

CREATE OUTSIDE SAFETY REPORTS

Description: OnCore provides a place for study teams to record, display, and update Outside Safety Reports (OSR) that might need to be reported to the IRB and/or the sponsor.

Audience: Study teams who wish to track their OSRs in OnCore.

CREATE AN OUTSIDE SAFETY REPORTS (OSR)

Outside Safety Reports (OSR) document adverse drug/device effects that are both serious and unexpected.

1. Navigate to **Menu > Protocols > OSR.**

OSR Search ?

OSR ID

Issued From (MM/DD/YYYY)

Agent

To Do

OSR Report No.

Protocol No. Type here to search

IRB Reporting

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Note: Avoid Duplicate Entries. You will need to see if your particular report has already been entered into OnCore. The best way to find out is to use the "OSR Report No." search field, if available. Alternatively, you can also search for OSRs by agent and protocol.

2. Click on the **[New]** button. The *New OSR* form opens.
3. Enter the required fields: **Agent, Event Date, AE Category, Adverse Event, and Protocol.**

New OSR ?

*Agent *Event Date (MM/DD/YYYY) Issued Date (MM/DD/YYYY)

Drug Company OSR Report# Subject Description

Death within Hospitalization Follow-Up No.

Reviewed by the DSMC (MM/DD/YYYY)

Sponsor Comments

Adverse Events

AE Category	Adverse Event	Comments	Grade
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Internal Tracking

*Protocol No.	Received Date (MM/DD/YYYY)	PI Notified (MM/DD/YYYY)	Attribution	PI Comments	Consent Form Changed	PI Signed (MM/DD/YYYY)	Not Reportable	Reported to IRB (MM/DD/YYYY)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>

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Listed below is a guide to the fields you will fill out, potentially, and where you can find them on your SAE report or email notification.

- **Agent:** The drug used in the study. You can find this easily enough in your notification as the “compound”.
- **Event date:** The “Event Onset Date” on your report
- **Issued date:** The “Latest Received Date” on your report
- **Drug Company:** You can find this through OSR by going back and searching by “Agent”. You will see all studies that use the same drug and then look at what drug company they used.
- **OSR Report #:** The “AER number” on your report
- **Subject Description:** On your report: Scroll down to the CIOMS form and find Age, Sex. Use these and one or more of the “Event Terms” found back up top. For example: 71YO F; Fatal Pneumonitis.
- **Death Within:** Only if the patient died. Check the report to confirm if the “Patient Died” is checked. The 30 days or 100 days options are available. These are the days that the death occurred from the event date. Typically, these are dates within a day of each other so your option will usually just be the “within 30 days” option. You can always read the response data in the report to make sure.
- **Hospitalization:** On your report, check only if the “Involved or Prolonged Inpatient Hospitalization” is checked.
- **Follow-Up No.:** Find the follow-up number on your report. If Initial, leave it blank.
- **Adverse Events:** Comments = put “No Toxicities defined for this OSR.”
- **Protocol No.:** The OCR number of the study you are doing this for.
- **PI:** Should Auto-fill once you click “Submit”.

4. Click **[Submit]** and **[Close]**.

Once finished, you will have a new report in the system. From here you can add follow ups to this report, as applicable.

CREATE A FOLLOW-UP FOR AN EXISTING OSR

1. Navigate to **Menu > Protocols > OSR**.
2. Find your pre-existing OSR using the OSR Report No., Agent, or Protocol No.
3. Click on the latest recorded follow up, click **[Create Follow Up]**.

The screenshot shows the OSR interface for OSR ID: 59592. It includes a table with the following data:

*Agent	5-aza-2'-deoxycytidine	Event Date	02/21/2023	Issued Date	
Drug Company		OSR Report#		Subject Description	
Death within		Hospitalization	N	Follow-Up Number	
Reviewed by the DSMB					
Sponsor Comments					

Below the table, there are sections for Adverse Events and Internal Tracking. The Adverse Events section shows a table with columns for AE Category, Adverse Event Detail, Comments, and Grade. The Internal Tracking section shows "No Internal Trackings defined for this OSR." At the bottom right, there are three buttons: "View PDF", "Create Follow-Up" (highlighted with a red box), and "Update".

4. Some of the fields will carry forward, click **[Update]** and enter information as needed.



Note: *The system automatically makes the Follow-Up you have created to become the next consecutive number to what was most recently submitted. This may need to be changed depending on what the actual Follow-Up number is on the report you are submitting.*