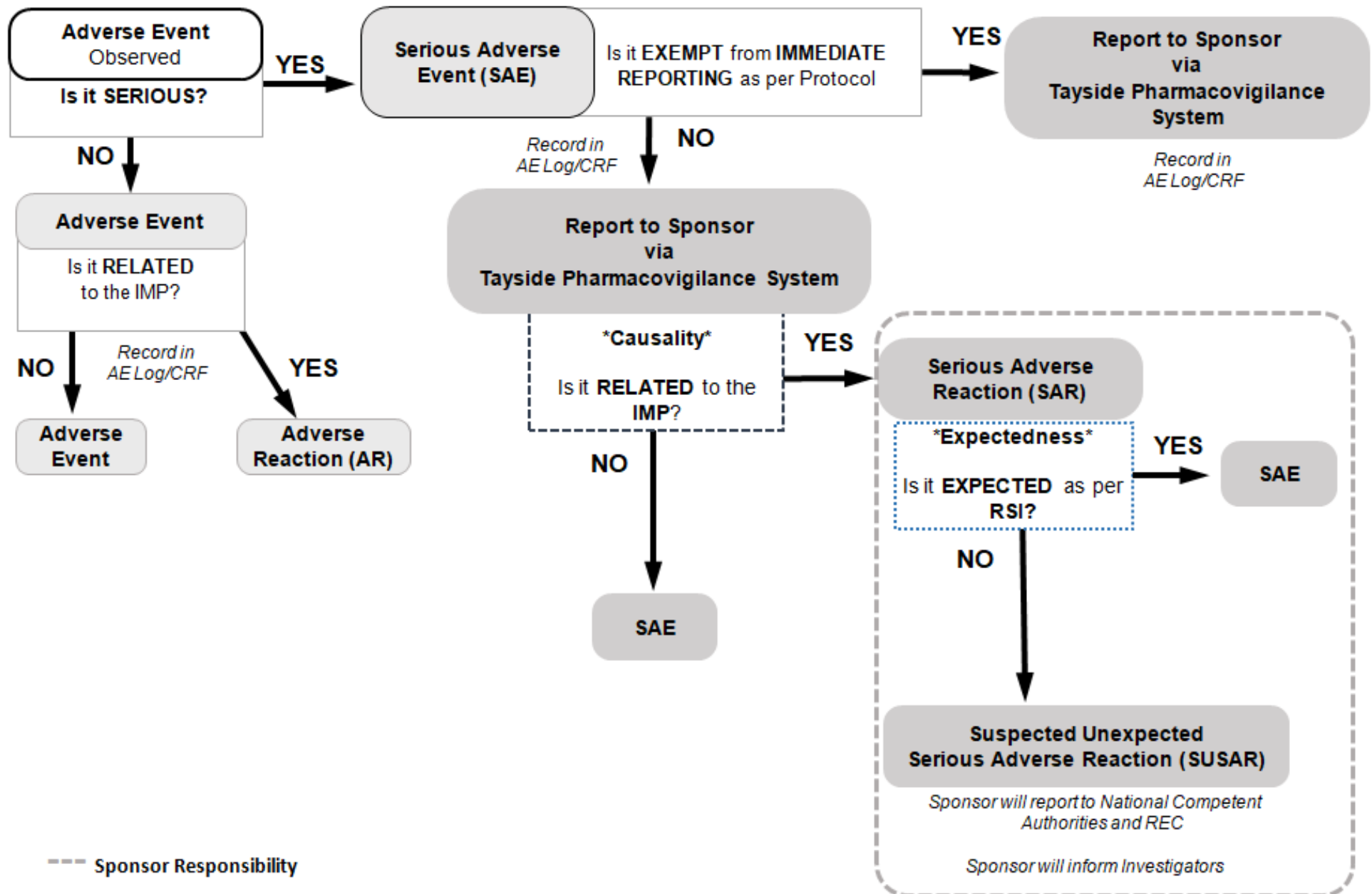


**Basic User & Principal Investigator**  
**PV Database User Guide**  
April 2023, TASC Pharmacovigilance

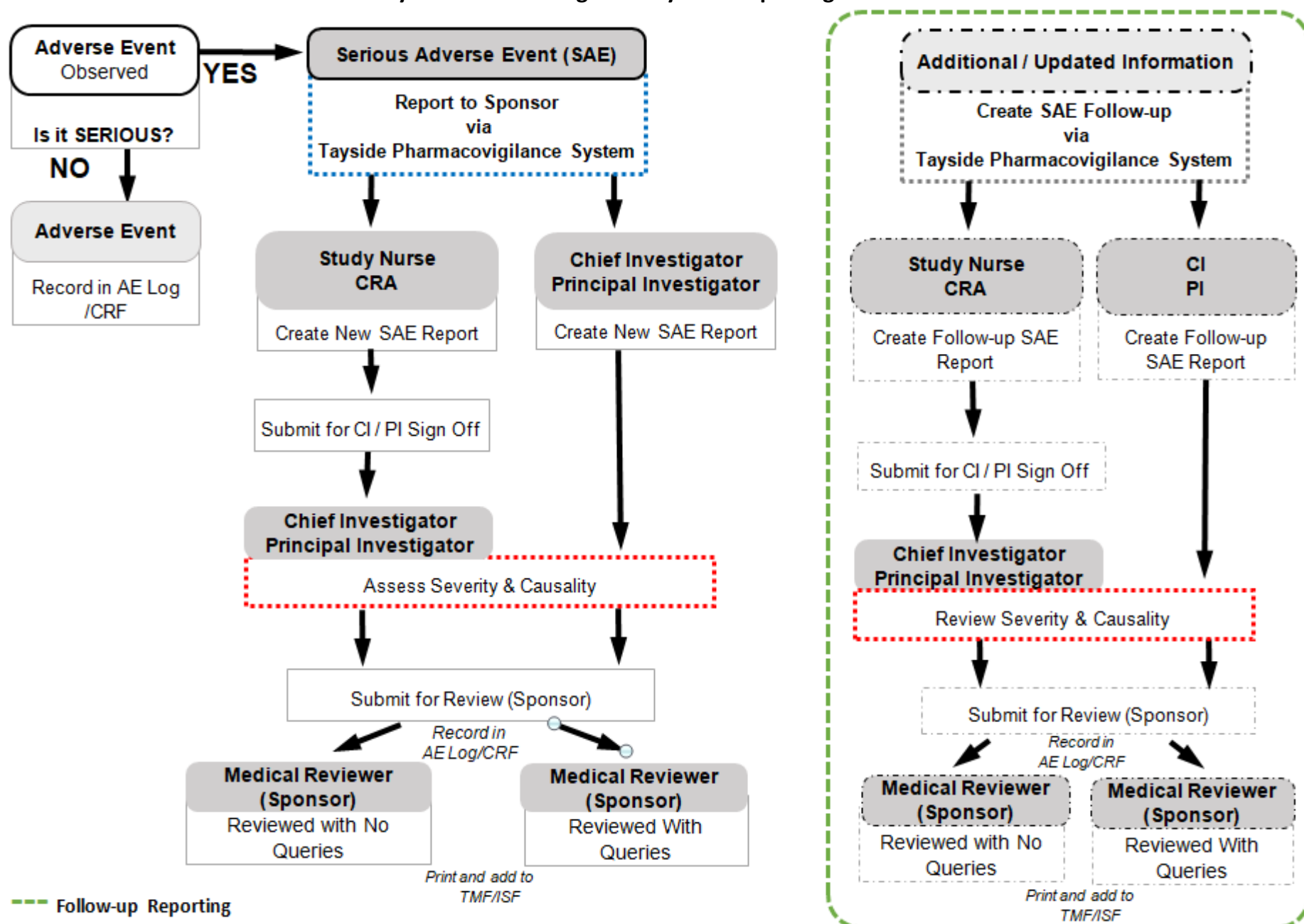
**Contents**

Serious Adverse Event Assessment Flow Chart .....	2
Tayside Pharmacovigilance System Reporting Flow Chart .....	3
1. Introduction .....	4
2. Getting started .....	4
2.1. Home page .....	4
2.2. Account types.....	4
3. Login & Change Password .....	5
4. SAE Data Entry & Basic User Reports.....	5
4.1. Home page .....	5
4.2. Reports.....	5
4.3. Creating an SAE Report .....	6
4.3.1 Study Details .....	6
4.3.2 Subject Details.....	7
4.3.3 Serious Adverse Event Details.....	8
4.3.4 Trial Treatment .....	9
4.3.5 Relevant Medical History .....	10
4.3.6. Concomitant Medications.....	10
4.3.7. Relevant Tests .....	10
4.3.8. Re-challenge.....	11
4.4. Submit a Report .....	11
4.5 Viewing Submitted SAEs .....	12
5. Create a Follow-up report.....	12
6. Answering Queries .....	14
7. PI SAE Sign off and Reports .....	15
7.1. Homepage.....	15
7.2. PI Reports .....	15
7.3. PI SAE Sign Off.....	15
7.3.1. Signing off SAE Report.....	15

## Serious Adverse Event Assessment Flow Chart



## Tayside Pharmacovigilance System Reporting Flow Chart



## 1. Introduction

The Tayside Pharmacovigilance 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://hicservices.dundee.ac.uk/Pharmacovigilance/> and TASC website under [www.dundee.ac.uk/tasc/policies-sops-templates](http://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://hicservices.dundee.ac.uk/Pharmacovigilance/>.

## Pharmacovigilance

Welcome, Basic monitor. ▾

1. Go to top right-hand side of the Homepage and add your details.

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

Note: We recommend users change their password after they log in.

## 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](mailto: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.](#)

### 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**

## Pharmacovigilance

Welcome, Basic monitor. ▾

Home

### 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

Reviewed with Queries

Show 10 ▾ entries

Search:

Reference	Site ID	Subject ID	Diagnosis	Type	Outcome	Created By	Date Created
-----------	---------	------------	-----------	------	---------	------------	--------------

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

Pharmacovigilance

Welcome, B...

Home

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

Reviewed with Queries

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**.

Pharmacovigilance

W...

Home

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

Reviewed with Queries

Pharmacovigilance

Home

Study Details

Study\*

Select a study

Site\*

Select a site

Is this a reportable SAE?\*

☐ Yes ☐ No

Save

Back

Required fields are marked with an asterisk (\*).



Pharmacovigilance

Home

Study Details

Study\*

TEST BM 23

Eudra CT number

000000

IRAS

000-07.08

Site\*

Test site BM

Is this a reportable SAE?\*

☒ Yes ☐ No

Save

Back

Required fields are marked with an asterisk (\*).

- 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.

- Select **Subject Details** and enter all available subject information.
- Selecting a pre-existing **Subject** will auto-populate the **Subject Details** fields.
- If you are entering a new **Subject** click **New** and complete all mandatory fields.
- 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.

### Serious Adverse Event Details

Onset date

16/01/2023

Date SAE Notified To Investigator\*

16/01/2023

Diagnosis\*

Diagnosis Guidance...

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

Tick all that apply

Outcome

Recovered

Date of Recovery

Action Taken

Drug Withdrawn

Event Narrative

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

### Serious Adverse Event Details

Onset date

Date SAE Notified To Investigator\*

Diagnosis\*

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.

Additional Diagnosis

☐ Yes ☐ No

Severity\*

Select...



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

Seriousness Criteria ☒ Resulted in death Tick all that apply

☐ Life-threatening

☐ Hospitalisation/Prolongation of hospitalisation

☐ Persistent/Significant Disability/incapacity

☐ Congenital anomaly/Birth Defect

☐ Other important medical event

**Complete fatal outcome**

Date of Death

Was the SAE the cause of death ☐ Yes ☐ No

Cause of Death Determined By Autopsy ☐ Yes ☐ No

Outcome Fatal

Event Narrative

Provide information on the circumstances, sequence, diagnosis and treatment of the event, including results of relevant investigations – please exclude identifiable information

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.

**Trial Treatment**

Please indicate what stage of the protocol the participant was in Select...

Was the participant receiving the trial IMP (any test drug including comparators) prior to the event? ☒ Yes ☐ No

Did the subject have to be unblinded? ☒ Yes ☐ No ☐ N/A

Was subject on placebo?\* ☐ Yes ☒ No

Action Taken Select...

**Study Drugs**

If 'End Date' is not known then use "NK" for missing values, e.g. NK/05/1980

Study Drug*	Dose	Unit	Frequency	Route	Start Date	End Date	Ongoing?
<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<input type="text"/>	<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="checkbox"/>

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

**Study Drugs**

If 'End Date' is not known then use "NK" for missing values, e.g. NK/05/1980

Study Drug*	Dose	Unit	Frequency	Route	Start Date	End Date	Ongoing?
<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<input type="text"/>	<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<span style="border: 1px solid #ccc; padding: 2px 5px;">Select...</span>	<input type="text" value="dd/mm/yyyy"/>	<input type="text" value="dd/mm/yyyy"/>	<input type="checkbox"/>

Is the SAE causally related to the IMP? ☒ Yes ☐ No

Relationship to Study Drug\* ☐ Possible ☐ Probable ☐ Definite

**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"/>

[Add New Medical Condition Details](#)

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..."/>

[Add New Row](#)

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"/>

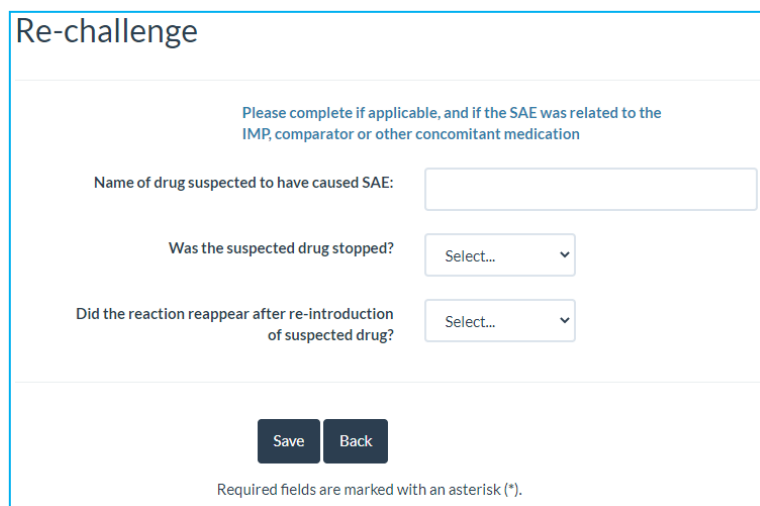
[Add New Test Details](#)

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.



The 'Re-challenge' form contains the following fields and instructions:

- Instruction: "Please complete if applicable, and if the SAE was related to the IMP, comparator or other concomitant medication"
- Field: "Name of drug suspected to have caused SAE:" (text input)
- Field: "Was the suspected drug stopped?" (dropdown menu with "Select..." option)
- Field: "Did the reaction reappear after re-introduction of suspected drug?" (dropdown menu with "Select..." option)
- Buttons: "Save" and "Back"
- Footer: "Required fields are marked with an asterisk (\*)"

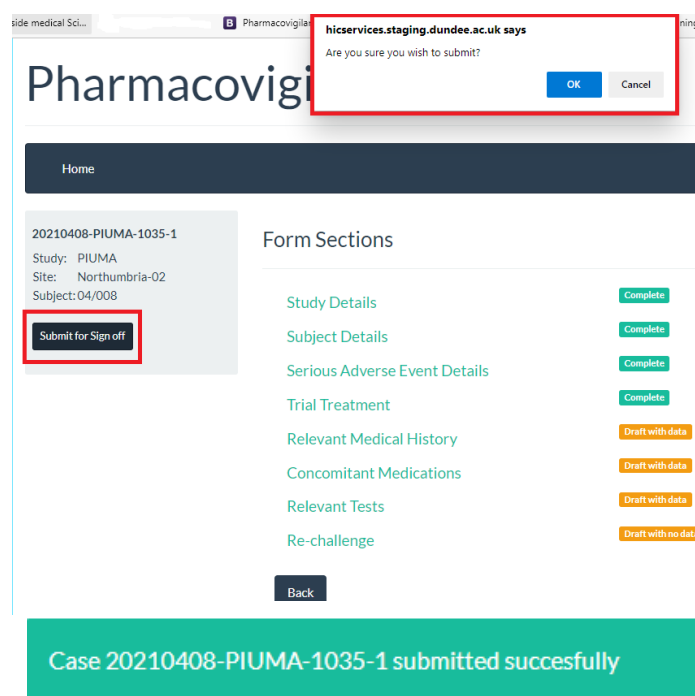
#### 4.4. Submit a Report

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.).



The screenshot shows the Pharmacovigilance system interface with the following elements:

- Header: "Pharmacovigilance" and a confirmation dialog box: "Are you sure you wish to submit?" with "OK" and "Cancel" buttons.
- Home button
- Case details: 20210408-PIUMA-1035-1, Study: PIUMA, Site: Northumbria-02, Subject: 04/008. A "Submit for Sign off" button is highlighted.
- Form Sections table:

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

Back button

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.

The screenshot shows the Pharmacovigilance system interface. A red box highlights a confirmation dialog from 'hicservices.staging.dundee.ac.uk' asking 'Are you sure you wish to create a follow-up?' with 'OK' and 'Cancel' buttons. The main form is titled 'Serious Adverse Event Report'. It includes a 'Study Details' section with fields for Reference (20210331-PIUMA-1030-1), Study\* (PIUMA), EudraCT Number (2018-000000-12), R&D Number (4.011.18), Reportable SAE (Yes), and Site\* (Nottingham-03). The 'Subject Details' section includes Subject ID\* (02007), Initials (AC), and Date of Birth (26/09/1961). On the right, there is a 'This revision' section showing submission history and an 'All revisions' section with a 'Create Follow Up' button highlighted by a red box. A 'Comments' section with an 'Add Comment' button is also visible.

- 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.).

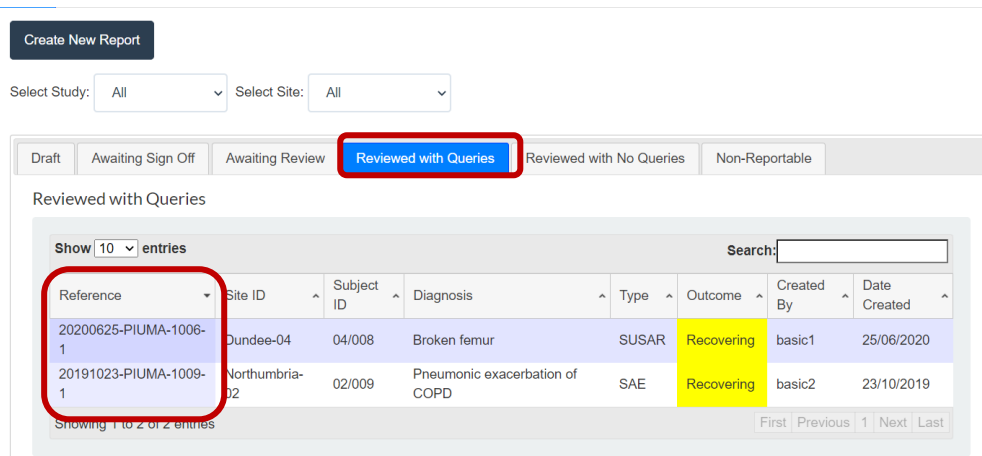
The screenshot shows the Pharmacovigilance system interface after a successful submission. A green message box on the left states 'Case 20200713-PIUMA-1008-2 submitted successfully'. A red box highlights a confirmation dialog from 'hicservices.staging.dundee.ac.uk' asking 'Are you sure you wish to submit?' with 'OK' and 'Cancel' buttons. The main form is titled 'Form Sections' and lists various sections with their completion status: Study Details (Complete), Subject Details (Complete), Serious Adverse Event Details (Complete), Trial Treatment (Complete), Relevant Medical History (Draft with no data), Concomitant Medications (Draft with data), Relevant Tests (Draft with no data), and Re-challenge (Draft with no data). A 'Submit for Sign off' button is visible. On the right, there is a 'Comments' section showing a review comment: 'Reviewer on 09/11/2022 13:49: good'. A 'Back' button is at the bottom.

## 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'.

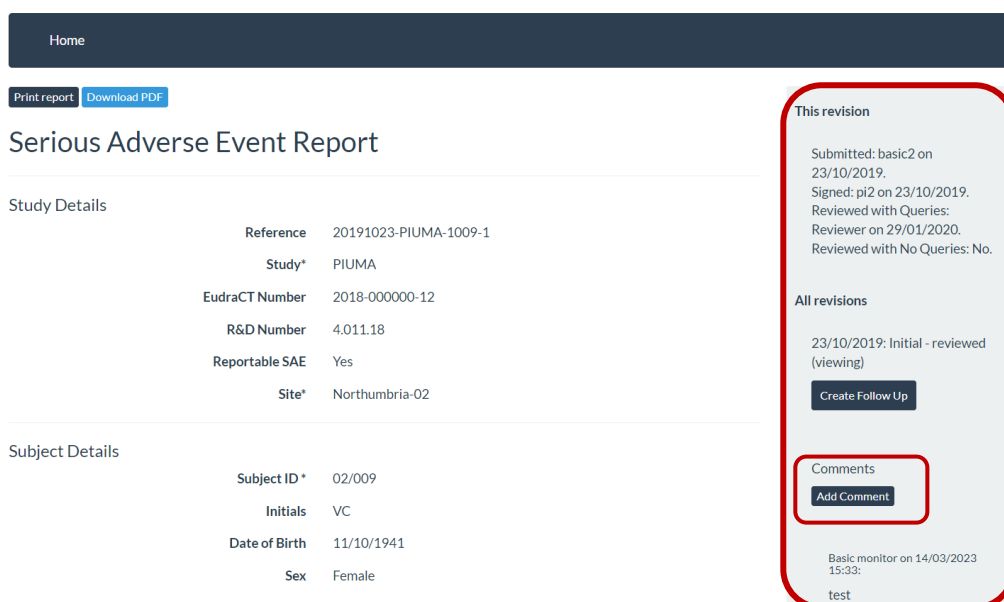


The screenshot shows the 'Reviewed with Queries' tab selected in the top navigation bar. Below the tab, there is a table of SAE reports. The first row is highlighted, and the 'Reference' column is circled in red. The table has columns: Reference, Site ID, Subject ID, Diagnosis, Type, Outcome, Created By, and Date Created.

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 two main sections: 'Study Details' and 'Subject Details'. The 'Study Details' section includes fields for Reference, Study\*, EudraCT Number, R&D Number, Reportable SAE, and Site\*. The 'Subject Details' section includes fields for Subject ID\*, Initials, Date of Birth, and Sex. On the right side, there is a 'This revision' section with a red border, containing a 'Comments' section with an 'Add Comment' button. Below the 'Comments' section, there is a 'Basic monitor on 14/03/2023 15:33: test' entry.

**Study Details**

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

**Subject Details**

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

**This revision**

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.

**All revisions**

23/10/2019: Initial - reviewed (viewing)

Create Follow Up

**Comments**

Add Comment

Basic monitor on 14/03/2023 15:33: test

## 7. PI SAE Sign off and Reports

### 7.1. Homepage

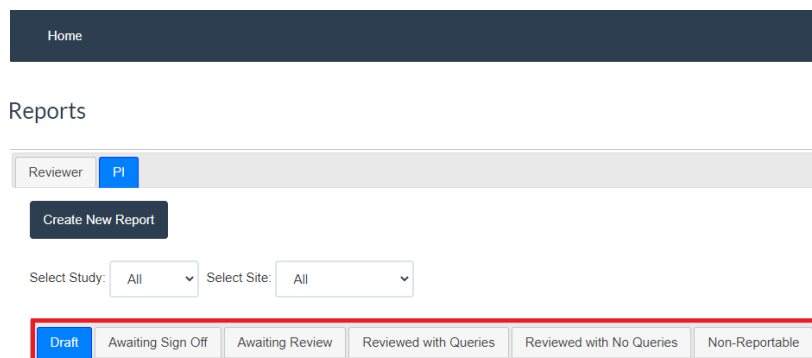
The [Home Page](#) is the same for all the users, what changes are the [Report](#) tabs.

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**

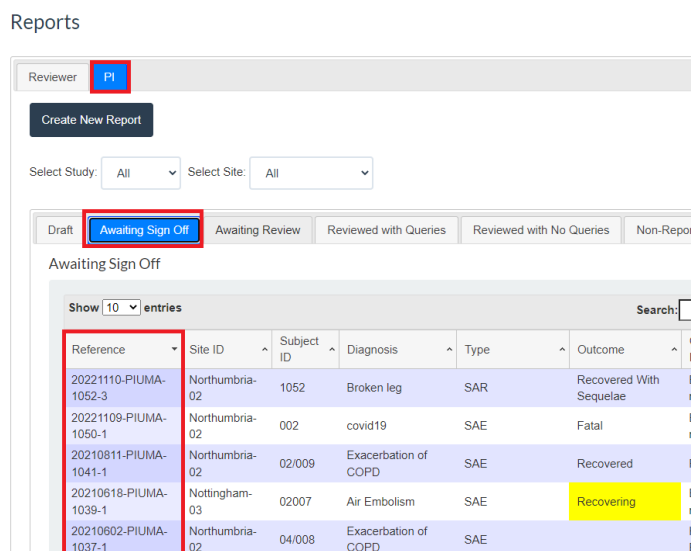
### 7.3. PI SAE Sign Off

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'.



Reference	Site ID	Subject ID	Diagnosis	Type	Outcome
20221110-PIUMA-1052-3	Northumbria-02	1052	Broken leg	SAR	Recovered With Sequelae
20221109-PIUMA-1050-1	Northumbria-02	002	covid19	SAE	Fatal
20210811-PIUMA-1041-1	Northumbria-02	02/009	Exacerbation of COPD	SAE	Recovered
20210618-PIUMA-1039-1	Nottingham-03	02007	Air Embolism	SAE	Recovering
20210602-PIUMA-1037-1	Northumbria-02	04/008	Exacerbation of COPD	SAE	

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.

**Serious Adverse Event Details**

Onset date

Date SAE Notified To Investigator\*

Diagnosis\*

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.

Additional Diagnosis ☐ Yes ☐ No

Severity\*

Seriousness Criteria ☐ Resulted in death  
☐ Life-threatening  
☐ Hospitalisation/Prolongation of hospitalisation  
☐ Persistent/Significant Disability/incapacity  
☐ Congenital anomaly/Birth Defect  
☐ Other important medical event

Tick all that apply

Outcome

**Pharmacovigilance**

Home

20210618-PIUMA-1039-1  
Study: PIUMA  
Site: Nottingham-03  
Subject: 02007

Submit for Review

**Form Sections**

Study Details

Subject Details

Serious Adverse Event Details

Trial Treatment

Relevant Medical History

Concomitant Medications

Relevant Tests

Re-challenge

Back

- 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.

**Study Drugs**

If 'End Date' is not known then use "NK" for missing values, e.g. NK/05/1980

Study Drug*	Dose	Unit	Frequency	Route	Start Date	End Date	Ongoing?
Select...		Select...	Select...	Select...	dd/mm/yyyy	dd/mm/yyyy	<input type="checkbox"/>

Is the SAE causally related to the IMP? ☒ Yes ☐ No

Relationship to Study Drug\* ☐ Possible ☐ Probable ☐ Definite

**Trial Treatment**

Please indicate what stage of the protocol the participant was in

Was the participant receiving the trial IMP (any test drug including comparators) prior to the event? ☒ Yes ☐ No ☐ N/A

Did the subject have to be unblinded? ☒ Yes ☐ No ☐ N/A

Was subject on placebo? ☐ Yes ☐ No

Action Taken

**Study Drugs**

If 'End Date' is not known then use "NK" for missing values, e.g. NK/05/1980

Study Drug*	Dose	Unit	Frequency	Route	Start Date	End Date	Ongoing?
Select...		Select...	Select...	Select...	dd/mm/yyyy	dd/mm/yyyy	<input type="checkbox"/>

Is the SAE causally related to the IMP? ☐ Yes ☒ No



- 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. The 'Concomitant Medications' section is highlighted in red. The right screenshot shows the 'Concomitant Medications' form. A dropdown menu for 'Causal relationship' is open, showing options: Select, None, Possible. The dropdown is highlighted in red.

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.

**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'.**

The left screenshot shows the 'Pharmacovigilance' home page with a sidebar menu. The 'Submit for Review' button is highlighted in red. The right screenshot shows a confirmation dialog box with the text 'Are you sure you wish to submit?' and 'OK' and 'Cancel' buttons. The dialog box is highlighted in red.