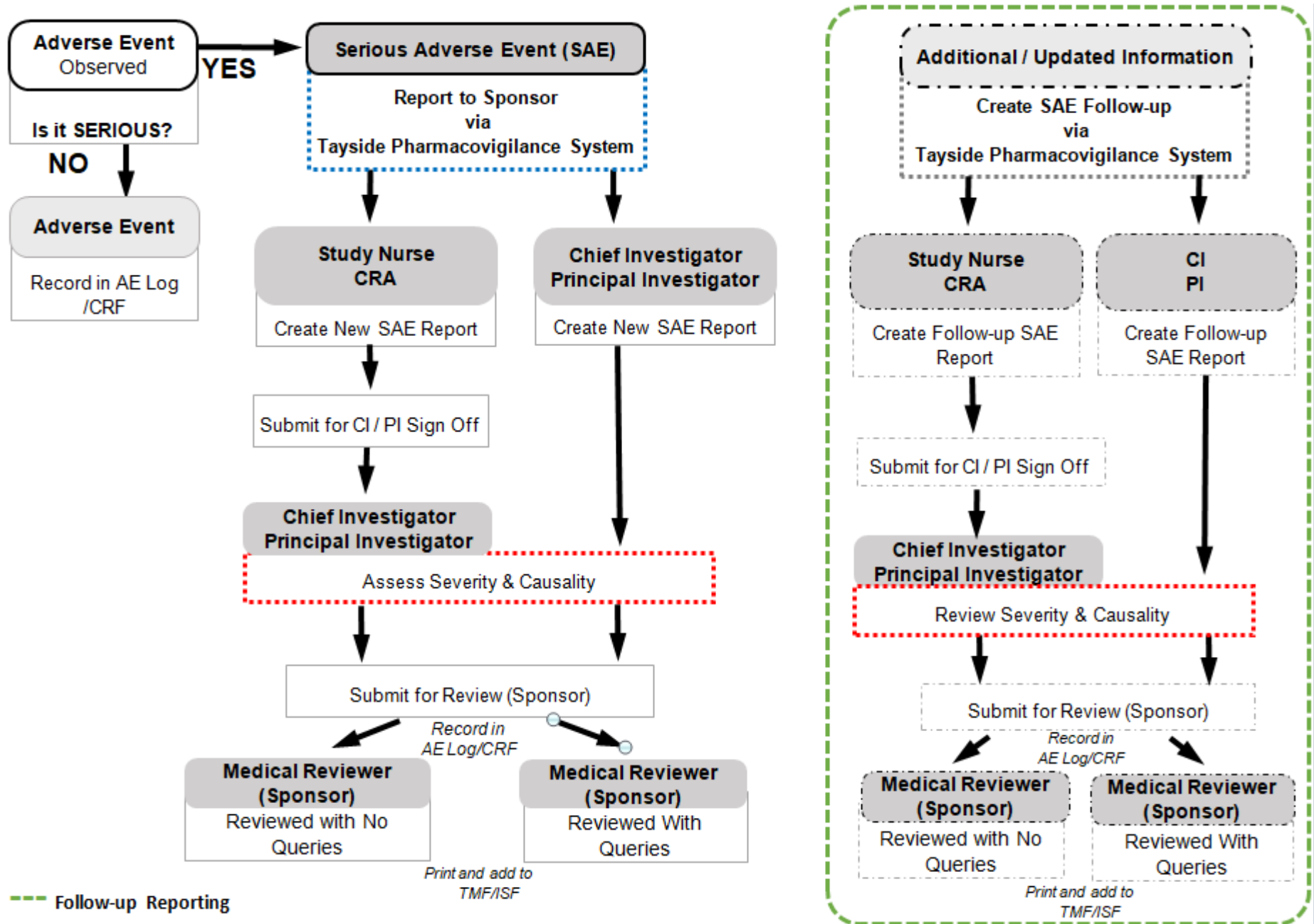
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Serious Adverse Event Assessment Flow Chart



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

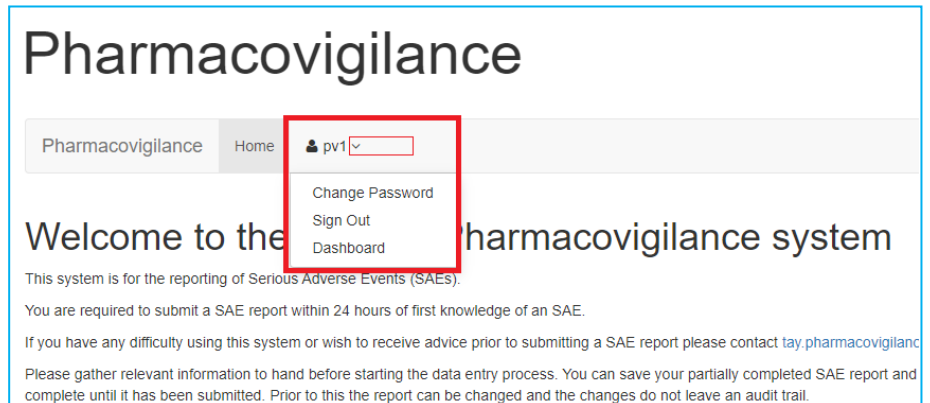
1. Go to top of the Homepage and add your details.
2. Once logged on click on 'here' at the bottom left of the homepage to access reports.



3.2. Password Change or Recovery

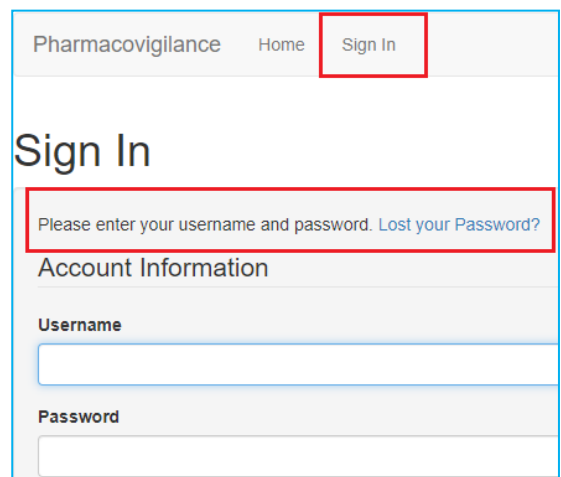
We recommend users change their password after they log in.

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.

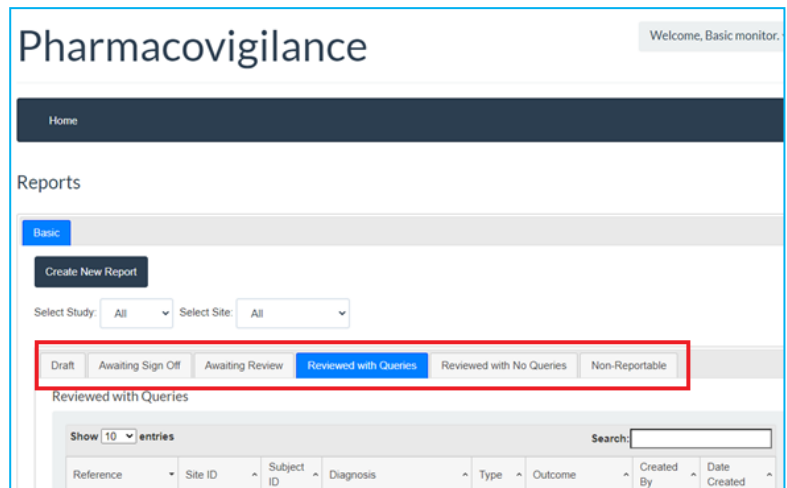
1. Go to top of the Homepage, select [Sign In](#).
2. Select [Lost your Password?](#) And complete the required information.



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.

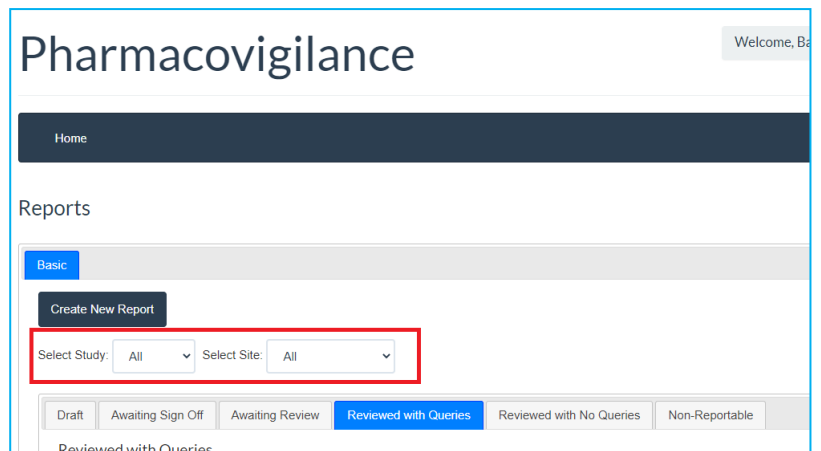


4.2. Reports

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.

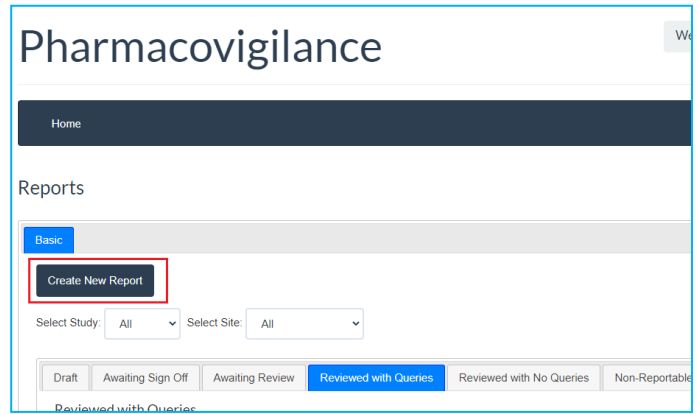


4.3. Creating an SAE Report

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

4.3.1 Study Details

1. Click 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

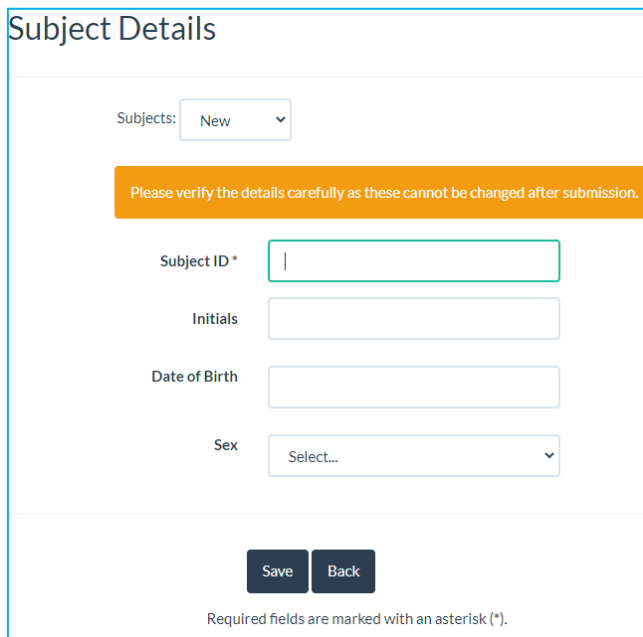
Draft with no data – no data

4.3.2 Subject Details

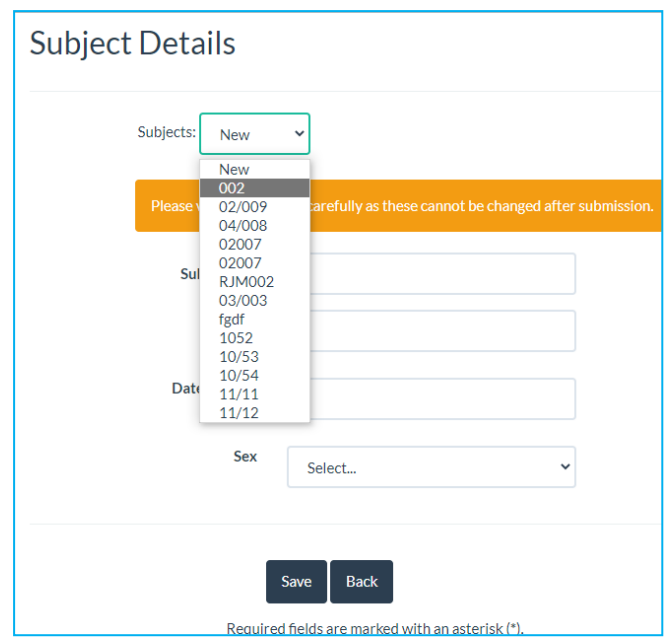
Users can enter details for an existing participant, or add a new participant. Users will be able to view all existing **Subject Ids** in dropdown.

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.



The screenshot shows the 'Subject Details' form. At the top left, there is a 'Subjects:' dropdown menu with 'New' selected. Below this is an orange warning banner that reads 'Please verify the details carefully as these cannot be changed after submission.' The form contains several input fields: 'Subject ID *' (a text box with a vertical cursor), 'Initials' (a text box), 'Date of Birth' (a text box), and 'Sex' (a dropdown menu with 'Select...' selected). At the bottom, there are 'Save' and 'Back' buttons, and a note that 'Required fields are marked with an asterisk (*)'.



This screenshot shows the same 'Subject Details' form, but with a dropdown menu open over the 'Subjects:' field. The dropdown menu lists the following options: 'New', '002', '02/009', '04/008', '02007', '02007', 'RJM002', '03/003', 'fgdf', '1052', '10/53', '10/54', '11/11', and '11/12'. The 'New' option is currently selected in the main dropdown. The rest of the form, including the orange warning banner, input fields, and buttons, is identical to the previous screenshot.

4.3.3 Serious Adverse Event Details

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

The screenshot shows the 'Serious Adverse Event Details' form with the following filled-in fields:

- Onset date: 16/01/2023
- Date SAE Notified To Investigator*: 16/01/2023
- Diagnosis*: (empty)
- Additional Diagnosis: Yes No
- Severity*: Moderate
- Seriousness Criteria: Resulted in death, Life-threatening, Hospitalisation/Prolongation of hospitalisation, Persistent/Significant Disability/incapacity, Congenital anomaly/Birth Defect, Other important medical event
- Outcome: Recovered
- Date of Recovery: (empty)
- Action Taken: Drug Withdrawn
- Event Narrative: (empty)

Additional text on the right side of the form includes 'Diagnosis Guidance...', 'Tick all that apply', and 'Provide information on the circumstances, sequence, diagnosis...'.

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 Sequela

The screenshot shows the 'Serious Adverse Event Details' form with the following empty fields:

- Onset date: (empty)
- Date SAE Notified To Investigator*: (empty)
- Diagnosis*: (empty)
- Additional Diagnosis: Yes No
- Severity*: Select...

A blue text box on the right side of the form provides guidance: 'Please enter the specific diagnosis. If this is not available at this stage, please add signs and/or symptoms but keep the description concise. Use the space in Event Narrative below to provide the relevant information.'

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.

Home

Relevant Medical History

Medical History - Include all conditions current at the time of the SAE
If date is not known then use "NK" for missing values, e.g. NK/05/1980

Condition	Start Date	End Date	Ongoing	Medication Required	Remove
<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="checkbox"/>	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="button" value="X"/>
<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="checkbox"/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="button" value="X"/>

Required fields are marked with an asterisk (*).

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.

Concomitant Medications

Was the subject on any concomitant medication at the time of the event? Yes No Unknown

Provide Information Below
If start or end date is not known then use "NK" for missing values, e.g. NK/05/1980

Drug*	Start*	End	Ongoing?	Dose*	Unit*	Frequency*	Route*	Indications*	Causal relationship*
<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>
<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>	<input type="text" value="Select..."/>

Required fields are marked with an asterisk (*).

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.

Relevant Tests

Tests - Please list only confirmatory test results for the event, for example blood test, diagnosis imaging.
If date is not known then use "NK" for missing values, e.g. NK/05/1980

Test	Date	Result	Normal Low	Normal High	Units	Comments	Remove
<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="X"/>
<input type="text"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="X"/>

Required fields are marked with an asterisk (*).

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.

Re-challenge

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

Name of drug suspected to have caused SAE:

Was the suspected drug stopped?

Did the reaction reappear after re-introduction of suspected drug?

Required fields are marked with an asterisk (*).

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.).

side medical Sci... Pharmacovigilance hiservices.staging.dundee.ac.uk says Are you sure you wish to submit?

Pharmacovigilance

Home

20210408-PIUMA-1035-1
Study: PIUMA
Site: Northumbria-02
Subject: 04/008

Form Sections

- Study Details
- Subject Details
- Serious Adverse Event Details
- Trial Treatment
- Relevant Medical History
- Concomitant Medications
- Relevant Tests
- Re-challenge

Case 20210408-PIUMA-1035-1 submitted succesfully

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.

Print report **Download PDF**

Serious Adverse Event Report

Study Details

Reference	20221110-PIUMA-1052-3
Study*	PIUMA
EudraCT Number	2018-000000-12
R&D Number	4.011.18
Reportable SAE	Yes
Site*	Northumbria-02

Subject Details

Subject ID*	1052
Initials	JR
Date of Birth	17/09/1985
Sex	Male

Serious Adverse Event Details

Onset date	10/11/2022
------------	------------

This revision

Submitted: Basic monitor on 14/11/2022.
Signed: No.
Reviewed with Queries: No.
Reviewed with No Queries: No.

All revisions

10/11/2022: Initial - reviewed
11/11/2022: Follow-up 1 - reviewed
14/11/2022: Follow-up 2 - not reviewed (viewing)

Comments

Reviewer on 14/11/2022 10:54:
reviewed

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.

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**

Reviewed with Queries

Show 10 entries Search:

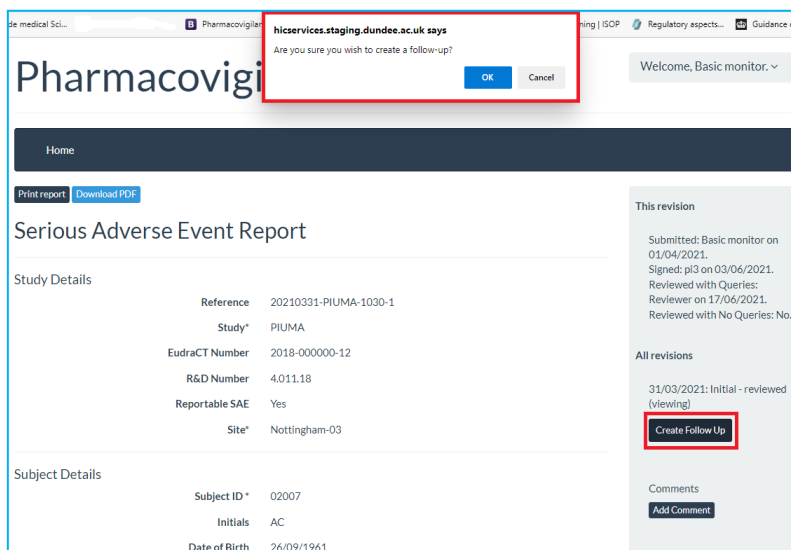
Reference	Site ID	Subject ID	Diagnosis	Type	Outcome	Created By
20221114-PIUMA-1053-1	Northumbria-02	10/54	COPD	SUSAR	Recovering	pi3
20210331-PIUMA-1030-1	Nottingham-03	02007	GI bleed due to gastric angiodysplasia	SAE	Recovered With Sequelae	Heather Basic
20191023-PIUMA-1009-1	Northumbria-02	02/009	Pneumonic exacerbation of COPD	SAE	Recovering	basic2

Showing 1 to 3 of 3 entries First Previous

- 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.

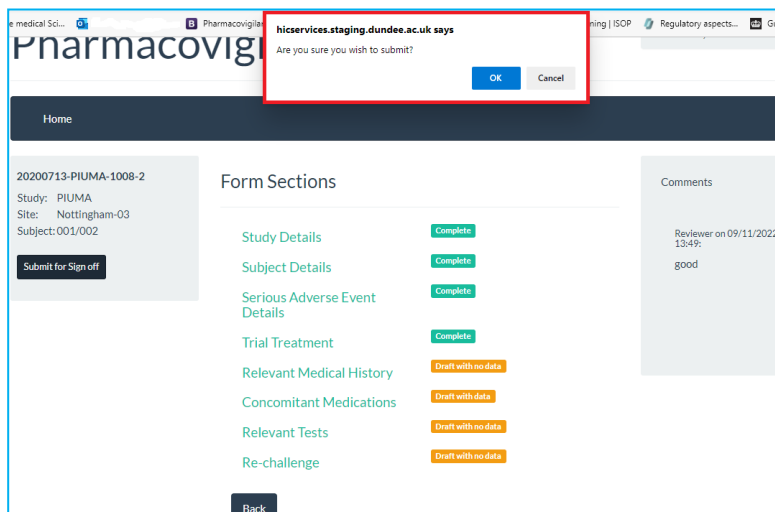
After changes are made, the form can be submitted.



- 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 successfully



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'.

The screenshot shows the 'Reviewed with Queries' tab selected in the system. Below the tab, there is a table with the following data:

Reference	Site ID	Subject ID	Diagnosis	Type	Outcome	Created By	Date Created
20200625-PIUMA-1006-1	Dundee-04	04/008	Broken femur	SUSAR	Recovering	basic1	25/06/2020
20191023-PIUMA-1009-1	Northumbria-02	02/009	Pneumonic exacerbation of COPD	SAE	Recovering	basic2	23/10/2019

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'.

The screenshot shows the 'Serious Adverse Event Report' overview page. The page is divided into sections for Study Details, Subject Details, and a right-hand sidebar. The Study Details section includes:

- Reference: 20191023-PIUMA-1009-1
- Study*: PIUMA
- EudraCT Number: 2018-000000-12
- R&D Number: 4.011.18
- Reportable SAE: Yes
- Site*: Northumbria-02

The Subject Details section includes:

- Subject ID*: 02/009
- Initials: VC
- Date of Birth: 11/10/1941
- Sex: Female

The right-hand sidebar contains a 'This revision' section with the following text:

Submitted: basic2 on 23/10/2019.
Signed: pi2 on 23/10/2019.
Reviewed with Queries: Reviewer on 29/01/2020.
Reviewed with No Queries: No.

Below this is an 'All revisions' section with the text: '23/10/2019: Initial - reviewed (viewing)'. A 'Create Follow Up' button is located below the revisions.

At the bottom of the sidebar, there is a 'Comments' section with an 'Add Comment' button. The text 'Basic monitor on 14/03/2023 15:33: test' is visible at the very bottom of the sidebar.

7. PI SAE Sign off and Reports

7.1. Homepage

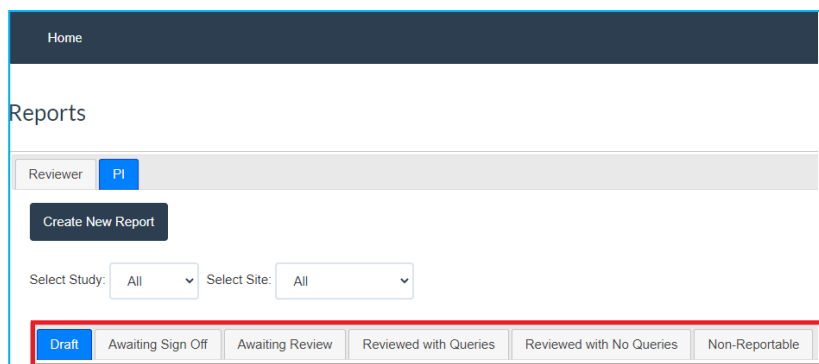
The **Home Page** is the same for all the users, what changes are the **Report** tabs.

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**

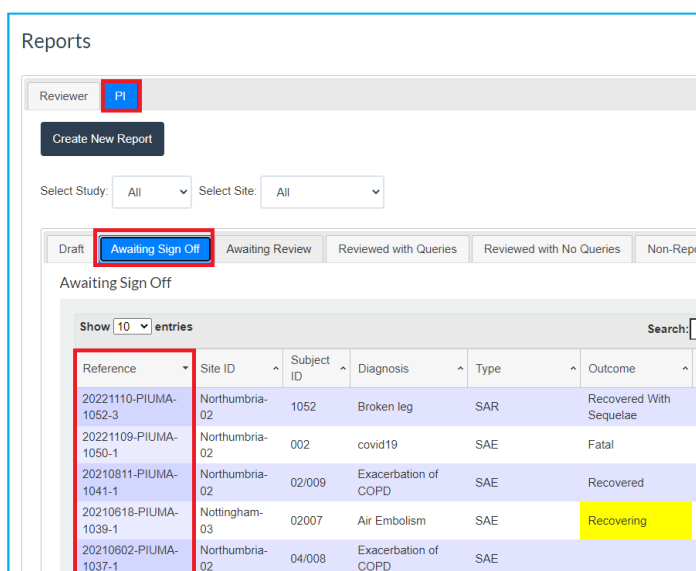
7.3. PI SAE Sign Off

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.

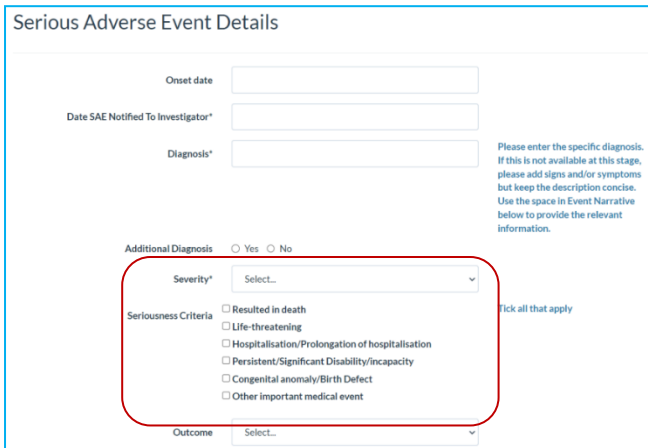
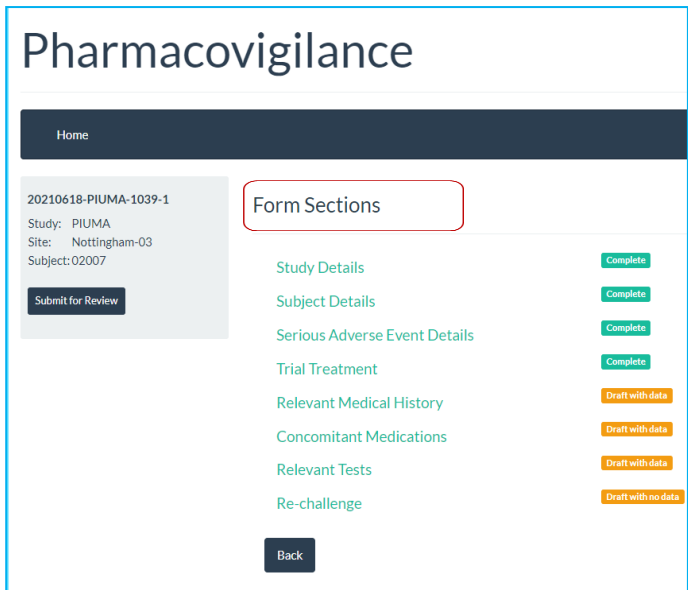
7.3.1. Signing off SAE Report

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’.



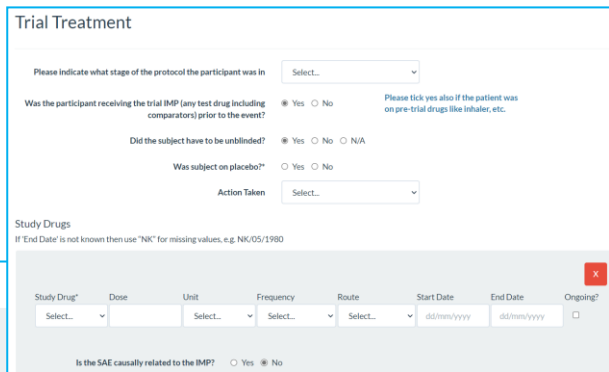
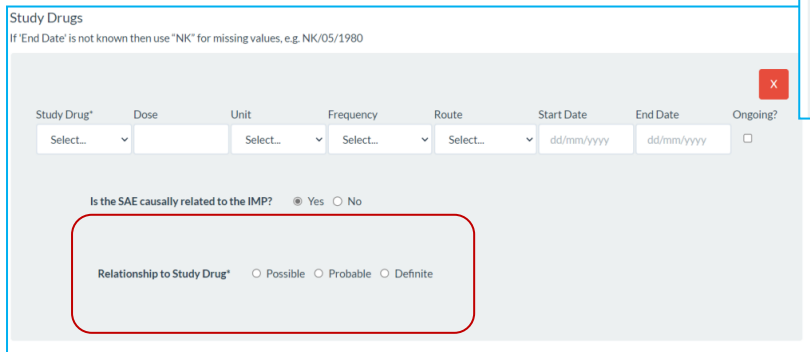
The **Form Sections** page will show up for PI to review and amend/add any information to the existing SAE report.

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



- 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.



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

The left screenshot shows the 'Pharmacovigilance' home page with a sidebar menu. Under 'Form Sections', 'Concomitant Medications' is highlighted with a red box. The right screenshot shows the 'Concomitant Medications' form. A table lists medication entries with columns for Drug, Start, End, Ongoing? Dose, Unit, Frequency, Route, and Indications. The 'Causal relationship' dropdown menu is open, showing options 'Select...', 'None', and 'Possible', with 'Possible' highlighted in a red box.

Once happy with the form PI should submit for Medical Review

- 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.

The screenshot shows a confirmation dialog box with the text 'Are you sure you wish to submit?' and 'OK' and 'Cancel' buttons. In the background, the 'Submit for Review' button in the sidebar is highlighted with a red box.

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'.