

SAE Dundee

User Guide

Version 1.0 16 October 2026

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 \(SAE Dundee Version\)](#) which describes the pharmacovigilance processes, roles and responsibilities.

Content

1. Introduction	1
2. Using this Guide	4
2a Role Categories.....	4
2b. Role permissions:	5
2c. Conventions Used in this Guide	5
2d. Mandatory Fields	6
3. Accessing SAE Dundee	6
3a. Requesting Access.....	6
3b. Sign In.....	7
3c. SAE Dundee Unavailable or Downtime	7
3d. Welcome Page	7
3d. Home Page	8
4. Creating an Initial Report	9
4a. Starting an Initial Report	9
4b. Completing Form Sections	9
4c. Participant Details.....	10
4d. Serious Adverse Event Details.....	10
4e. Trial Treatment	11
4f. Concomitant Medications	12
4g. Re-challenge	13
4h. Submitting the Report for Sign-off	13
5. Creating an Important Medical Event (IME) Report	14
6. Creating a Pregnancy Report.....	14
6a. Starting a New Report.....	15
6b. Pregnancy Details	15
6c. Submitting the Pregnancy Report for Sign-off	16
7. Follow-up Reports	17
7a. Creating a Follow-up Report	17
7b. Updating the Follow-up Report	17
7c. Changes to Diagnosis.....	18
7d. Submitting the Follow-up Report for PI Sign Off	18

8. Principal Investigator (PI) Sign Off.....	19
8a. Report Notification	19
8b. Assessing and Updating the Report.....	19
8c. Trial Treatment – Causality Assessment.....	20
8d. Serious Adverse Event Details.....	21
8e. Submitting the Report for Review	21
9. Chief Investigator (CI) Review.....	22
9a. Expectedness Assessment.....	22
10. CRA Reviewer	24
10a. Opening a Report for Review	24
10b. Reviewing a Report.....	24
11 System Administration.....	25
11a. Accessing PV Administration	25
11b. Studies tab.....	25
11c. Drugs tab	26
11d. User Management – PV Administrator only	26
12. Reports and Line Listings	27

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 • Submits for PI review • Delegated study team member
Principal Investigator (PI)	• Creates, edit and reviews reports • Assesses causality and severity • Submits for Sponsor review. • May delegated to a <i>medically qualified</i> PI or Sub-Investigator.
Chief Investigator (CI)	• Assesses expectedness (where required) • Reviews reports (cannot edit) • May delegated to a Medical Monitor
Clinical Research Associate (CRA)	• Reviews SAE reports • Reviews reports (cannot edit)
PV Administrator	• Manages user accounts and system administration. • 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

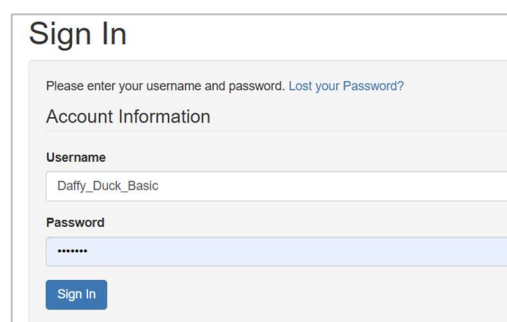
If you need to request a new user account or changes to any existing accounts, please contact the KHP-CTO CRA for your trial.

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 Login Page](#)
- 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:

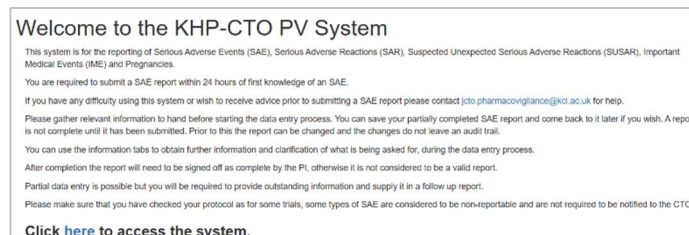
- Trial, site name and reporter's name
- Participant ID
- Event term, severity and seriousness criteria
- Randomised arm (if applicable)
- IMP(s)
- Causality assessment for each IMP

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

Reports

Basic

Create Initial Report

Select Study: All Select Site: All

Draft (1) Awaiting Sign Off (2) Awaiting Review (0) Reviewed with Queries (2) Reviewed with No Queries (0) Non-Reportable (0)

Draft

Show 10 entries Search:

Reference	Site ID	Participant ID	Diagnosis	Type	Outcome	Created By	Date Created
20260921-DNU KRAKEN-1031-2	County Hospital	1017	anaphylaxis	SAE		Basic	21/09/2026

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

- **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

The 'Study Details' form contains the following fields:

- Study***: Dropdown menu with 'DNU KRAKEN' selected.
- Study Register and number**: Text field with 'N/A'.
- IRAS**: Text field with '1111111'.
- Sponsor**: Text field with 'County Hospital'.
- Site***: Dropdown menu with 'County Hospital' selected.
- Principal Investigator**: Text field with 'Professor Plum'.
- Is this a reportable SAE?***: Dropdown menu with 'Reportable' selected.

Buttons: 'Save' and 'Back'.

Footnote: Required fields are marked with an asterisk (*).

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.

The 'Form Sections' page shows the following sections and their status:

- Study Details**: Complete (green indicator)
- Participant Details**: Draft (red indicator)
- Serious Adverse Event Details**: Draft (red indicator)
- Trial Treatment**: Draft (red indicator)
- Concomitant Medications**: No data (orange indicator)
- Re-challenge**: No data (orange indicator)

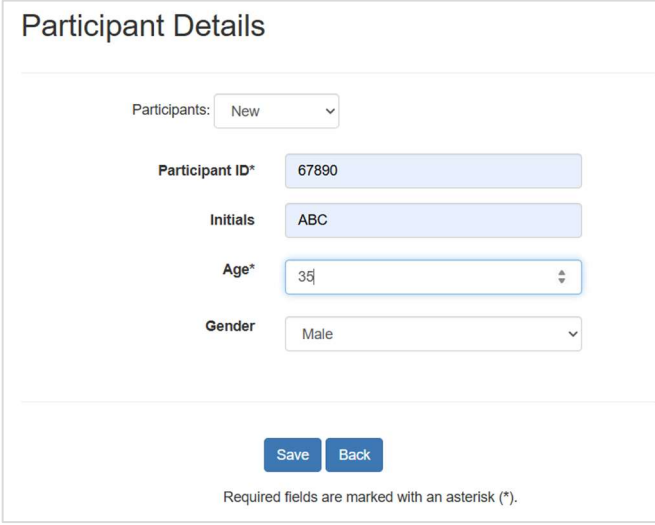
Buttons: 'Submit for Sign off', 'Delete report', and 'Back'.

Message: Changes saved successfully.

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**



The screenshot shows a web form titled "Participant Details". At the top, there is a dropdown menu labeled "Participants:" with "New" selected. Below this are five input fields: "Participant ID*" with the value "67890", "Initials" with the value "ABC", "Age*" with the value "35", and "Gender" with the value "Male". At the bottom of the form are two buttons, "Save" and "Back". A small note at the very bottom states "Required fields are marked with an asterisk (*)".

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**

Date of onset

21/09/2028

Time of onset (if available)

13:00

Date person completing report became aware of event

Date SAE Notified To Investigator

22/09/2028

Diagnosis*

Anaphylaxis

Additional Diagnosis

☐ Yes
☒ No

Severity

Severe

Seriousness Criteria

Life-threatening

Outcome

Resolved

Date of Recovery*

21/09/2028

Event Narrative

The participant developed anaphylaxis shortly after receiving the study drug. They required emergency treatment. The reaction resolved following treatment.

Person to contact

Professor Plumb

Phone number

07771231234

Email address

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 there is more than one criterion, choose the more/most significant one. Seriousness is a regulatory definition and should not be confused with severity.

A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.

Save

Back

Required fields are marked with an asterisk (*)

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**

Trial Treatment

Please indicate what stage of the protocol the participant was in* On Treatment

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

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

Action Taken* Drug Withdrawn

Study Drugs

If 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?	Date of dose prior to SAE onset*
Vasovist	1	g	As require	Intraveno	nk/08/2026	dd/mm/yyyy	☒	nk/08/2026

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**

Concomitant Medications

Was the participant 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?	Date of dose prior to SAE onset	Dose*	Unit*	Frequency*	Route*	Indications*	Causal relationship
Paracetamol	nk/nk/2026	dd/mm/yyyy	☒	dd/mm/yyyy	1	g	As required	Oral	Headache	Non

[Add New Row](#)

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**

Re-challenge

Please complete if applicable.

Name of drug suspected to have caused SAE:	Vasovist
Was the suspected drug stopped?	Yes
Did the reaction abate after stopping the suspected drug?	Yes
Did the reaction reappear after re-introduction of suspected drug?	No

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**

Pharmacovigilance King's

Home

orange_one_basic

20260921-DNUKRAKEN-1033-1

Study: DNU KRAKEN

Site: County Hospital

Participant: 67890

Submit for Sign off

Delete report

Changes saved successfully.

Form Sections

Study Details

Participant Details

Serious Adverse Event Details

Trial Treatment

Concomitant Medications

Re-challenge

Back

Complete

Complete

Complete

Complete

Data entered

Data entered

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**

The screenshot shows the 'Serious Adverse Event Details' form. It contains the following fields and values:

- Date of onset: 06/09/2026
- Time of onset (if available): hh:mm
- Date person completing report became aware of event: 20/09/2026
- Date SAE Notified To Investigator: 20/09/2026
- Diagnosis*: Suspected malignancy
- Additional Diagnosis: ☐ Yes ☒ No
- Severity: Moderate
- Seriousness Criteria: Other important medical event
- Outcome: Continuing
- Event Narrative: A suspicious mass was identified during study assessments. Further investigations have been arranged to determine whether this represents a malignancy. The participant remains under clinical review.
- Person to contact: Professor Plum
- Phone number: 020 7946 0123
- Email address: Professor.Plumb@nhs.net

On the right side of the form, there are two instructional text blocks:

- Top block:** 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.
- Bottom block:** If there is more than one criterion, choose the more/most significant one. Seriousness is a regulatory definition and should not be confused with severity. **Please ensure a follow-up report is submitted.** A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.

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.

20260921-DNUKRAKEN-1036-1

Study: DNU KRAKEN
Site: County Hospital
Participant:

Submit for Sign off

Delete report

Changes saved successfully.

Form Sections

Study Details	Complete
Participant Details	Draft
Pregnancy Details	Draft
Trial Treatment	Draft
Concomitant Medications	No data

Back

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

Pregnancy Details

Who are you reporting pregnancy for?*	Study participant
Date pregnancy reported*	20/09/2026
Start date of last menstruation	10/08/2026
Date pregnancy confirmed	18/09/2026
Anticipated date of childbirth	17/05/2027
	☐ N/A
Pregnancy outcome*	Not known at this stage

Partners of Study Participant

Pregnancy Details

Who are you reporting pregnancy for?*	Partner of study participant
Has partner consented for pregnancy to be reported?*	☒ Yes ☐ No
Partner's initials*	CDE
Partner's age*	45
Date pregnancy reported*	20/09/2026
Start date of last menstruation	10/08/2026
Date pregnancy confirmed	18/09/2026
Anticipated date of childbirth	17/05/2027
	☐ N/A
Pregnancy outcome*	Not known at this stage

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**.

This revision

Submitted: white_one_basic on 23/09/2026 08:23.
Signed: white_PI on 23/09/2026 08:27.
Reviewed with Queries: Reviewer on 23/09/2026 08:33.
Reviewed with No Queries: No.
Resolved: No

All revisions

23/09/2026 08:15: Initial - reviewed (viewing)

Create Follow Up

Comments

Add Comment

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.

Participant Details

Participant ID* 1003

Initials DEF

Age* 45

Gender Male

Transcription Error

Save Back

Required fields are marked with an asterisk (*).

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

Date SAE Notified To Investigator

Diagnosis* Wrist fracture

23/09/2026 08:15: Hospitalisation
23/09/2026 14:02: Wrist fracture

Please enter t
If this is not a

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.

⚠ The diagnosis in this follow up report is different to the original report. Please ensure that the following data is still correct:

MedDRA (in Serious Adverse Event Details)
Causality (in Trial Treatment)

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.

Reports

The screenshot displays the 'Reports' section of the SAE Dundee system. At the top, there is a 'PI' tab and a 'Create Initial Report' button. Below these are dropdown menus for 'Select Study:' (set to 'All') and 'Select Site:' (set to 'All'). A horizontal bar contains several status tabs: 'Draft (1)', 'Awaiting Sign Off (2)', 'Awaiting Review (0)', 'Reviewed with Queries (1)', 'Reviewed with No Queries (0)', and 'Non-Reportable (0)'. The 'Awaiting Sign Off' tab is currently selected. Below the tabs, the section is titled 'Awaiting Sign Off'. It features a 'Show' dropdown set to '10' and a 'Search:' input field. A table lists two entries. The first entry has a Reference of '20280923-DNUKRAKEN-1042-1', Site ID of 'County Hospital', Participant ID of '1003', Diagnosis of 'Anaphylaxis', Type of 'SAE', Outcome of 'Resolved', Created By of 'orange_one_basic', and Date Created of '23/09/2026'. The second entry has a Reference of '20280922-DNU KRAKEN-1038-4', Site ID of 'County Hospital', Participant ID of '69356', Diagnosis of 'Influenza infection', Type of 'SAE', Created By of 'white_one_basic', and Date Created of '23/09/2026'. At the bottom of the table, it says 'Showing 1 to 2 of 2 entries' and includes navigation buttons: 'First', 'Previous', '1', 'Next', and 'Last'.

Reference	Site ID	Participant ID	Diagnosis	Type	Outcome	Created By	Date Created
20280923-DNUKRAKEN-1042-1	County Hospital	1003	Anaphylaxis	SAE	Resolved	orange_one_basic	23/09/2026
20280922-DNU KRAKEN-1038-4	County Hospital	69356	Influenza infection	SAE		white_one_basic	23/09/2026

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 screenshot displays the 'Reports' section of the SAE Dundee system. At the top, there are filters for 'Select Study:' (set to 'All') and 'Select Site:' (set to 'All'). Below these are tabs for report status: 'Draft (1)', 'Awaiting Sign Off (1)', 'Awaiting Review (1)', 'Reviewed with Queries (1)', 'Reviewed with No Queries (0)', and 'Non-Reportable (0)'. The 'Awaiting Review' tab is selected and highlighted. Under this tab, there is a 'Show' dropdown set to '10 entries' and a search bar. A table lists the reports with columns: Reference, Site ID, Participant ID, Diagnosis, Type, Outcome, Created By, and Date Created. One report is visible: Reference '20260923-DNUKRAKEN-1042-1', Site ID 'County Hospital', Participant ID '1003', Diagnosis 'Anaphylaxis', Type 'SAE', Outcome 'Resolved', Created By 'orange_one_basic', and Date Created '23/09/2026'. At the bottom of the table, it says 'Showing 1 to 1 of 1 entries' and includes navigation buttons: 'First', 'Previous', '1', 'Next', and 'Last'.

Reference	Site ID	Participant ID	Diagnosis	Type	Outcome	Created By	Date Created
20260923-DNUKRAKEN-1042-1	County Hospital	1003	Anaphylaxis	SAE	Resolved	orange_one_basic	23/09/2026

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**

Trial Treatment

Please indicate what stage of the protocol the participant was in*

On Treatment

Was the participant receiving the trial IMP (any test drug including comparators) prior to the event?*

Yes

Action Taken*

Drug Withdrawn

Did the participant have to be unblinded?*

No

Study Drug*	Dose	Frequency	Route	Start Date*	End Date	Ongoing?	Date of dose prior to SAE onset*	Is the SAE causally related to the IMP?
Vasovist	1 g	As required	Intravenous	20/09/2026	21/09/2026	No	21/09/2026	Yes

Drug	Relationship to Study Drug*	Expectedness*	IB or SmPC containing RSI	RSI File Version
Vasovist	Possible	Unexpected ▼	Test	1.0

[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.

Reports

CRA Reviewer

Select Study: All Select Site: All

Draft (1) Awaiting Sign Off (1) **Awaiting Review (1)** Reviewed with Queries (1) Reviewed with No Queries (0) Line Listing

Awaiting Review

Show 10 entries

Search:

Reference	Site ID	Participant ID	Diagnosis	Type	Outcome	Created By	Date Created
20260923-DNUKRAKEN-1042-1	County Hospital	1003	Anaphylaxis	SUSAR	Resolved	orange_one_basic	23/09/2026

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

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

This revision

Submitted: orange_one_basic on 29/09/2026 08:30.
Signed: orange_PI on 29/09/2026 12:18.
Reviewed with Queries: No.
Reviewed with No Queries: No.
Resolved: No

Mark as Reviewed (With Queries)

Mark as Reviewed (With No Queries)

Additional CRA function

CRA's 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:

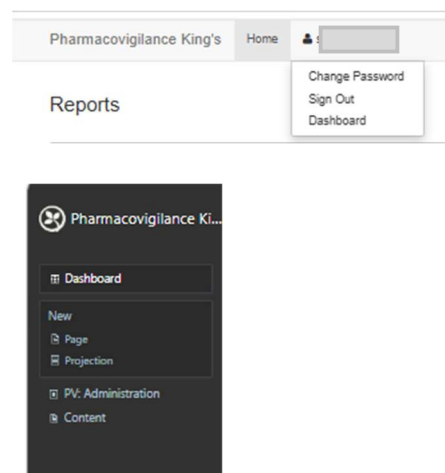
- **Study Management** – CRA and PV Admin
- **Site Management** – CRA and PV Admin
- **Drug Management / RSI** – CRA and PV Admin
- **User Management** – PV Admin only
- **Resolving/closing reports** – PV Admin only

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.

The image shows a 'Relationships' form with the title 'Relationships (changes are saved as they are entered)'. It contains four main sections: 'Study', 'Sites', 'Drugs', and 'Files'. The 'Study' section has a dropdown menu with 'DEMO-001' selected. The 'Sites' section is a list of checkboxes with the following items: King's College Hospital (checked), Guy's Hospital (checked), St Thomas' Hospital (unchecked), Royal Free Hospital (unchecked), Barts Health (checked), and Leeds Teaching Hospital (unchecked). The 'Drugs' section is a list of checkboxes with the following items: Drug A (checked), Drug B (unchecked), Drug C (checked), Placebo (unchecked), and Comparator (unchecked). The 'Files' section is a list of checkboxes with the following items: Protocol v1.0 (checked) and Investigator Brochure (unchecked).

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.

Relationships (changes are saved as they are entered)

Drug Drug A	Units ☒ mg ☐ mcg ☐ g ☐ ml ☒ tablet ☐ capsule ☐ other	Frequencies ☐ once daily ☒ twice daily ☐ three times daily ☐ weekly ☐ every 2 weeks ☐ monthly ☐ as needed ☐ other	Routes ☒ oral ☐ intravenous ☐ subcutaneous ☐ topical ☐ inhalation ☐ other	RSI Files ☒ Protocol v1.0 ☐ Investigator Brochure v1.0 ☐ SmPC v2.1
-----------------------	---	---	---	--

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.

Administration									
Users Studies Drugs									
Search: Filter: Approved Users Sort by: Name Filter Add User									
Name	Email	Title	Department	Staff role	Date account activated	Date account deactivated	Role	Study associations	Options
Bugs_Bunny_Basic	Bugs_Bunny_Basic@nhs.net	Mr	Research	Clinical Research Associate	01/09/2026 09:15:23		Basic	WBUNNY	Edit Disable
Daffy_Duck_Pi	Daffy_Duck_Pi@nhs.net	Dr	Research	Principal Investigator	01/09/2026 09:22:17		PI	Coyote	Edit Disable
Porky_Pig_CI	Porky_Pig_CI@nhs.net	Dr	Research	Chief Investigator	01/09/2026 09:28:41		CI	Tweety	Edit Disable
Tweety_Bird_CRA	Tweety_Bird_CRA@nhs.net	Ms	Research	Clinical Research Associate	01/09/2026 09:35:06		CRA	Roadrunner	Edit Disable
Wile_Coyote_Admin	Wile_Coyote_Admin@nhs.net	Mr	CTO	PV Administrator	01/09/2026 09:42:19		PV	All studies	Edit Disable

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.

Reports

CRA Reviewer

Select Study: All Select Site: All

Draft (2)

Awaiting Sign Off (0)

Awaiting Review (1)

Reviewed with Queries (0)

Reviewed with No Queries (1)

Line Listing

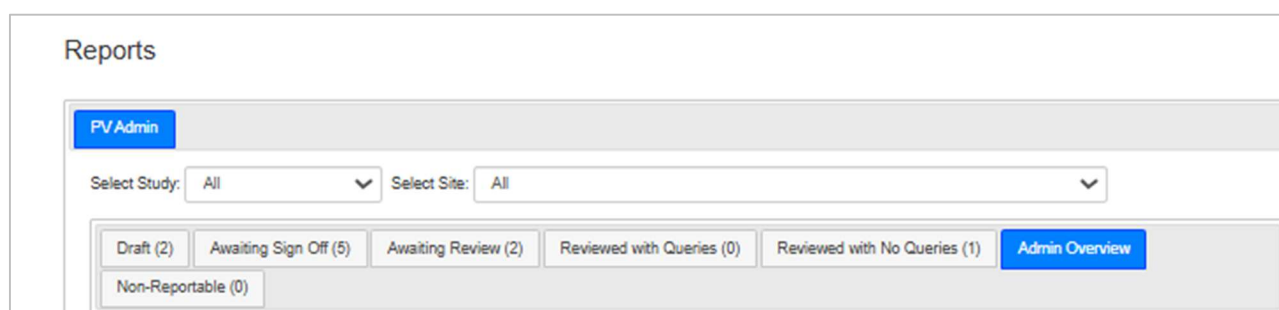
Download Line Listing Report

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**



The screenshot shows the 'Reports' section of the PV Admin interface. It features a 'PV Admin' tab, two dropdown menus for 'Select Study' and 'Select Site' (both set to 'All'), and a row of report status buttons: 'Draft (2)', 'Awaiting Sign Off (5)', 'Awaiting Review (2)', 'Reviewed with Queries (0)', 'Reviewed with No Queries (1)', and 'Admin Overview' (highlighted in blue). A 'Non-Reportable (0)' button is located below the first row.