# SAE Dundee User Guide

Version 1.2, 12 November 2026

## About this guide

Step-by-step instructions for using SAE Dundee to record, review and manage safety reports for KHP-CTO managed studies.

## Prepared by

**Scott Vezina**

Senior Clinical Trials Training Executive

King's Health Partners Clinical Trials Office

# Contents


1. Introduction ..... 4

1.a SAE/IME Reporting Workflow in SAE Dundee ..... 5

2. Using this Guide ..... 6

2a Role Categories ..... 6

2b. Role permissions: ..... 7

2c. Conventions Used in this Guide ..... 7

2d. Mandatory Fields ..... 8

3. Accessing SAE Dundee ..... 8

3a. Requesting Access ..... 8

3b. Sign In ..... 9

3c. SAE Dundee Unavailable or Downtime ..... 9

3d. Welcome Page ..... 9

3d. Home Page ..... 10

4. Creating an Initial Report ..... 11

4a. Starting an Initial Report ..... 11

4b. Completing Form Sections ..... 11

4c. Participant Details ..... 12

4d. Serious Adverse Event Details ..... 12

4e. Trial Treatment ..... 13

4f. Concomitant Medications ..... 14

4g. Re-challenge ..... 15

4h. Submitting the Report for Sign-off ..... 15

5. Creating an Important Medical Event (IME) Report ..... 16

6. Creating a Pregnancy Report ..... 16

6a. Starting a New Report ..... 17

6b. Pregnancy Details ..... 17

6c. Submitting the Pregnancy Report for Sign-off ..... 18

7. Follow-up Reports ..... 19

7a. Creating a Follow-up Report ..... 19

7b. Updating the Follow-up Report ..... 19
7c. Changes to Diagnosis ..... 20
7d. Submitting the Follow-up Report for PI Sign Off ..... 20
8. Principal Investigator (PI) Sign Off ..... 21
8a. Report Notification ..... 21
8b. Assessing and Updating the Report ..... 21
8c. Trial Treatment – Causality Assessment ..... 22
8d. Serious Adverse Event Details ..... 23
8e. Submitting the Report for Review ..... 23
9. Chief Investigator (CI) Review ..... 24
9a. Expectedness Assessment ..... 24
10. CRA Reviewer ..... 26
10a. Opening a Report for Review ..... 26
10b. Reviewing a Report ..... 26
11 System Administration ..... 27
11a. Accessing PV Administration ..... 27
11b. Studies tab ..... 27
11c. Drugs tab ..... 28
11d. User Management – PV Administrator only ..... 28
12. Reports and Line Listings ..... 29
13. Frequently Asked Questions (FAQs) ..... 30
13a. Access and Roles ..... 30
13b. Creating Reports ..... 31
13c. Review, Sign-off and Follow-up Reports ..... 32
14. Change History ..... 34

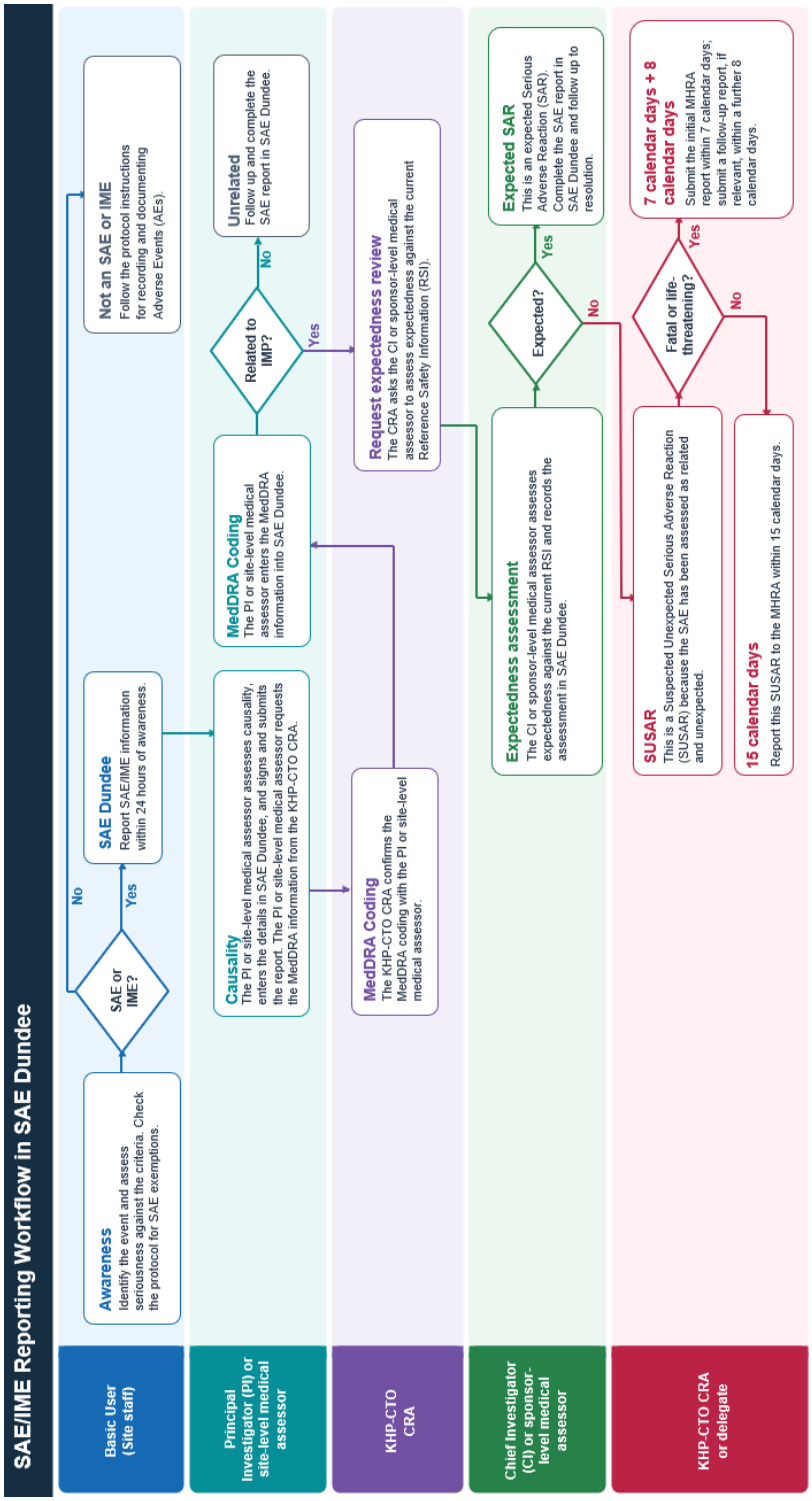
# 1. Introduction

The **SAE Dundee User Guide** provides step-by-step instructions for using the SAE Dundee system to record, review and manage safety reports, including Serious Adverse Events (SAEs), pregnancies and Important Medical Events (IMEs), for studies managed by the **King's Health Partners Clinical Trials Office (KHP-CTO).**

SAE Dundee replaces the previous 'paper-based' SAE reporting process. It provides an electronic workflow that supports the creation, review, sign-off and management of SAE reports throughout their lifecycle.

This guide should be used alongside **KHP-CTO Pharmacovigilance Policy (SAE Dundee Version)** https://khpcto.co.uk/standard-operating-procedures/policy-pharmacovigilance-and-safety-reporting/ which describes the pharmacovigilance processes, roles and responsibilities.

## 1.a SAE/IME Reporting Workflow in SAE Dundee



# 2. Using this Guide

## 2a Role Categories

SAE Dundee uses role-based permissions to ensure users only have access to the functions required for their responsibilities. *Users can only access the studies and sites assigned to them.*

| Role | Description |
|---|---|
| **Basic User** | • Creates initial or follow-up reports<br>• Submits for PI review<br>• Delegated study team member |
| **Principal Investigator (PI)** | • Creates, edit and reviews reports<br>• Assesses causality and severity<br>• Submits for Sponsor review.<br>• May delegated to a *medically qualified* PI or Sub-Investigator. |
| **Chief Investigator (CI)** | • Assesses expectedness (where required)<br>• Reviews reports (cannot edit)<br>• May delegated to a Medical Monitor |
| **Clinical Research Associate (CRA)** | • Reviews SAE reports<br>• Reviews reports (cannot edit) |
| **PV Administrator** | • Manages user accounts and system administration.<br>• Has access to all studies. |

## 2b. Role permissions:

Your user role determines which functions you can access in SAE Dundee. You will only see the functions available for your assigned role.

*The table below summarises the permissions for each user role.*

| Function | Basic User | PI | CI | CRA | PV Admin |
|---|---|---|---|---|---|
| **Create Initial Reports** | ✓ | ✓ | | | |
| **Submit for PI Sign-off** | ✓ | | | | |
| **Add/Edit Causality** | | ✓ | | | |
| **Add/Edit MedDRA** | | ✓ | | | |
| **Add/Edit Expectedness (SAR only)** | | | ✓ | | |
| **Submit for sponsor level (CI ) review** | | ✓ | | | |
| **Mark as Reviewed** | | | | ✓ | |
| **Create Follow-up Reports** | ✓ | ✓ | | | |
| **Delete Draft Reports** | ✓ | ✓ | | | |
| **Delete Reports** | | | | | ✓ |
| **Resolve Reports** | | | | | ✓ |
| **Resolve Comments** | | | | ✓ | |
| **View Study Line Listing** | | | | ✓ | ✓ |
| **View Overview Reports** | | | | | ✓ |
| **Add new or amend existing study** | | | | ✓ | ✓ |
| **Add new or amend existing IMP details** | | | | ✓ | ✓ |
| **Add new or amend existing user accounts** | | | | | ✓ |

## 2c. Conventions Used in this Guide

- **SAE naming convention:** SAE Dundee automatically assigns each report a unique reference number using the format **YYYYMMDD-STUDY-REPORT-VERSION**
    - **YYYYMMDD** – date the initial report was drafted
    - **STUDY** – study name
    - **REPORT** – unique report number
    - **VERSION** – version number of the report (Initial report number= 1, follow up reports for the same event are numbered 2, 3, 4 and so on).
- **Unknown Dates:** Enter NK for unknown data (e.g. NK/DEC/2026)

## 2d. Mandatory Fields

**Mandatory fields:** Fields marked with an **asterisk (*)** are mandatory. The lists below show mandatory fields for each user role. Some depend on the report type or previous answer

**Basic User**

- **Study Details:** Study, Site, Report Type
- **Participant Details:** Participant ID, Age
- **Serious Adverse Event Details:** Diagnosis, Date of Recovery (if applicable).
  ***If the event resulted in death:*** Date of Death, Was the SAE the Cause of Death? Cause of Death Obtained From
- **Trial Treatment:** Stage of Protocol, Receiving Trial IMP, Unblinded, Action Taken
- **Study Drugs**: (if **Yes,** selected) Study Drug, Start Date, Date of Dose Prior to SAE Onset
- **Concomitant Medications** (if **Yes** is selected for taking medication):
  Drug, Start Date, Dose, Unit, Frequency, Route, Indications (if applicable)
- **Pregnancy Details:** Who are you reporting pregnancy for? Date Pregnancy Reported, Pregnancy Outcome. If **Partner selected**: Partner Consent, Partner's Initials, Partner's Age.

**Principal Investigator (PI)** All applicable Basic User mandatory fields, plus:

- **Serious Adverse Event Details:** Severity, serious criteria
  (these fields can also be entered by Basic user but not a 'mandatory field' for Basic User)
- **Trial Treatment:** Is the SAE Causally Related to the IMP?
  Relationship to Study Drug (if related).

**Chief Investigator (CI)**

- **Trial Treatment:** Expectedness (where required for related events)

# 3. Accessing SAE Dundee

## 3a. Requesting Access

Access to SAE Dundee is managed by the KHP-CTO.

Before you can use the system, you must be provided with:

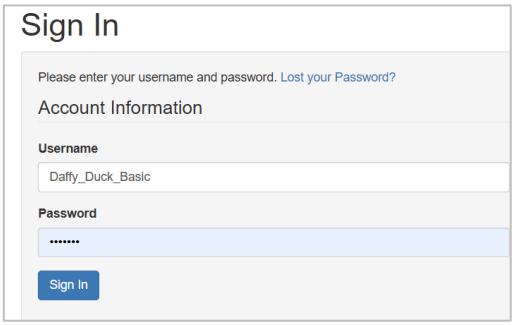
- A user account
- An assigned user role
- Access to the relevant study or studies

If you need to request a new user account or changes to any existing accounts, please contact the KHP-CTO CRA for your trial.

**Before access is requested:**

- Staff entering SAE information must be appropriately delegated and have completed the required SAE Dundee training
- **At least two medically qualified investigators at each trial location must be delegated to review SAE reports and perform causality assessments**

## 3b. Sign In




- Access SAE Dundee by clicking this link: https://pharmacovigilance-kings.hicservices.dundee.ac.uk/
- Use any browser open the SAE Dundee web address
- Enter your **Username** and **Password**
- Select **[Sign In]**

Note: If you have forgotten your password, select **[Lost your Password]** and follow the on-screen instructions. If you continue to experience problems, contact khp-ctotrainingteam@kcl.ac.uk or the KHP-CTO CRA for your trial.

## 3c. SAE Dundee Unavailable or Downtime

**If SAE Dundee is unavailable for more than one business day:**
Email new event and follow information to **jcto.pharmacovigilance@kcl.ac.uk** within 24 hours or awareness. For new events include:

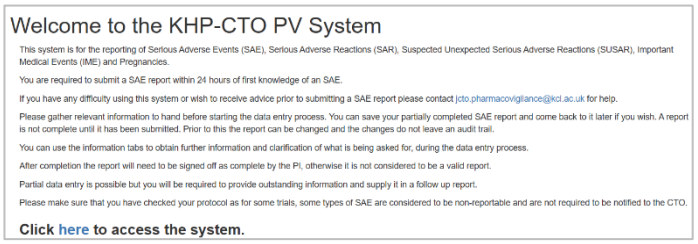
- Trial, site name and reporter's name
- Participant ID
- Event term, severity and seriousness criteria
- Randomised arm (if applicable)
- IMP(s)
- Causality assessment for each IMP

Once SAE Dundee is working again, **submit the report in the system.**

## 3d. Welcome Page

After signing in, the Welcome page is displayed. It provides information about the SAE Dundee system and safety reporting requirements.

To continue, **Click [here] to access the system**.



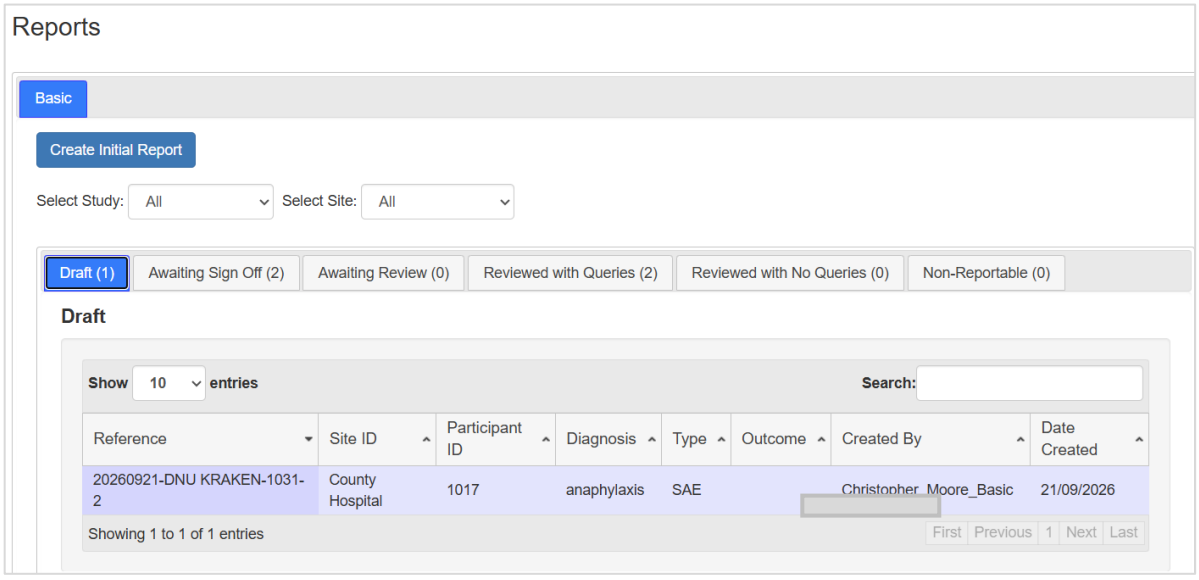
## 3d. Home Page

After signing in, the Home page is displayed.

This is the main workspace for creating, viewing and managing safety reports.

The Home page includes:

- **Create Initial Report** – Start a new safety report *(visible to Basic and PI users)*
- **Study and Site filters** – Filter the reports displayed by study or site.
  Only studies and sites assigned to the user account are available
- **Search** – Search for a specific report
- **Report Reference** – Select a report reference to open and view the report
- **Report Status Tabs** – Reports are organised according to their current stage in the reporting workflow:
  - **Drafts** – Reports started but not yet submitted for PI sign-off
  - **Awaiting Sign-off** – Reports awaiting PI review and sign-off
  - **Awaiting Review** – Reports awaiting CRA review and, where applicable, CI assessment
  - **Reviewed with Queries** – Reports reviewed by the CRA where further information or clarification is required
  - **Reviewed with No Queries** – Reports where CRA review has been completed with no outstanding queries




- **NOTE:** Reports that remain in Draft status are not considered complete.
  Users assigned to the report will receive an email reminder every 24 hours until the report is submitted for PI Sign-off.

# 4. Creating an Initial Report

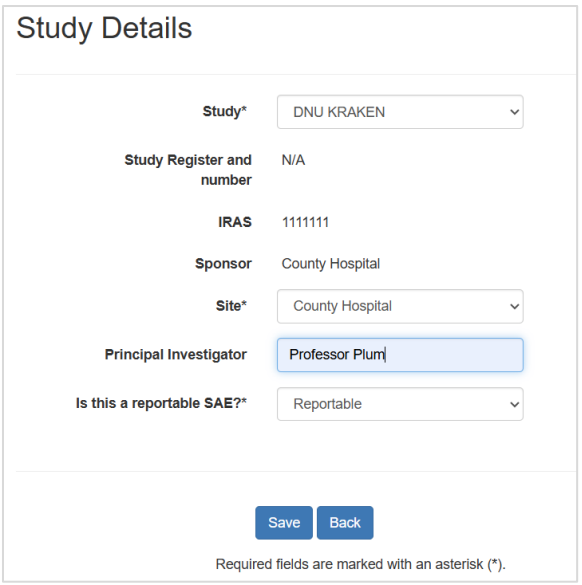
*Applicable roles: Basic User and Principal Investigator (PI)*
This section explains how to create and submit an initial safety report in SAE Dundee.

## 4a. Starting an Initial Report

To create a new initial report, select **Create Initial Report** on Home Page

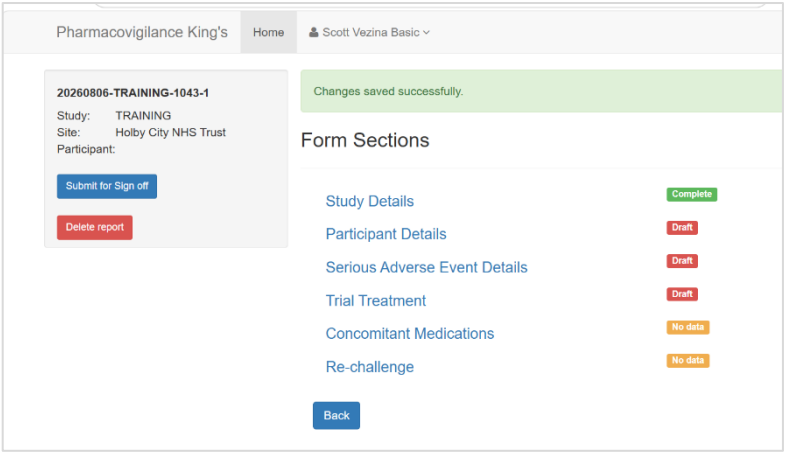
### Enter Study Details

- Select the **Study***
- Study Register and Number, IRAS and Sponsor populate automatically
- Select the **Site***
- Enter **Principal Investigator**'s name consistently when reporting
- Select whether the event is **Reportable**, **Non-Reportable, Pregnancy, IME***
- **Note:** Do not use **Non-Reportable** category for creating event




## 4b. Completing Form Sections

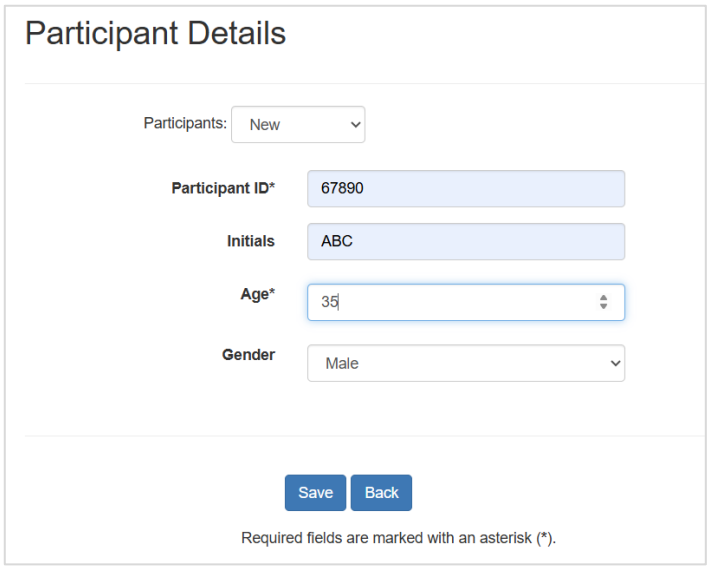
- After creating an initial report, the **Form Sections** page is displayed.
- The page lists each section of the report and shows its current completion status.
- Select a section to begin entering or reviewing information.
- The status indicators show the progress of each section.
- A section changes from Draft to Complete once all mandatory fields have been completed and saved.
- The form can only be submitted for sign off after all the mandatory fields have been completed and saved.



## 4c. Participant Details

Complete the participant details.

- Select **New** to create a new participant record or select the **Participant ID** from the drop-down menu if a report has been submitted for the participant previously.
- Enter the **Participant ID***
- Enter the **participant's Initials**
- Enter the participant's **Age***
- Select the participant's **Gender**
- Select **Save**
-

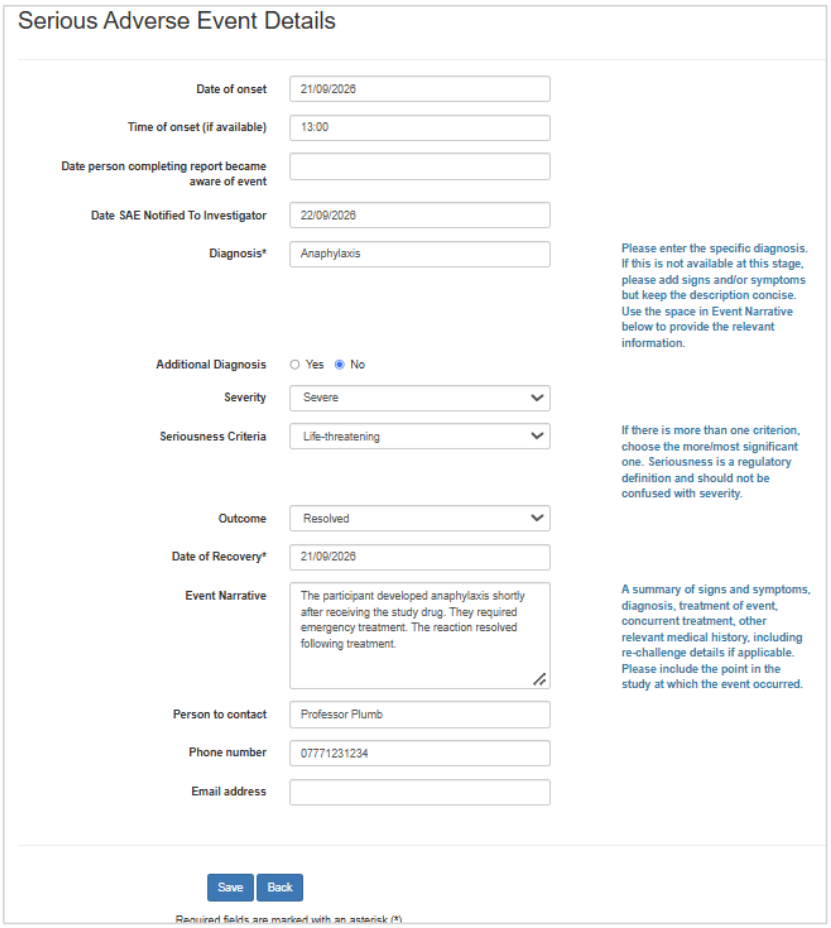



## 4d. Serious Adverse Event Details

- Enter **Date of onset**
- Date **person completing report became aware of the event**
- **Date SAE Notified to Investigator** This is the date the Investigator or any member of the study team first became aware of the event.
- Enter the **Diagnosis*** If the diagnosis is not yet known, enter **"Unknown"** or the participant's signs and symptoms. Update the diagnosis when it becomes available.
- Select **Yes** if there are additional diagnoses which also need to be reported in the Dundee system, otherwise select **No.**
  ***NOTE: If there is an additional diagnosis which is also categorised as serious per regulations or trial protocol, complete a separate SAE report.***
- Select the **Severity** (mild, moderate severe)
- Select the **Seriousness Criteria.**
  *If more than one criterion applies, select the most significant criterion.*
  - **Results in death**
  - **Life-threatening**
  - **Hospitalisation/Prolongation of hospitalisation**
  - **Persistent/Significant Disability/Incapacity**
  - **Congenital anomaly/Birth Defect**
  - **Other important medical event**

- Select the **Outcome:**
  - **Resolved**
  - **Resolved with Sequelae**
  - **Continuing**
  - **Resulted in death**
  - **Unknown**

- *If resolved or resolved with Sequelae enter **Date of Recovery****
  - Enter the **Event Narrative**
  - Enter the **Person to contact**
  - Enter the **Phone number**
  - Enter the **Email address**
  - Select **Save**

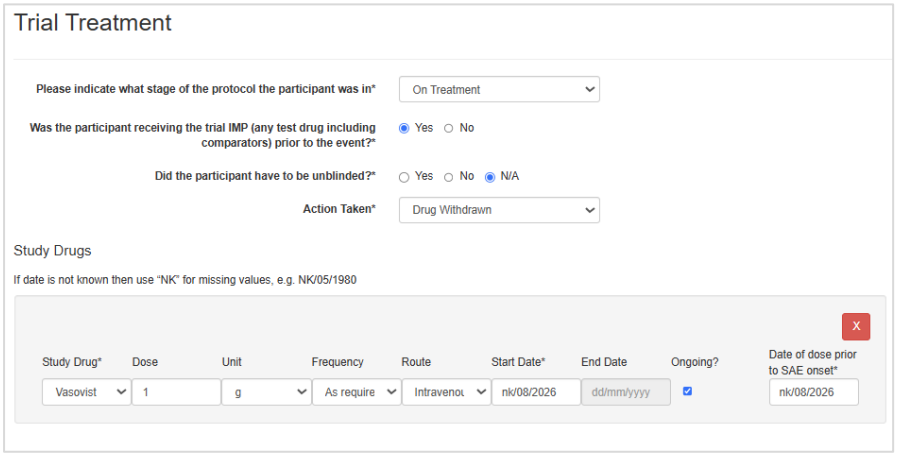



## 4e. Trial Treatment

Complete the trial treatment details.

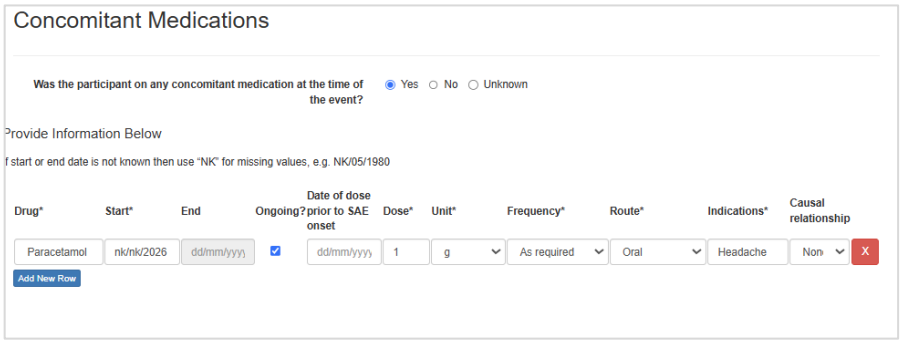
- Select the **stage of the protocol*** the participant was in at the time of the event
  - **Pre-Randomisation**
  - **On Treatment**
  - **Washout**
  - **Intention To Treat**
  - **Post Trial Completion**
  - **Standard Care**
- Indicate whether the **participant was receiving the trial IMP* (including any comparator) before the event*.** If Yes is selected, complete the remaining trial treatment details.
- **KHP-CTO Convention:** For question **participant had to be unblinded*,** answer **n/a'**
  - ✓ **IMPORTANT: Do NOT answer 'yes' even if the participant was unblinded.**
  - ✓ **Do NOT complete 'was participant on placebo' question which will be revealed if 'yes' is entered.**

- Select the **Action Taken***
  - **Drug Withdrawn**
  - **Dose Reduced**
  - **Dose Increased**
  - **Dose Not Changed**
  - **Unknown**
  - **Not Applicable**
- Complete **Study Drugs** section, if applicable
  - **Study Drug***
  - **Dose**
  - **Unit**
  - **Frequency**
  - **Route**
  - **Start Date***
  - **End Date**
  - **Ongoing?**
  - **Date of dose prior to SAE onset***
- Select **Save**




## 4f. Concomitant Medications

- Indicate whether the **participant was taking any concomitant medication at the time of the event**. If **Yes**, complete the concomitant medication details:
  - **Drug***
  - **Start Date***
  - **End Date, or select Ongoing**
  - **Date of dose prior to SAE onset**
  - **Dose***
  - **Unit***
  - **Frequency***
  - **Route***
  - **Indication***
  - **Causal relationship**, if applicable

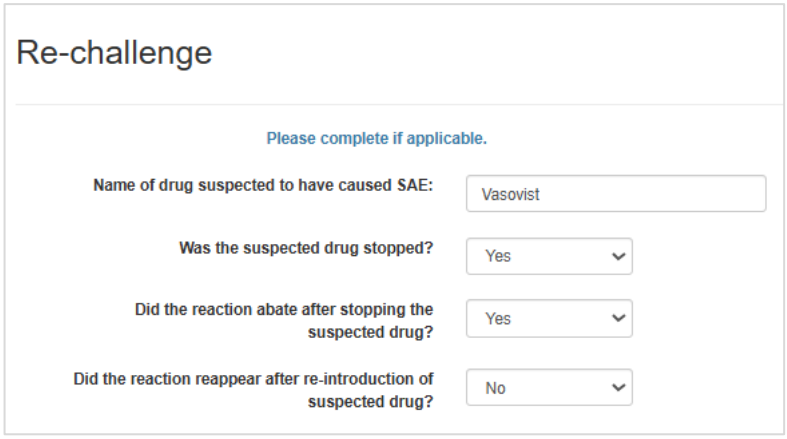



- Select **Add New Row** to record additional concomitant medications, if required per protocol or investigator opinion.
- Select **Save**

## 4g. Re-challenge

Complete the re-challenge details, if applicable.

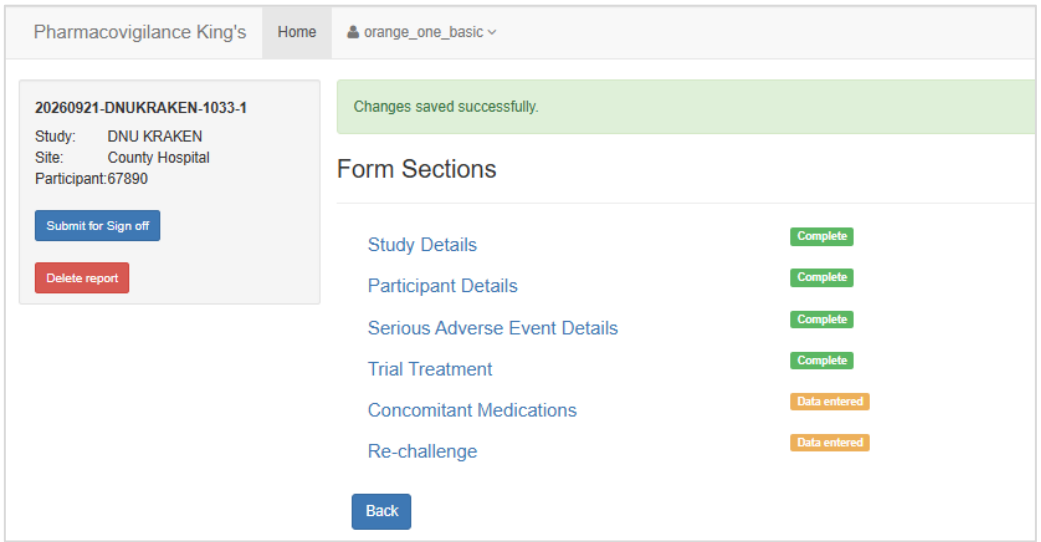
- Enter the **Name of drug suspected to have caused SAE**
- Indicate whether the suspected drug was stopped
- Indicate whether the reaction abated after stopping the suspected drug
- Indicate whether the reaction reappeared after re-introduction of the suspected drug
- Select **Save**




## 4h. Submitting the Report for Sign-off

Once all required sections are complete, the report is ready to be submitted for PI Sign-off.

- Review the status of each form section
- Ensure all required sections are marked **Complete**
- Select **Submit for Sign-off**
- If any mandatory fields are incomplete, the report cannot be submitted.
  Refer to section above (*Conventions Used in this Guide*) for a list of mandatory fields
- Once submitted, the report status changes to **Awaiting Sign-off**
- A notification email is automatically sent to the **PI and delegated Sub-investigators**



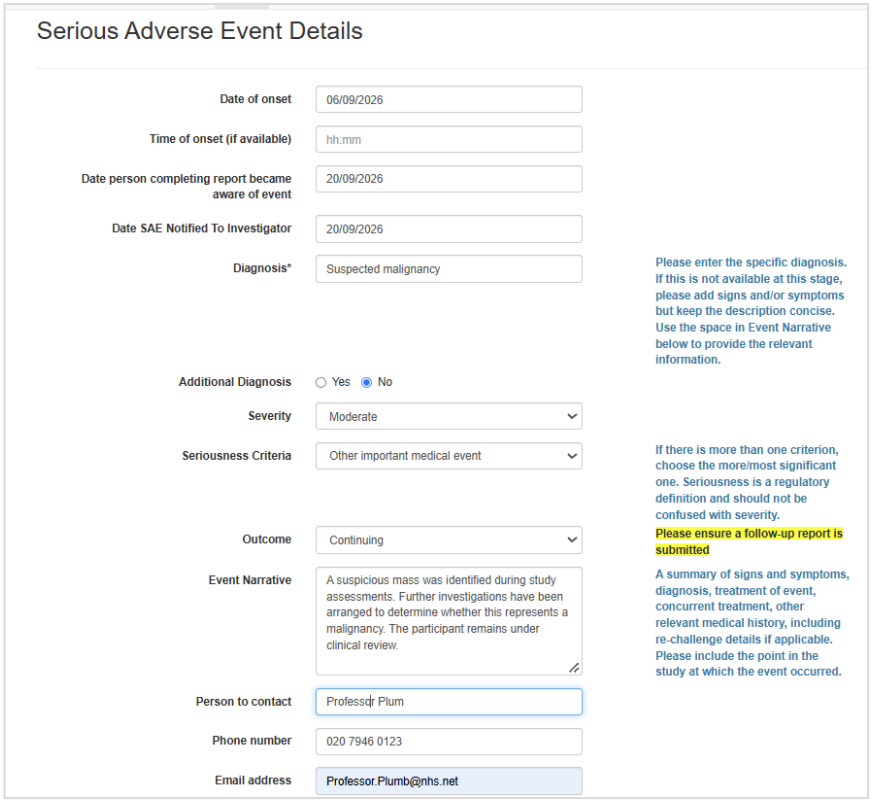
# 5. Creating an Important Medical Event (IME) Report

*Applicable roles: Basic User and Principal Investigator (PI).*

This section explains how to create and submit an initial safety report in SAE Dundee.

An IME report follows the same process as an Initial Report described in **Section 4 – Creating an Initial Report**, except for the following:

- In **Study Details**, select **IME** as the report type
- In **Serious Adverse Event Details**, select **Other important medical event** from **Seriousness Criteria**




# 6. Creating a Pregnancy Report

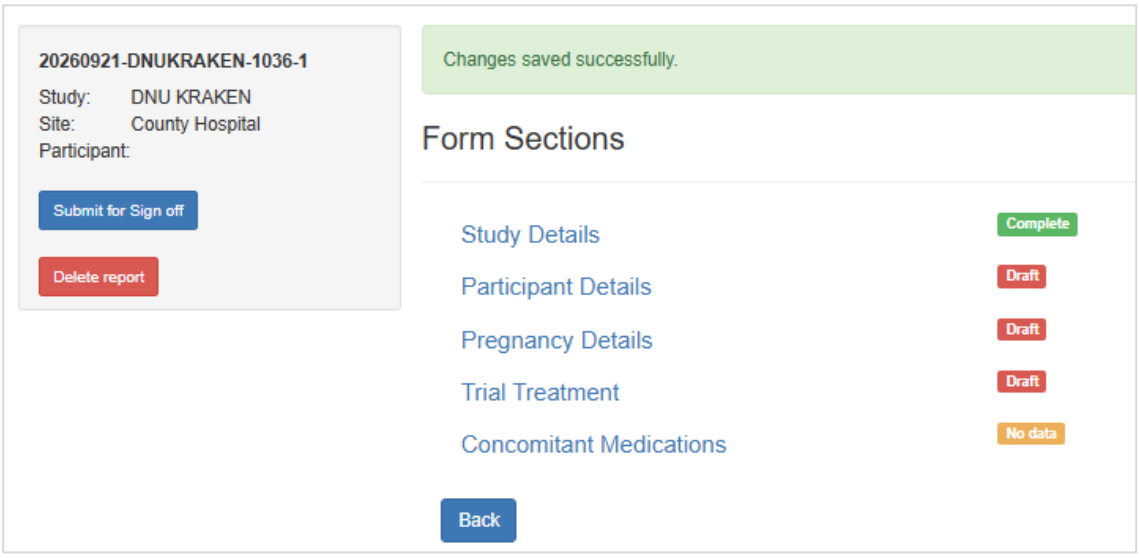
*Applicable roles: Basic User and Principal Investigator (PI)*
*This section explains how to create and submit a Pregnancy Report in SAE Dundee.*

**Pregnancy is not itself an SAE but must be reported through SAE Dundee if required by the trial protocol. Any pregnancy complication that meets the SAE criteria must also be reported in accordance with the trial's SAE reporting requirements.**

## 6a. Starting a New Report

A Pregnancy Report follows the same process as an Initial Report described in **Section 4 – Creating an Initial Report**, except for the following:

- In **Study Details**, select **Pregnancy** as the report type
- Pregnancy reports follow the same process as an Initial Report described in **Section 4 – Creating an Initial Report**, except for the following:
  - **Participant Details**, **Trial Treatment** and **Concomitant Medications** are completed in the same way.
  - Complete **Pregnancy Details** instead of **Serious Adverse Event Details**.
  - The **Re-challenge** section is not included.



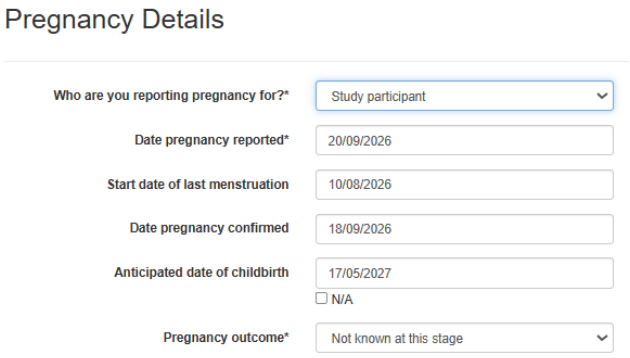

## 6b. Pregnancy Details

Complete the pregnancy-specific information

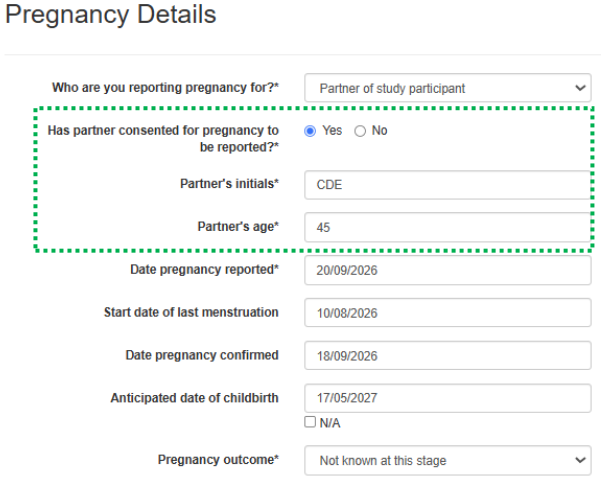
- Select **Who are you reporting pregnancy for? ***
  - **Study participant**
  - **Partner of study participant**
- If **Partner of study participant** is selected: Select **Yes** or **No** to indicate whether the partner has consented for the pregnancy to be reported*****
  - Enter the **Partner's initials***
  - Enter the **Partner's age***
- Enter the **Date pregnancy reported***
- Enter the **Start date of last menstruation**, if known
- Enter the **Date pregnancy confirmed**, if known

- Enter the **Anticipated date of childbirth**, or select **N/A** if not applicable
- Select the **Pregnancy outcome*:**
    - **Not known at this stage**
    - **Induced abortion**
    - **Spontaneous abortion**
    - **Uneventful (normal/healthy birth)**
    - **Congenital anomaly/birth defect (report as SAE)**
    - **Neonatal death (report as SAE)**
- Select **Save**

**Study participant**




**Partners of Study Participant**




## 6c. Submitting the Pregnancy Report for Sign-off

Once all required sections have been completed, the Pregnancy Report is ready to be submitted for Principal Investigator (PI) Sign-off

- Review the status of each form section
- Ensure all required sections are marked **Complete**
- Select **Submit for Sign-off**
- Once submitted, the report status changes to **Awaiting Sign-off**
- A notification email is automatically sent to the PI

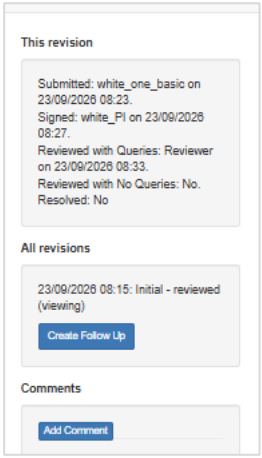
***Note:*** *System-generated notification emails use the term Serious Adverse Event (SAE) for all report types, including Pregnancy Reports*

# 7. Follow-up Reports

*Applicable roles: Basic User and Principal Investigator (PI)*

- A Follow-up Report is used to add or update information after an initial or previous Follow-up Report has been submitted for sponsor review.
- A Follow-up report can only be created when the previous report is marked **Awaiting Review, Reviewed with Queries** or **Reviewed with No Queries.**
- A **Basic User** cannot create a Follow-up Report while the report is **Awaiting Sign-off**.
- A **PI** can amend existing information or add new information before submitting the report for Sponsor review.

## 7a. Creating a Follow-up Report

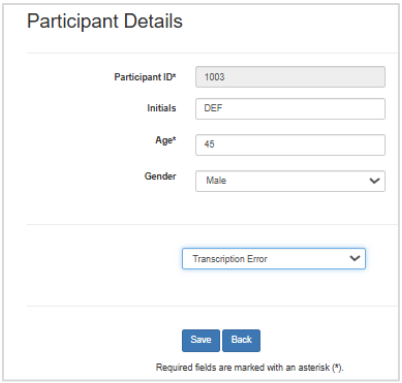



- Locate and open the relevant report.
- Select **Create Follow-Up** from the Revision section.
- Select **OK** to confirm
- The Follow-up Report opens automatically as a new revision and saved under Drafts
- All information from the previous version is automatically copied into the Follow-up Report

If a Follow-up Report is created in error, the draft can be deleted

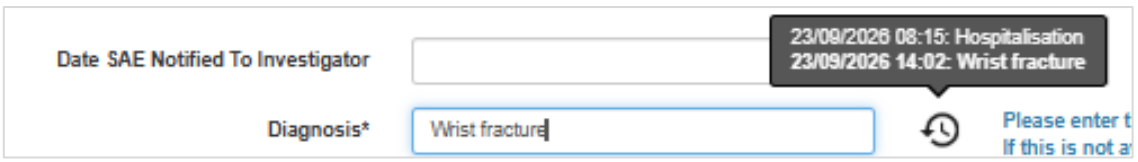
For report version naming, see **Section 2c – conventions Used in this Guide**.

## 7b. Updating the Follow-up Report



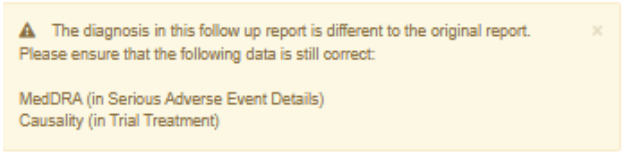

- Open the section requiring an update
- Update information as required
- Select the appropriate **Reason for Change**
- Select **Save**.
- Repeat for any other sections that require updating.

**Viewing changes:** A history icon appears next to updated fields. Select it to view the previous value and version number.



## 7c. Changes to Diagnosis

- If the diagnosis is changed in a Follow-up Report, SAE Dundee displays a warning




- The PI should review the **MedDRA coding** and **causality assessment** to ensure they remain appropriate for the updated diagnosis before submitting the report for sponsor review.

## 7d. Submitting the Follow-up Report for PI Sign Off

Once the information has been updated, check that all required Form Sections are complete.

- **Basic User:** Select **Submit for Sign-off**. The report is sent to the PI or delegated Sub-Investigator for review.
- Reports saved in 'draft' status trigger an alert email each working day to each basic account holder at the relevant study site.
- NB initial reports created by a PI user are submitted for sponsor review without a PI sign off step.

Next Steps:

- **PI Review:** See **Section 8** for reviewing and signing off report
- **CI Review** See **Section 9** for expectedness assessment of related events.

# 8. Principal Investigator (PI) Sign Off

*Applicable role: Principal Investigator (PI), including delegated Sub-Investigators*
This section explains how to assess and sign-off safety reports in SAE Dundee.

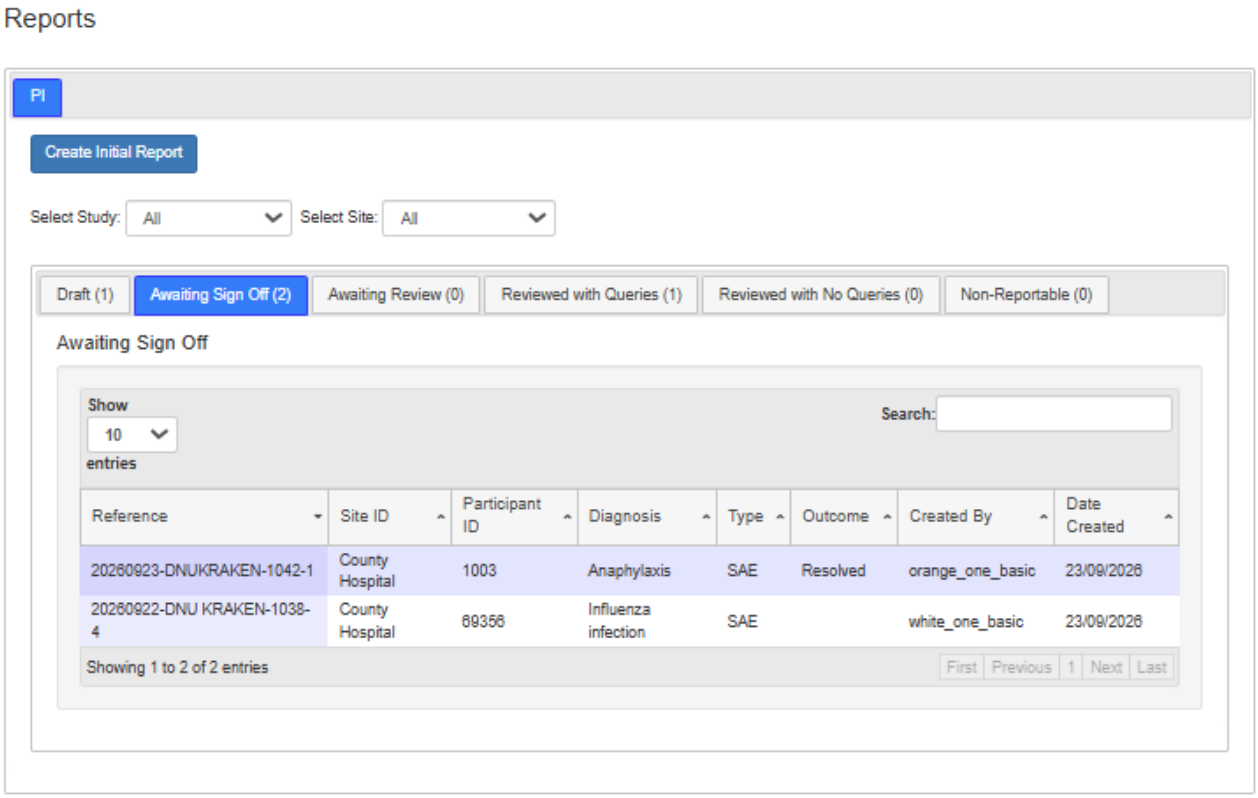
## 8a. Report Notification

- When a report is submitted for PI Sign-off, the **Principal Investigator (PI)** and delegated Sub-investigator(s) receive an automated email notification.
- The email includes the study and report reference and a link to **SAE Dundee**.
- The PI should access the report, add or update any report fields as appropriate, complete the causality and severity assessments and assign relatedness to IMP (where participant has been exposed to IMP) **within 24 hours** from initial SAE data entry
- Reminder emails are sent every 24 hours until the PI review is completed.

## 8b. Assessing and Updating the Report

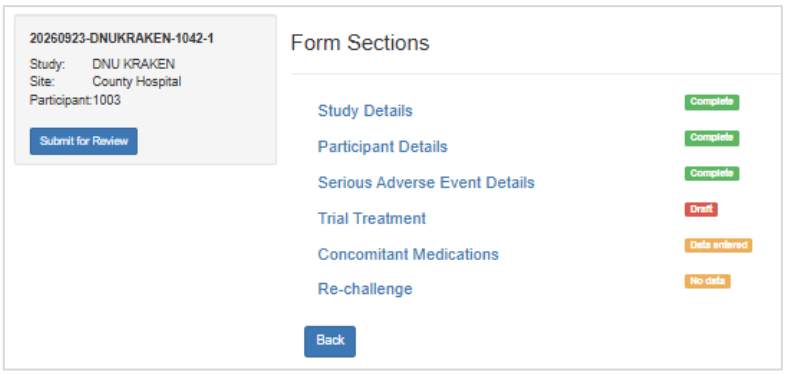
Reports submitted by the Basic User are displayed in the **Awaiting Sign-off** tab.

- Select the **Awaiting Sign-off** tab
- Select the report to be viewed



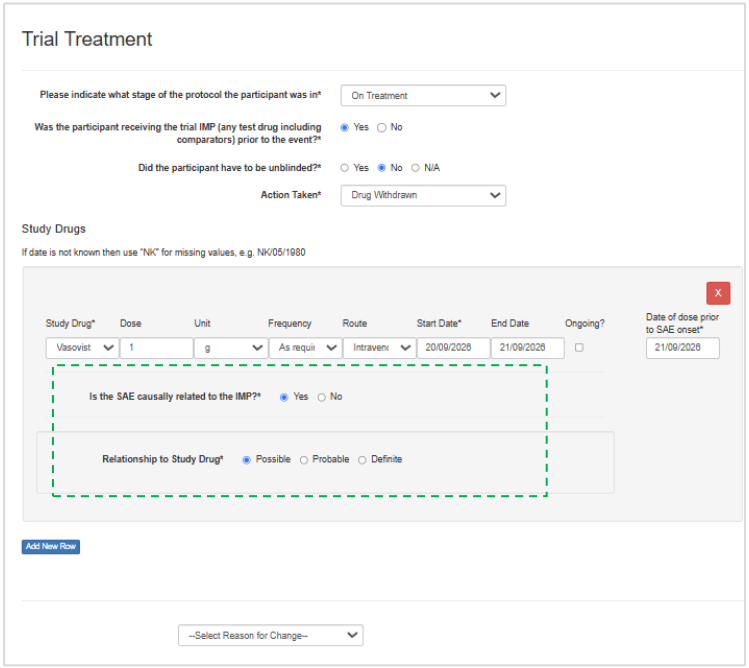
## Form Sections

- The **Form Sections** page shows each section of the report and its current completion status.
- Review each section for **accuracy and completeness**
- If new or changed information is added to the report, select the appropriate **Reason for Change**
- Complete the required PI assessments as described below



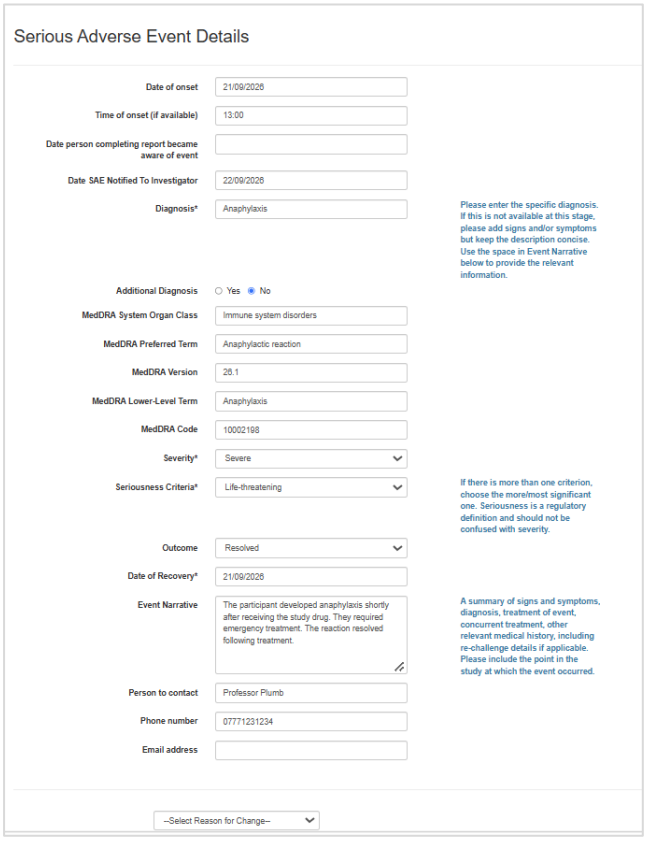

## 8c. Trial Treatment – Causality Assessment

- Open **Trial Treatment**
- For each study drug, answer **Is the SAE causally related to the IMP**
- **KHP-CTO Reporting convention**
  - **No**
    - Unrelated or
    - Unlikely related
  - **Yes:**
    - Possibly
    - Probably or
    - Definitely related
- If Yes is selected, select the corresponding option under **Relationship to Study Drug*:** Possible, Probable or Definite
- Select **Reason for Change**
- Select **Save**



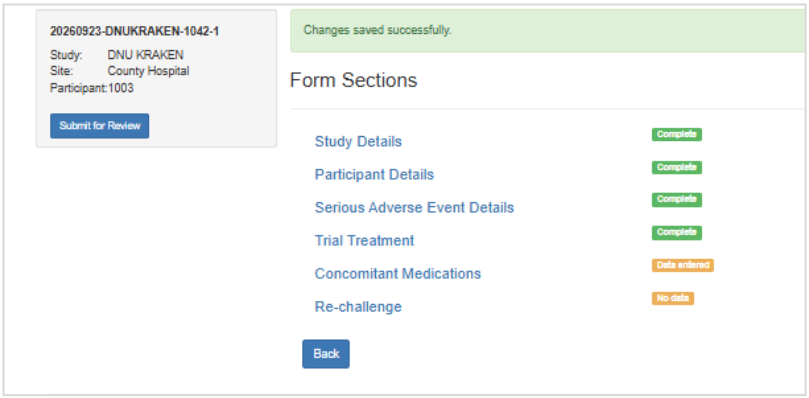

**Note:** Where more than one study drug is recorded, complete the causality assessment for each applicable study drug

## 8d. Serious Adverse Event Details




- Open **Serious Adverse Event Details.**
- Review the information for accuracy and completeness
- **Date of onset:** Check that the date is correct. For related events requiring CI assessment, the system uses this date to automatically display the applicable RSI version.
- Select the **Severity*:** Mild, Moderate or Severe
- Select **SAE Criteria*:**
  - **Results in death**
  - **Life-threatening**
  - **Hospitalisation/Prolongation of hospitalisation**
  - **Persistent/Significant Disability/Incapacity**
  - **Congenital anomaly/Birth Defect**
  - **Other important medical event**
- **MedDRA coding:** Your **KHP-CTO CRA** will provide the required MedDRA information. Enter this into the relevant MedDRA fields. Contact the CRA if coding is unclear or you disagree with it.
- Select **Save**

## 8e. Submitting the Report for Review




- Once the PI assessment is complete, submit the report for Sponsor review.
- Return to the **Form Sections** page
- Check that all required sections are complete
- Select **Submit for Review**
- Once submitted, the report status changes to **Awaiting Review**
- A notification email is automatically sent to the CRA

**Further actions:** **Follow-up Reports:** See Section 7 – Follow-up Reports.

# 9. Chief Investigator (CI) Review

*Applicable role: Chief Investigator (CI) / Medical Monitor*

This section explains how to review safety reports and complete expectedness assessments in SAE Dundee.

## 9a. Expectedness Assessment

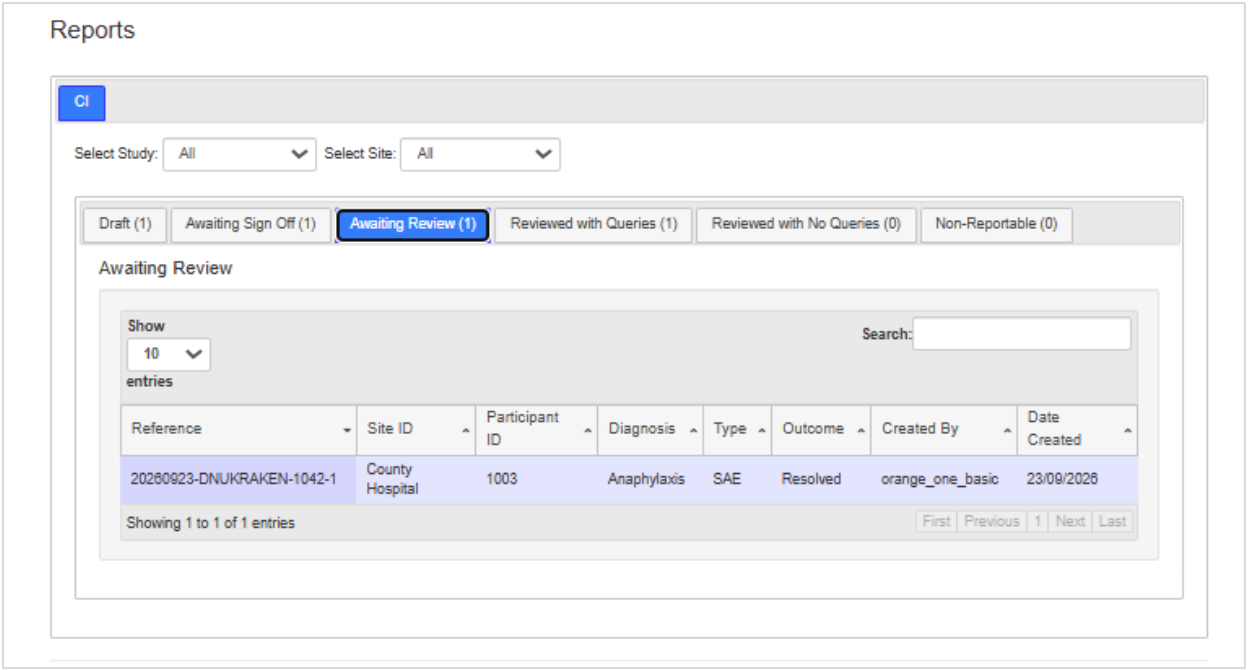
Reports awaiting Sponsor review are displayed under **Awaiting Review**.
However, not all reports require a CI expectedness assessment:

- **SAE assessed by PI as not related to IMP and Pregnancy**: The Expectedness field is **not displayed**.
- **SAE assessed by PI as related to IMP**: The **Expectedness field is displayed** and requires assessment.

The CI will be notified when required to complete an expectedness assessment.

*To open a report:*

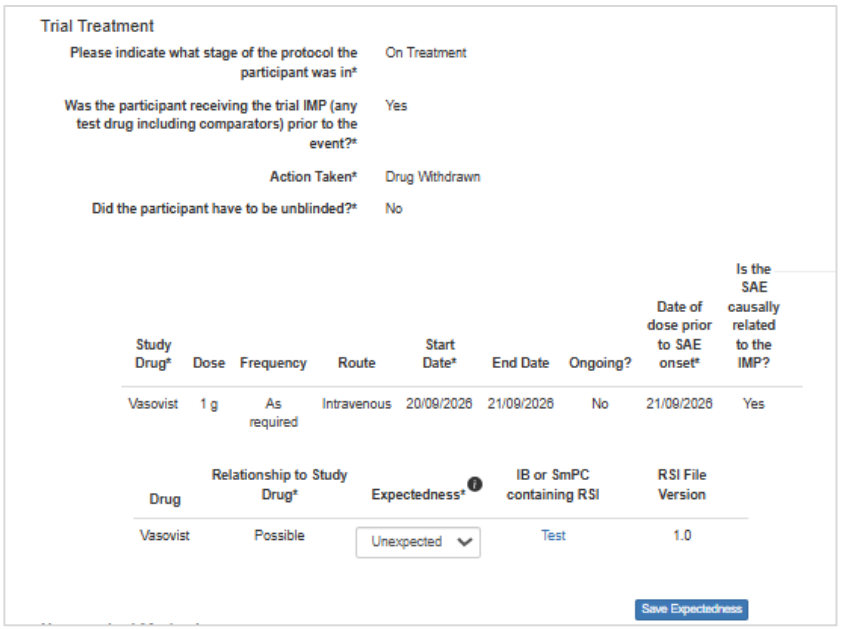
- Select the required **Study** and **Site** to filter the reports, if required
- Select **Awaiting Review**
- Select the report **Reference** to open the report




The full **Serious Adverse Event Report** will display.

Review the information relevant to the expectedness assessment. Where the SAE has been assessed as causally related to the IMP, the **Expectedness*** assessment field is displayed near the bottom of the **Trial Treatment** section.

- Review the Trial Treatment section, including the PI's **Relationship to Study Drug*** assessment.
- Select the link under **IB or SmPC containing RSI** to review the applicable Reference Safety Information (RSI). The system automatically displays the RSI version applicable to the date of onset entered by the Basic User or PI.
- Under **Expectedness*** select:
  - **Expected** – the reaction is consistent with the applicable RSI
  - **Unexpected** – the reaction is not consistent with the applicable RSI
- Select **Save Expectedness**




## Further actions

- **Follow-up Reports:** The CI cannot create these. These are created by the **Basic User or PI**.
- **Expectedness:** The CI must complete a new assessment for Follow-up Reports where required. **See Section 7 – Follow-up Reports**

# 10. CRA Reviewer

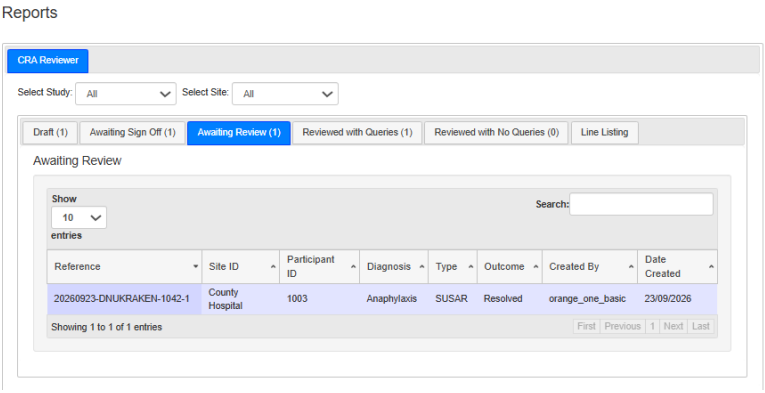
*Applicable role: KHP-CTO Clinical Research Associate (CRA)*

This section explains how to review safety reports, and complete Sponsor review.

## 10a. Opening a Report for Review

From the CRA Reviewer Home page:

- Use the **Study** and **Site** filters to find the required report, if needed.
- Select **Awaiting Review.**
- Select the report Reference to open it.




## 10b. Reviewing a Report

The report is displayed in read-only format.

The panel on the right displays the current revision status and previous revisions.

- Review the information contained within the report.
- CI expectedness assessment must be completed before CRA
- If further information or clarification is required, select **Mark as Reviewed (With Queries)**.
- If no further information or clarification is required, select **Mark as Reviewed (With No Queries)**
- The report will appear under Reviewed with Queries or Reviewed with No Queries on the Home page, as applicable




## Additional CRA function

CRAs can also manage study, site, drug and RSI information in SAE Dundee.

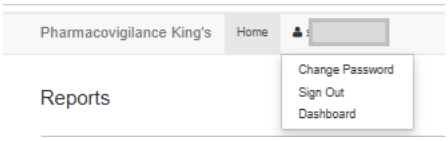
See **Section 11 – System Administration** for instructions on these functions.

# 11 System Administration

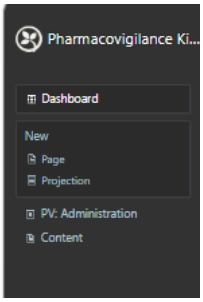
The **PV Administration** area is used to manage information and administrative functions within SAE Dundee. Access depends on your role:

- **Study Management** – CRA and PV Admin
- **Site Management** – CRA and PV Admin
- **Drug Management / RSI** – CRA and PV Admin
- **User Management** – PV Admin only
- **Resolving/closing reports** – PV Admin only

## 11a. Accessing PV Administration




- To access **PV Administration**
- Select the **username** at the top of the page
- From the drop-down menu, select Dashboard.
- Select **PV: Administration** from the menu on the left




The **Administration** page opens.

- **CRAs** have access to the **Studies** and **Drugs** tabs
- **PV Admin** also have access to **User Management**

## 11b. Studies tab

The **Studies** tab is used to manage **Files**, **Sites** and **Studies**, and link them using **Relationships**.

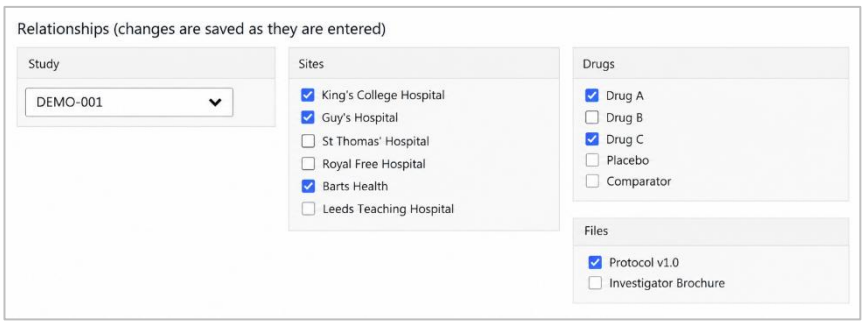
**Important:** Check whether an item already exists before adding a new one, as records cannot currently be deleted. Do not create duplicate **Sites**.

## Relationships

Use **Relationships** to link information to a study:

- Select the **Study**.
- Select the applicable **Sites**.
- Select the applicable **Drugs**.
- Select any applicable **Files**.

Changes are saved automatically.



## 11c. Drugs tab

The **Drugs** tab is used to add and maintain drug information and associated **Units**, **Frequencies**, **Routes** and **RSI Files**.

**Important:** Check whether an item already exists before adding a new one, as records cannot currently be deleted.

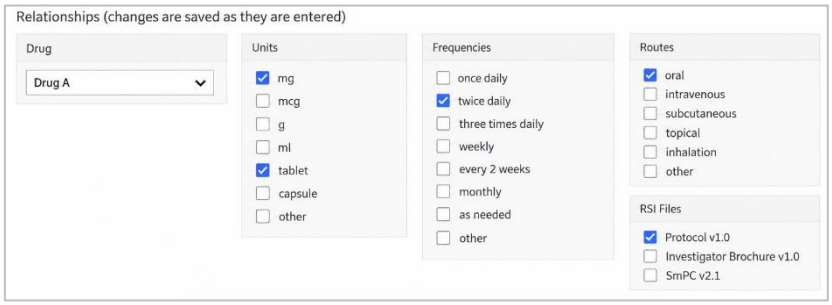
## Relationships

Use **Relationships** to link a **Drug/IMP** to the applicable:

- **Units**
- **Frequencies**
- **Routes**
- **RSI File**

Select the required **Drug/IMP**, then select the applicable items.

Changes are saved automatically.




## 11d. User Management – PV Administrator only

The **Users** tab is used to add and manage SAE Dundee user accounts and assign the appropriate study and site access.

## Information required

Before creating an account, the user should provide:

- User **name** and **email address**
- Required SAE Dundee **role**
- Applicable **Study**
- Applicable **Site(s)**, where required
- Confirmation that the user is appropriately delegated
- Confirmation that the required SAE Dundee training has been completed

The applicable **Study** and **Site(s)** must already be set up and linked in SAE Dundee before access can be assigned.

## Username

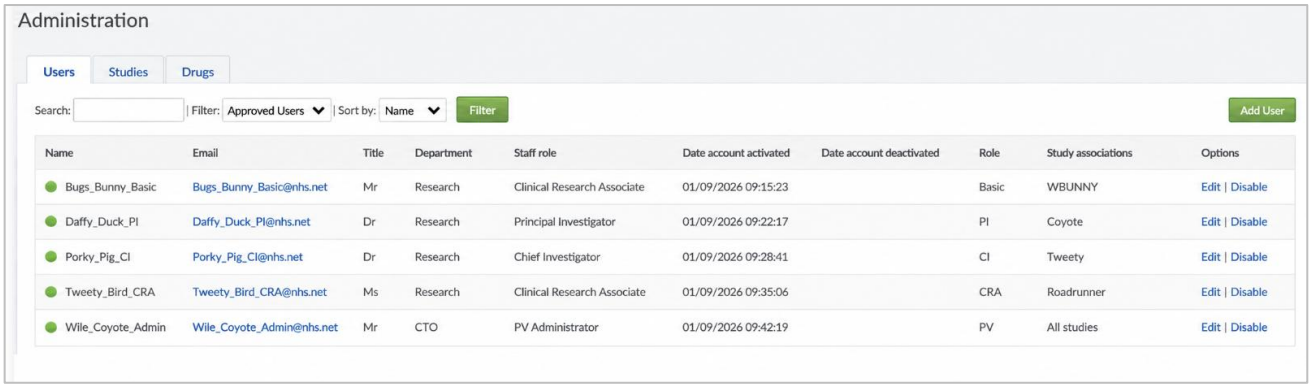
**First Name_Surname_Role**

For example:

- Bugs_Bunny_Basic
- Daffy_Duck_PI
- Porky_Pig_CI
- Tweety_Bird_CRA
- Wile_Coyote_Admin

Replace non-standard English characters, including accents and umlauts, with the equivalent standard English character (for example, **ë** becomes **e**).

**Note:** Before creating a new user, search the existing user list by **name** or **email address** to check whether an account already exists.

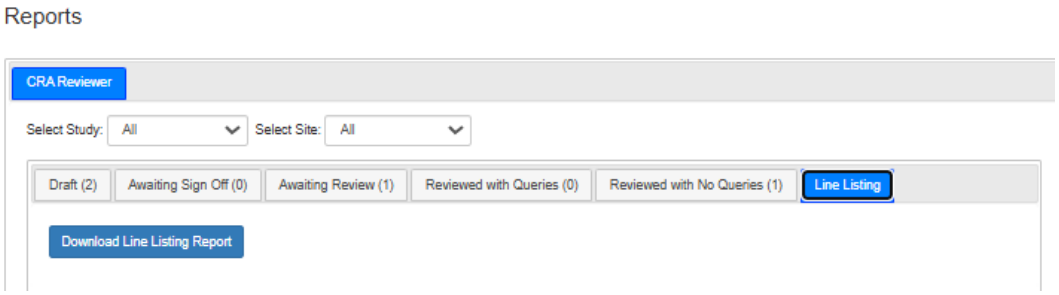



# 12. Reports and Line Listings

SAE Dundee provides additional reporting views for **CRAs** and **PV Administrators**.

## CRA

From the **CRA Reviewer** area, select **Line Listing** to view the CRA line listing.



## PV Administrator

From the **PV Admin** area, select **Admin Overview** to view the administration overview.

The **Admin Overview** includes:

- **Download Detailed Report**
- **Study Report Totals**
- **Site Summaries**
- **Study Summaries**




# 13. Frequently Asked Questions (FAQs)

## 13a. Access and Roles

**Q1. How do I get access to SAE Dundee?**

Access is managed by the KHP-CTO. Before you can use the system you need a user account, an assigned user role and access to the relevant study or studies. Staff entering SAE information must be appropriately delegated and have completed the required SAE Dundee training. To request a new account, or changes to an existing one, contact the KHP-CTO CRA for your trial. At least two medically qualified investigators at each trial location must be delegated to review SAE reports and perform causality assessments.

**Q2. Why can't I see certain functions, studies or sites?**

SAE Dundee uses role-based permissions, so you only see the functions available for your assigned role (Basic User, PI, CI, CRA or PV Administrator). You can also only access the studies and sites assigned to your account. Section 2b summarises the permissions for each role.

**Q3. I have forgotten my password. What should I do?**

On the sign-in page, select [Lost your Password] and follow the on-screen instructions. If you continue to experience problems, contact khp-ctotrainingteam@kcl.ac.uk or the KHP-CTO CRA for your trial.

**Q4. What should I do if SAE Dundee is unavailable?**
If SAE Dundee is unavailable for more than one business day, email the new event and follow-up information to jcto.pharmacovigilance@kcl.ac.uk within 24 hours of awareness. For new events include the trial, site name and reporter's name; the Participant ID; the event term, severity and seriousness criteria; the randomised arm (if applicable); the IMP(s); and the causality assessment for each IMP. Once SAE Dundee is working again, submit the report in the system.

## 13b. Creating Reports

**Q5. What does the report reference number mean?**
SAE Dundee automatically assigns each report a unique reference in the format YYYYMMDD-STUDY-REPORT-VERSION: the date the initial report was drafted, the study name, a unique report number, and the version number. The initial report is version 1, and follow-up reports for the same event are numbered 2, 3, 4 and so on.

**Q6. How do I enter a date that is unknown?**
Enter NK for any unknown part of a date, for example NK/DEC/2026.

**Q7. What should I enter if the diagnosis is not yet known?**
Enter "Unknown" or the participant's signs and symptoms, then update the diagnosis when it becomes available.

**Q8. Which report type should I select, and how do IME and Pregnancy reports differ?**
In Study Details you choose between Reportable, Non-Reportable, Pregnancy and IME, but do not use the Non-Reportable category when creating an event. An IME report follows the same process as an Initial Report, except that you select IME as the report type and Other important medical event as the seriousness criterion. A Pregnancy report also follows the Initial Report process, except that you select Pregnancy as the report type, complete Pregnancy Details instead of Serious Adverse Event Details, and the Re-challenge section is not included. Pregnancy is not itself an SAE but must be reported through SAE Dundee if required by the trial protocol, and any pregnancy complication that meets the SAE criteria must also be reported.

**Q9. How should I answer "participant had to be unblinded"?**
Under the KHP-CTO convention, answer n/a. Do not answer "yes" even if the participant was unblinded, and do not complete the "was participant on placebo" question that is revealed if "yes" is entered.

**Q10. Why can't I submit my report for sign-off?**
The report can only be submitted once all mandatory fields (marked with an asterisk *) have been completed and saved. A section changes from Draft to Complete when its mandatory fields are complete and saved, so check the Form Sections page for any section that is not marked Complete. Section 2d lists the mandatory fields for each role. Once submitted, the report status changes to Awaiting Sign-off and a notification email is sent to the PI and delegated Sub-Investigators.

**Q11. What happens if I leave a report in Draft status?**
Reports that remain in Draft status are not considered complete. Users assigned to the report receive reminder emails until the report is submitted for PI Sign-off.

**Q12. What if more than one seriousness criterion or more than one diagnosis applies?**
If more than one seriousness criterion applies, select the most significant criterion. If there is an additional diagnosis, select Yes to indicate this; however, if the additional diagnosis is also categorised as serious per regulations or the trial protocol, complete a separate SAE report.

## 13c. Review, Sign-off and Follow-up Reports

**Q13. What do the report status tabs on the Home page mean?**
Drafts are reports started but not yet submitted for PI sign-off. Awaiting Sign-off reports are awaiting PI review and sign-off. Awaiting Review reports are awaiting CRA review and, where applicable, CI assessment. Reviewed with Queries reports have been reviewed by the CRA and need further information or clarification. Reviewed with No Queries reports have completed CRA review with no outstanding queries.

**Q14. What must the PI do when a report is submitted for sign-off, and how quickly?**
The PI and delegated Sub-Investigators receive an automated email with the study and report reference and a link to SAE Dundee. Within 24 hours of the initial SAE data entry, the PI should review each section for accuracy and completeness, add or update any fields as appropriate, complete the causality and severity assessments and assign relatedness to the IMP (where the participant has been exposed to the IMP). Reminder emails are sent every 24 hours until the PI review is completed. Initial reports created by a PI user are submitted for sponsor review without a PI sign-off step.

**Q15. How do I complete the causality assessment?**
In Trial Treatment, answer "Is the SAE causally related to the IMP" for each study drug. Under the KHP-CTO reporting convention, select No for Unrelated or Unlikely related, and Yes for Possibly, Probably or Definitely related. If you select Yes, choose the corresponding Relationship to Study Drug (Possible, Probable or Definite). Then select the Reason for Change and Save. Where more than one study drug is recorded, complete the assessment for each applicable drug.

**Q16. Does every report need a CI expectedness assessment?**
No. The Expectedness field is not displayed where the PI has assessed the SAE as not related to the IMP, or for pregnancy reports. Where the SAE is assessed as related to the IMP, the CI is notified and must complete the assessment: review the applicable Reference Safety Information (the system automatically displays the RSI version for the date of onset), select Expected or Unexpected, then select Save Expectedness. The CI must complete a new assessment for Follow-up Reports where required, and the CI assessment must be completed before CRA review.

**Q17. How do I add or update information after a report has been submitted?**
Create a Follow-up Report. Open the relevant report, select Create Follow-Up from the Revision section and select OK. A Follow-up Report can only be created when the previous report is

marked Awaiting Review, Reviewed with Queries or Reviewed with No Queries; a Basic User cannot create one while the report is Awaiting Sign-off. All information from the previous version is copied across. When you update a section, select the appropriate Reason for Change and Save; a history icon then appears next to updated fields so the previous value and version number can be viewed. If a Follow-up Report is created in error, the draft can be deleted. The CI cannot create Follow-up Reports.

**Q18. What happens if the diagnosis changes in a Follow-up Report?**

SAE Dundee displays a warning. Before submitting the report for sponsor review, the PI should review the MedDRA coding and the causality assessment to ensure they remain appropriate for the updated diagnosis. Your KHP-CTO CRA provides the required MedDRA information; contact them if the coding is unclear or you disagree with it.

## 14. Change History

| CHANGE HISTORY | | | |
|---|---|---|---|
| Date | Version Number | Change details | Reviewed by |
| 16 OCT 2026 | 1.0 | Initial Version | Krista Wills |
| 23 OCT 2026 | 1.1 | Added SAE and IMP reporting workflow diagram | Craig Macpherson |
| 12 Nov 2026 | 1.2 | Added FAQs | Craig Macpherson |