

Introduction to SAE Dundee

The new KHP-CTO safety reporting system

Version 1.3, 16 October 2026

Introduction to SAE Dundee

- **SAE Dundee** is the **new KHP-CTO Pharmacovigilance safety reporting system**.
- Ongoing KHP-sponsored/co-sponsored trials are being moved to SAE Dundee.

Current 'paper' process	SAE Dundee
Initial and follow-up reports submitted by email using PDF forms	Reports entered directly into SAE Dundee
Report details transcribed into KHP-CTO SAE database	No separate transcription required
Follow-up reports require PDF forms to be manually updated	Follow-up reports are electronically generated from the existing report
Paper copies of all versions held by KHP-CTO and sites	Electronic record of all report versions

User Roles

Basic User *(delegated study team member)*

- Creates initial or follow-up reports
- Submits for PI review

Principal Investigator (PI) *(Sub I delegate)*

- Creates, edit and reviews reports
- Assesses causality and severity
- Submits for Sponsor review

Chief Investigator (CI) *(Medical Monitor delegate)*

- Assesses expectedness (where required)
- Reviews reports (cannot edit)

Clinical Research Associate (CRA)

- Reviews reports (cannot edit)

PV Administrator

- Manages user accounts
- System administration

Not covered in this session

Using SAE Dundee

Mandatory fields*

- Fields marked with an **asterisk (*)** are mandatory
- Required fields vary by **user role**
- Some fields depend on the **report type or previous answers**

Basic User

- **Study:** Study, Site, Report Type
- **Participant:** Participant ID, Age
- **SAE:** Diagnosis, Date of Recovery (if applicable)
- **Trial treatment:** Stage of Protocol, Receiving Trial IMP, Unblinded, Action Taken
- **Study drug:** Drug, Start Date, Date of Dose Prior to SAE Onset
- Additional fields apply for **death, concomitant medication and pregnancy**

PI User - Basic User fields plus:

- **SAE:** Severity, Seriousness Criteria
- **Causality:** Relationship to IMP

CI User

- **Expectedness:** For related events only

Using SAE Dundee: Conventions

Unknown dates

When an exact date is not known, enter **NK**

Blinding

Trial Treatment: for '**Participant had to be unblinded***', always select **N/A**

Causality assessment

Trial Treatment: for '**Is the SAE causally related to the IMP?***' select:

- **No** = Not related / Unlikely
- **Yes** = Possible / Probable / Definite

Change of diagnosis

If the SAE **Diagnosis*** changes, the PI should reassess event including:

- ✓ **Causality**
- ✓ **Severity**

Demonstration

SAE Dundee:

Pharmacovigilance King's - Welcome to the KHP-CTO PV System

Pharmacovigilance King's Home Sign In

Welcome to the KHP-CTO PV System

This system is for the reporting of Serious Adverse Events (SAE), Serious Adverse Reactions (SAR), Suspected Unexpected Serious Adverse Reactions (SUSAR), Important Medical Events (IME) and Pregnancies.

You are required to submit a SAE report within 24 hours of first knowledge of an SAE.

If you have any difficulty using this system or wish to receive advice prior to submitting a SAE report please contact jcto.pharmacovigilance@kcl.ac.uk for help.

Please gather relevant information to hand before starting the data entry process. You can save your partially completed SAE report and come back to it later if you wish. A report is not complete until it has been submitted. Prior to this the report can be changed and the changes do not leave an audit trail.

You can use the information tabs to obtain further information and clarification of what is being asked for, during the data entry process.

After completion the report will need to be signed off as complete by the PI, otherwise it is not considered to be a valid report.

Partial data entry is possible but you will be required to provide outstanding information and supply it in a follow up report.

Please make sure that you have checked your protocol as for some trials, some types of SAE are considered to be non-reportable and are not required to be notified to the CTO.

Click [here](#) to access the system.

Implementation and timelines

- **Training:** Complete SAE Dundee training by the **end of October 2026**
Open sessions available to book via KHP-CTO website:
[Introduction to SAE Dundee - King's Health Partners Clinical Trials Office](#)
- **Implementation: Starts November 2026**
Your CRA will confirm your trial's implementation date
- **System access:** Users will need to **request access** to SAE Dundee
- **KHP-CTO will transfer:** Prior and ongoing SAEs at implementation
- **Use SAE Dundee:** New SAEs and follow-ups after implementation

User Guide and PV Policy

- **SAE Dundee User Guide:** Will be made available on the KHP-CTO website and provided by your CRA
- **PV Policy:** Updated to include SAE Dundee and available on the KHP-CTO website: [KHP-CTO Pharmacovigilance and Safety Reporting Policy](#)
- **KHP-CTO website:** Contains both PV Policy versions:
 - [‘Paper based reporting’ KHP-CTO PV Policy \(Version 10\)](#)
 - [SAE Dundee KHP-CTO PV Policy \(Version 11\)](#)

Use the policy applicable to your trial

If SAE Dundee is unavailable

If SAE Dundee is unavailable:

- **Email** new event and follow-up information to KHP-CTO PV email: jcto.pharmacovigilance@kcl.ac.uk
- **Full instructions** are provided in the [**SAE Dundee PV Policy \(Version 11\)**](#)

For new events include

- Trial name
- Site
- Reporter
- Participant ID
- Event details;
 - Diagnosis
 - Severity
 - Seriousness criteria
- IMP(s)
- Causality assessment (if applicable)

Next steps and summary

- **For now:** Continue using the current PDF reporting process
- **Before implementation:**
 - SAE Dundee account username and password issued
 - Minor modification to trial (managed by CI or delegate)
- **Implementation:** your CRA will inform you when your trial switches to SAE Dundee
- **After implementation:** Use SAE Dundee for new SAEs and follow-ups

Support and contacts

	Trial-specific and implementation questions:	Contact your KHP-CTO CRA
	Technical support:	KHPCTO.CommercialData@kcl.ac.uk
	Training and training-material questions:	khp-ctotrainingteam@kcl.ac.uk
	If SAE Dundee is unavailable, send safety reports to:	jcto.pharmacovigilance@kcl.ac.uk

Thank you for attending

- Please complete the evaluation before leaving
- Thank you

