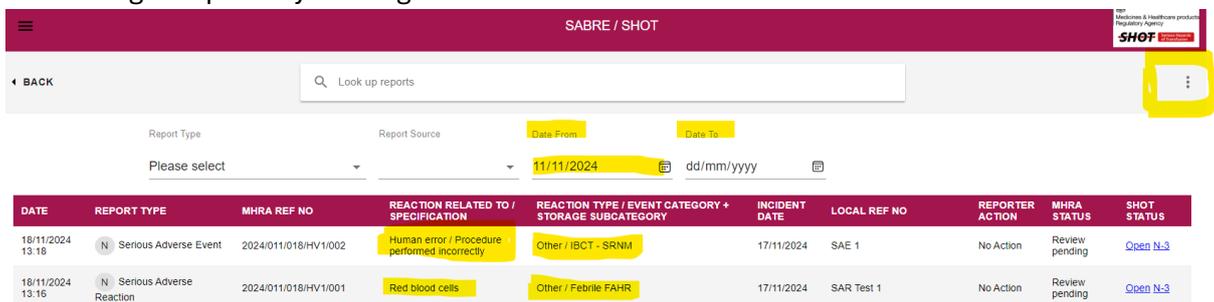


# SABRE Pilot quick start instructions and cheat-sheet

## List of changes to “New” SABRE

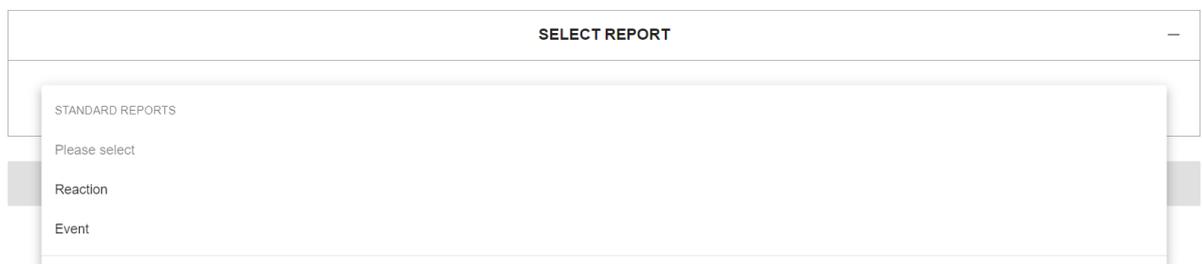
- Each reporter is required to create a user account. No longer are you expected to share a single set of log in details.
- There are two types of reporter account.
  - Organisation lead
  - Reporter
- The organisation lead has higher access rights and can control certain aspects of the organisation account
  - Invite users
  - Edit organisation details
  - Edit the list of linked establishments/ hospitals
- Reporters have basic reporting access rights as per “old” SABRE
- The workspace has been updated to give more detail about type of SAE and SAR reported
- The Workspace can be manipulated by displaying a date range
- The Workspace can be exported to a .csv file/ spreadsheet to allow trending and monitoring of reports by clicking the three dots



The screenshot shows the SABRE / SHOT workspace. At the top, there is a search bar labeled "Look up reports" and a date range filter set to "11/11/2024". Below the search bar, there are filters for "Report Type" and "Report Source". The main content is a table with the following columns: DATE, REPORT TYPE, MHRA REF NO, REACTION RELATED TO / SPECIFICATION, REACTION TYPE / EVENT CATEGORY + STORAGE SUBCATEGORY, INCIDENT DATE, LOCAL REF NO, REPORTER ACTION, MHRA STATUS, and SHOT STATUS. Two rows of reports are visible, with specific cells highlighted in yellow.

DATE	REPORT TYPE	MHRA REF NO	REACTION RELATED TO / SPECIFICATION	REACTION TYPE / EVENT CATEGORY + STORAGE SUBCATEGORY	INCIDENT DATE	LOCAL REF NO	REPORTER ACTION	MHRA STATUS	SHOT STATUS
18/11/2024 13:18	N Serious Adverse Event	2024/011/018/HV1/002	Human error / Procedure performed incorrectly	Other / IBCT - SRNM	17/11/2024	SAE 1	No Action	Review pending	<a href="#">Open N-3</a>
18/11/2024 13:16	N Serious Adverse Reaction	2024/011/018/HV1/001	Red blood cells	Other / Febrile FAHR	17/11/2024	SAR Test 1	No Action	Review pending	<a href="#">Open N-3</a>

- Type of report can be selected as the first step



The screenshot shows a "SELECT REPORT" dialog box. It has a title bar "SELECT REPORT" and a close button. Below the title bar, there is a dropdown menu with the following options: "STANDARD REPORTS", "Please select", "Reaction", and "Event".

- All fields are mandatory unless marked as optional

Blood component in question transfused

Further Details

### Patient/Donor Details

Date of birth (Optional)

Year	Month	Day	
<input type="text" value="YYYY"/>	<input type="text" value="MM"/>	<input type="text" value="DD"/>	

Age (Optional)

Sex (Optional)

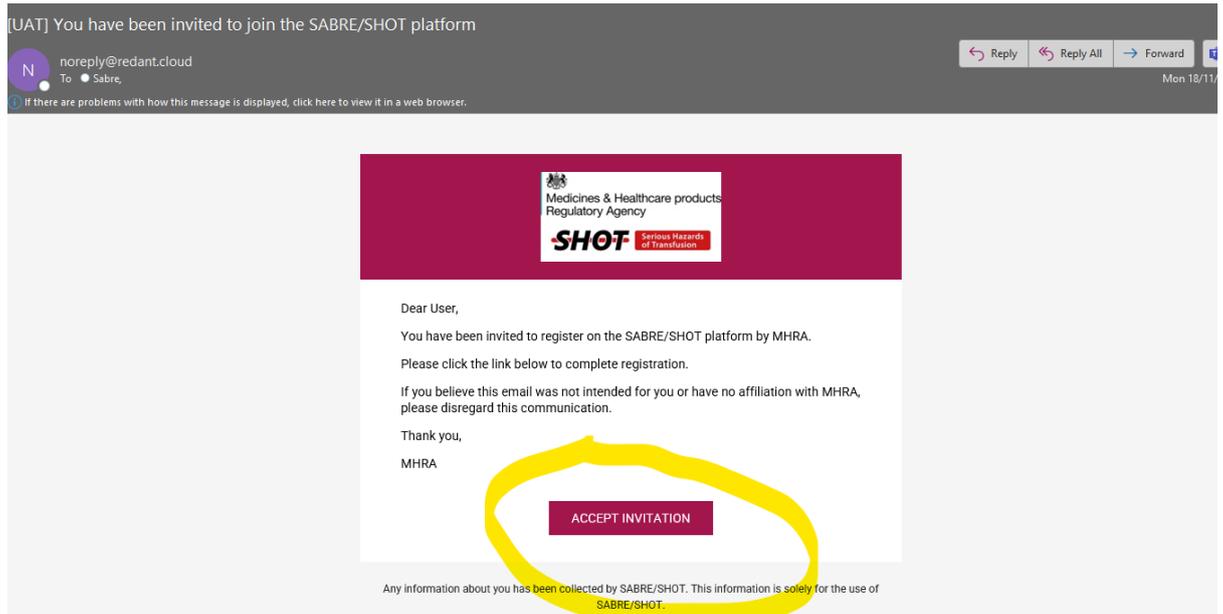
- To help ensure all Notification reports are made “as soon as known” you will no longer be able to report a Notification and Confirmation report concurrently. You are expected to report a Notification report separately to a Confirmation report.

## Quick start instructions

### Setting up your Organisation lead account

1. Hospital to nominate an “Organisation lead” and inform MHRA
2. MHRA to invite nominee and send email

### 3. Organisation lead receives invite and accepts



### 4. Organisation lead then completes a registration form and submits

SABRE / SHOT

Medicines & Healthcare products  
Regulatory Agency  
**SHOT** Serious Hazards  
of Transfusion

**CREATE ACCOUNT**

All fields marked with \* are required.

**PERSONAL DETAILS**

Title *	First Name *
_____	_____
Last Name *	Email *
_____	sabre@mhra.gov.uk
Position/Occupation *	Telephone *
_____	_____

**PASSWORD**

Password *	Confirm Password *
_____	_____

Password must

- Have at least one capital letter
- Have at least one lower case letter
- Have at least one numeric character
- Be at least 9 characters or more long

**CREATE USER**

### 5. Inform MHRA by email once this has been done to allow us to assign correct reporter status

6. Organisation lead then logs into new SABRE



Email

sabre@mhra.gov.uk|

Password

.....

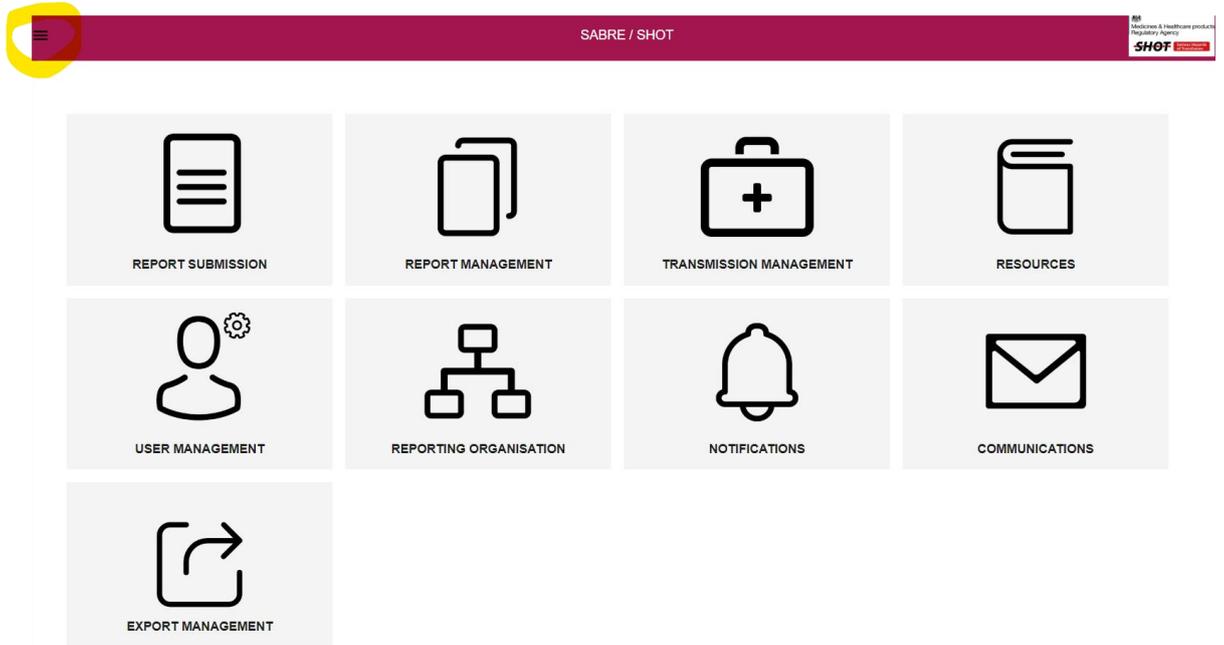
SIGN IN

[Forgot your password?](#)

[Create an account](#)

[Request reporting organisation](#)

7. You will see your new Dashboard



8. Clicking the highlighted menu opens a panel with a list of options as well as links to your

×

- DASHBOARD
- REPORT SUBMISSION
- REPORT MANAGEMENT
- TRANSMISSION MANAGEMENT
- RESOURCES
- USER MANAGEMENT
- REPORTING ORGANISATION
- NOTIFICATIONS
- COMMUNICATIONS
- EXPORT MANAGEMENT

SABRE Test  
MHRA  
1.1.3335.v598

MY ORGANISATION

MY PROFILE

SIGN OUT

profile etc

# Invite reporters to create accounts (Three methods)

## Method 1

1. Click the “reporting organisation” tile
2. Click the name of your organisation

ORGANISATION MANAGEMENT

Organisation	Sender Id	Type
MHRA		

Rows per page: 1-1 of 1

3. Click “Invite user”

BACK MHRA INVITE USER

All fields marked with \* are required.

REPORTING ORGANISATION CONTACT DETAILS EDIT

ORGANISATION NAME \* ADDRESS LINE 1 \*

4. Type the email of the person you wish to invite to be a reporter

E78D1

TELEPHONE NUMBER \*  
07810741851

### Invite User to Organisation

Email \*

CANCEL INVITE USER

- Once the reporter receives their invite they should accept it

Fw: [UAT] You have been invited to join the SABRE/SHOT platform

Mon 18/11/2024 15:06

If there are problems with how this message is displayed, click here to view it in a web browser.



Dear User,

You have been invited to register on the SABRE/SHOT platform by MHRA.

Please click the link below to complete registration.

If you believe this email was not intended for you or have no affiliation with MHRA, please disregard this communication.

Thank you,

MHRA

[ACCEPT INVITATION](#)

Any information about you has been collected by SABRE/SHOT. This information is solely for the use of SABRE/SHOT.

- Reporter completes the form and submits it.
- The reporter can then log in.
- The organisation lead can repeat the invite process from step 1.

## Method 2

- Alternatively, an Organisation lead can complete a new user account on behalf of another reporter from the "User Management" tile

BACK

Organisation(s) Role(s) Approval Status

Account Type  Include Deactivated

NAME	ROLE	USERS ORGANISATION	ACCOUNT TYPE
Christopher Robbie	Organisation Lead	MHRA	STANDARD
SABRE Test	Organisation Lead	MHRA	STANDARD
[REDACTED]	Reporter	MHRA	STANDARD

[ADD NEW USER](#)

## Method 3

1. From landing page [Sign in | SABRE/SHOT](#), reporter clicks “Create account” and completes the form
2. Organisation lead accepts request
3. The Organisation lead, should then accept it, Via Notifications tile, or User Management Tile

TODAY

User [redacted] as requested to join organisation [redacted] on Trust

or click name in list and accept

User has requested to join organisation [redacted] Foundation Trust

All fields marked with \* are required.

DE-ACTIVATE

PERSONAL DETAILS

EDIT

TITLE \* FIRST NAME \*

LAST NAME \* EMAIL \*

POSITION/OCCUPATION \* TELEPHONE \*

4.

**Note 1: An organisation is allowed more than one Organisation lead**

**Note 2: An individual Organisation lead or reporter only needs one user account, however. Should the need arise, a user is permitted to link to different organisation accounts. E.g. You have multiple SABRE accounts for each hospital within your organisation, one individual reporter can be invited to report on both accounts. Should this happen, then the reporter chooses which account to access**



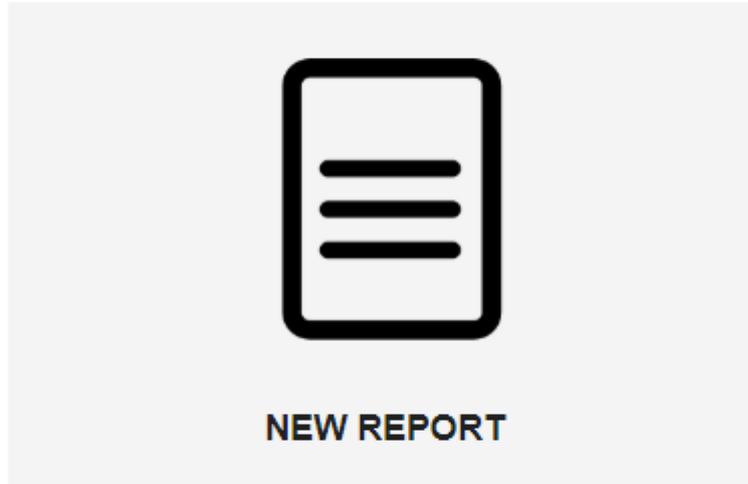
Please select your organisation

A screenshot of a web form showing a dropdown menu. The menu is titled 'Please select your organisation' and has a grey header with the text 'Please select'. Below the header, the following options are listed: 'A Hospital Foundation Trust Change', 'MDS NHS Hospital New', 'MHRA', 'Morlich and Cairn Health Trust', and 'NHS Hospital Milton Keynes'. A vertical scrollbar is visible on the right side of the menu.

## **Making a report**

[Sign in | SABRE/SHOT](#) and log in using your credentials

1. Click report submission and then “New report”



2. Select the report type
3. Complete all mandatory fields and optional fields as appropriate
4. Should you wish to attach a file click “add”

Attach file (Optional)

Press 'Add' Below
<b>Add</b>

Save draft

**Submit**

5. Complete the file details and “Cancel” to delete or “Add” to attach

Attach file (Optional)

File Name

Select File

**Select file** Please select a file

.docx, .doc, .xlsx, .xls, .pptx, .ppt, .jpg, .jpeg, .png, .pdf

[Cancel](#) **Add**

Save draft

Submit

6. Repeat as required.
7. Click “Save draft” or “Submit” to submit your Notification report.
8. To access reports already logged, from the dashboard, click “Report management” tile
9. In the Workspace, hover the mouse over the report you want to open and click or click the hyperlink in the SHOT column to access the SHOT database
10. Click “View report” to open

2024/011/018/HV1/002

Report Details

Creation Time	18/11/2024 13:18	Export As...	PDF
Updated Time	18/11/2024 13:18	<b>View Report</b>	
Reporter	Christopher Robbie	View Report	
Report Form	Serious Adverse Event		

Status Details

Receiver Name	Receiver Status	Validation Status	Created At
HV Blood (SAE)	SUCCESS	VALID	18/11/2024 13:18
SHOT SAE (UAT)	SUCCESS	VALID	18/11/2024 13:18
HALO Blood VAL	SUCCESS	VALID	18/11/2024 13:18

11. You can now add Footnotes or a Confirmation report to an SAE or Footnotes to an SAR

Attach file

Section 2/3

**Confirmation**



Section 3/3

**Footnotes**



Save draft

Submit

12. Click the down arrow to access the next section, either Confirmation or Footnotes

13. To open the Confirmation report of an SAE, click the up/down arrow as per snip below, and select “yes”

Section 2/3

**Confirmation**



Would you like to submit a confirmation at this time? (Optional)

You can submit a footnote without a confirmation by using the footnote section below.

No



Section 3/3

**Footnotes**



Save draft

Submit

14. Complete steps 3-7 to complete the Confirmation section and add attachments as required.

15. To add a Footnote, click the “Down arrow” (step 11) next to Footnotes

16. Click "Add Footnote"

Section 2/3

**Confirmation**



Section 3/3

**Footnotes**



Footnotes (Optional)

Press 'Add' Below
<b>Add Footnote</b>

Save draft

**Submit**

17. You can add a freetext comment or files as you wish

Section 3/3

## Footnotes



### Footnotes (Optional)

Description

Comments

File Name (Optional)

Select File (Optional)

**Select file**

Please select a file

.docx, .doc, .xlsx, .xls, .pptx, .ppt, .jpg, .jpeg, .png, .pdf

Author's first name

- For each individual Footnote you must click “Add footnote” again to add it and repeat as required.

Date

Year Month Day

2024 11 18

[Cancel](#) **Add Footnote**

- When you have added your Footnotes you must click “Submit” to submit your Footnotes to MHRA and SHOT. **Note: If you click “Save draft” you will only save them to your report but not submit them**

## Exporting your workspace to a spreadsheet

- From the dashboard click “Report management”
- Click the three dots

SABRE / SHOT

Medicines & Healthcare products Regulatory Agency

SHOT Serious Hazards of Transfusion

Look up reports

Report Type: Please select

Report Source: Please select

Date From: 11/11/2024

Date To: dd/mm/yyyy

DATE	REPORT TYPE	MHRA REF NO	REACTION RELATED TO / SPECIFICATION	REACTION TYPE / EVENT CATEGORY + STORAGE SUBCATEGORY	INCIDENT DATE	LOCAL REF NO	REPORTER ACTION	MHRA STATUS	SHOT STATUS
18/11/2024 13:18	N Serious Adverse Event	2024/011/018/HV1/002	Human error / Procedure performed incorrectly	Other / IBCT - SRNM	17/11/2024	SAE 1	No Action	Review pending	<a href="#">Open N-3</a>
18/11/2024 13:16	N Serious Adverse Reaction	2024/011/018/HV1/001	Red blood cells	Other / Febrile FAHR	17/11/2024	SAR Test 1	No Action	Review pending	<a href="#">Open N-3</a>

- Click “Export reports”



- Select the report type (multiple selections are acceptable) and date range and then Export

## Export Reports

Export Reports for your organisation.

Report Type \*

Start Date \*

2024

11

11

📅

End Date \*

2024

11

18

📅

CANCEL

EXPORT

- Your report is emailed to you, or you can find it in the “Export management” tile to download

BACK <span style="float: right;">Export Management</span>					
	Date From	Date To	Export Type		
	dd/mm/yyyy	dd/mm/yyyy	Please select	📅	📅
NAME	STATUS	AUTHOR	SHARED WITH	CREATED DATE	FILE
filtered-reports_sabreSAE_sabreSAR_20241111_20241118-cc3a6434-13c2-437b-b50e-804a24cc3a36.csv	SUCCESS	Christopher Robbie		18/11/2024 16:21	<a href="#" style="background-color: #800040; color: white; padding: 2px 5px; text-decoration: none;">DOWNLOAD</a>
filtered-reports_sabreSAR_sabreSAE_20240101_20241114-e29d460d-8e16-4f51-bd49-50b3717b164a.csv	SUCCESS	Christopher Robbie		14/11/2024 12:20	<a href="#" style="background-color: #800040; color: white; padding: 2px 5px; text-decoration: none;">DOWNLOAD</a>