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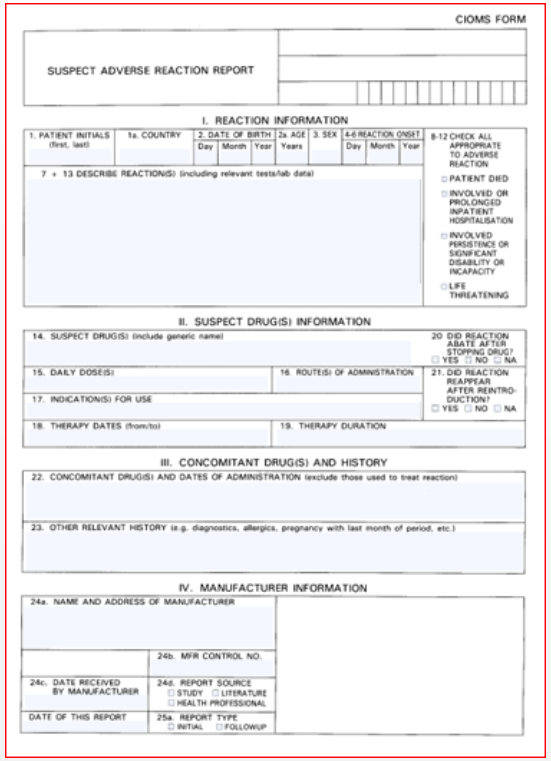
How to run a CIOMS Report

Version 1.0, For HALOPV 5.0

Content

About CIOMS Report



CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH Day Month Year | 2a. AGE Years | 3. SEX | 4-6 REACTION ONSET Day Month Year | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

- PATIENT DIED
- INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

20. DID REACTION ABATE AFTER STOPPING DRUG? YES NO NA

15. DAILY DOSE(S)

16. ROUTE(S) OF ADMINISTRATION

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? YES NO NA

17. INDICATION(S) FOR USE

18. THERAPY DATES (from/to)

19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

24b. MFR CONTROL NO.

24c. DATE RECEIVED BY MANUFACTURER

24d. REPORT SOURCE STUDY LITERATURE HEALTH PROFESSIONAL

DATE OF THIS REPORT

25a. REPORT TYPE INITIAL FOLLOWUP

- A **CIOMS Report** is a structured data published which includes case safety reports for both pre-approval and post-approval reporting periods and covers both adverse drug reaction (ADR) and adverse event (AE) reports. IT includes information related to Reaction, Suspect and concomitant drug and manufacturer.
- HALOPV supports automatic generation of latest CIOMS Form.

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Prerequisite

To be able to run a CIOMS Report from HALOPV, you need to be aware of (and access to):

- How to enter an Incident - ICSR (Individual Case Safety Report) using HALOPV.
- CIOMS form needs to be configured at your HALOPV instance.
  - Please reach to HALOPV Support to configure this form at your instance.

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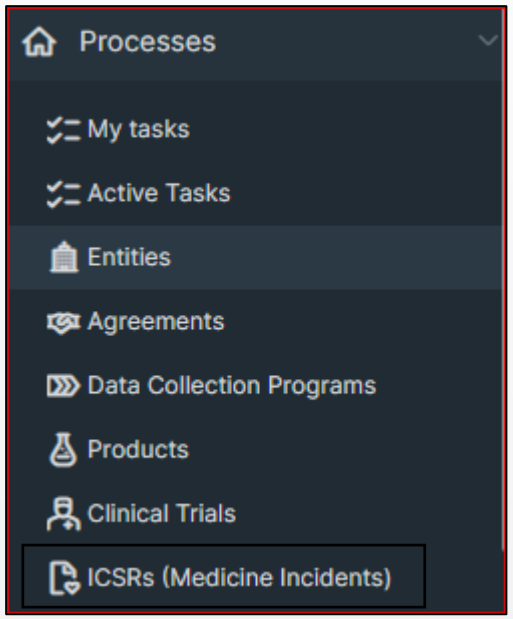
Getting to CIOMS Form



Processing an ICSR intake record

- On the left navigation pane ‘Processes’, select ICSRs (Medicine Incidents).
- Select ICSR Manual Intake from the available workflows
- Complete the ICSR intake form and push through the submission workflow state.

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Getting to CIOMS Form

CIOMS report generation

User has three ways to generate a CIOMS report for a completed record:

- Print CIOMS via processed intake record
- Print CIOMS via submission record
- Print CIOMS via manual submission record

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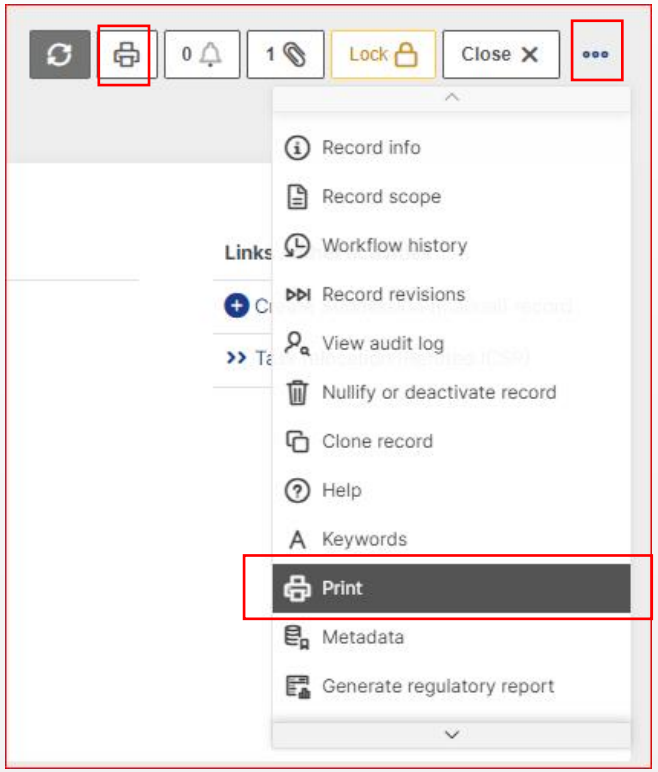
Getting to CIOMS Form



Print via processed intake record

Once an intake record has been completed:

- Click on the link to open the record
- Select Print option from either the three-pin or print icon. This opens a Print Document page.

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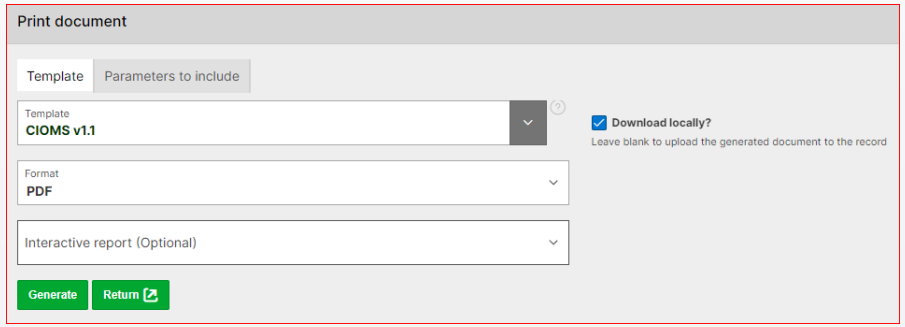
Getting to CIOMS Form



Print Document Page - Template

On the print document page – Template tab:

- Select the appropriate pre-configured CIOMS form from the 'Template Dropdown'
  - You can use the search functionality of the dropdown to filter the available list.
- Select the desired format from the 'Format' dropdown
- Check the checkbox 'Download locally?' to download the generated form at your system or upload at the HALOPV Cloud -
  - Leave blank to upload the generated document to the record
  - You can view/ download the uploaded document anytime by using the Attachment button .
- Click on 'Generate' button to generate the document.
- Click on 'Return' to return to the record.

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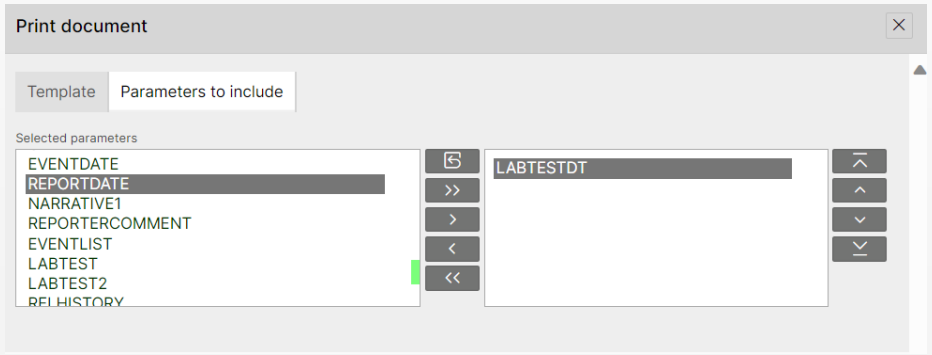
Getting to CIOMS Form



Print Document - Parameters

The Print document allows user to view/ select the parameters to be used while generating the form.
On the Print document page – Parameters to include tab:

- Include/exclude parameters as applicable to be printed on the CIOMS form
  - As a User you are advised to understand the parameters and their usage first before updating the default configuration.
  - To update a parameter, please contact HALOPV Support
- Parameters to Include tab displays two lists –
  - All the parameters in the ‘Selected Parameters’ will be used to generate the document.
  - All the parameters in the list on the right will be excluded while generating the document.

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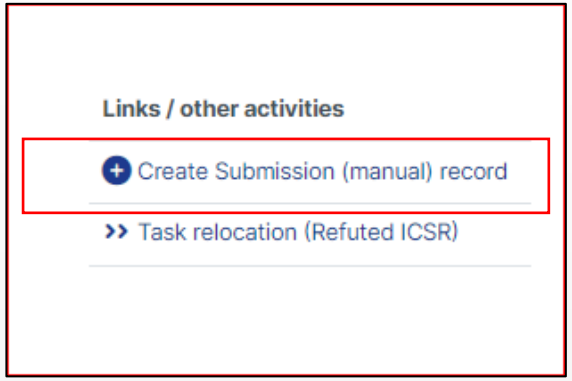
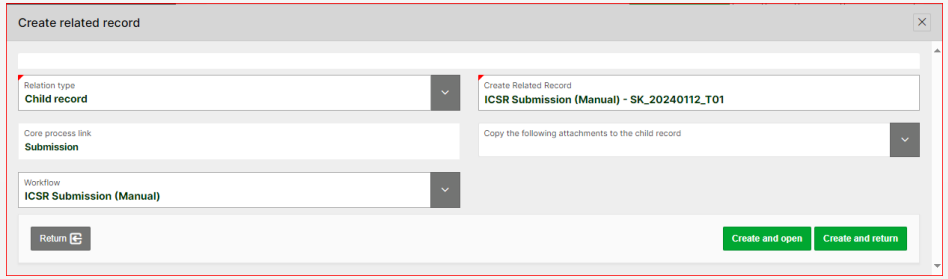
Getting to CIOMS Form





Print via manual submission record

On completion of Incident Reporting form:

- Click on the link to open the record
- Under Links / other activities, click on ‘Create Submission (manual) record’. This opens a ‘Create related record’ page.
- Select the ‘Relation type’ as Child record and click on ‘Create and open’. This open an ICSR submission record.
- Under the ‘Data forms’, select ‘Generate document from Template’. This opens ‘Document Link’ page.
- Under ‘Document Template’, select CIOMS template. Click on ‘Generate’.
- Click ‘Return’ to return to the submission record.
- When the CIOMS report is generated, a child record is created which is linked to the intake record.

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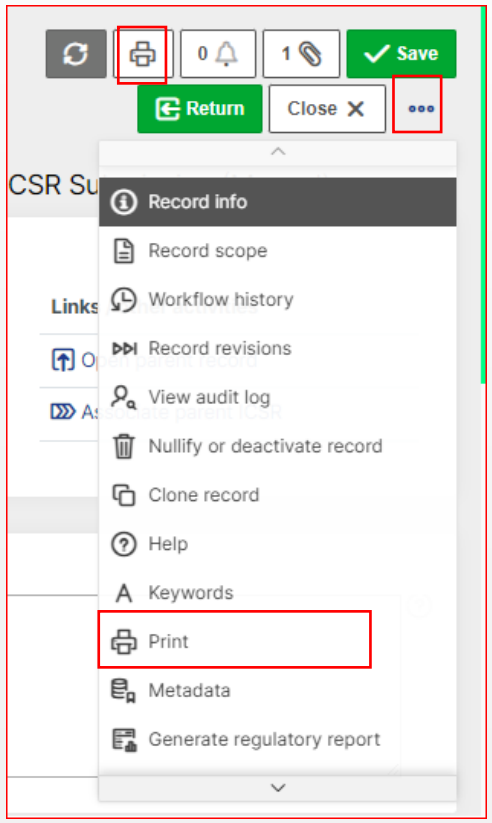
Getting to CIOMS Form



Print via submission record

Once a submission record is created and linked to a completed intake record:

- Click on the link to open the submission record from the intake record or navigate to ‘Submissions’ under processes and open the record.
- Select Print option from either the three-pin or print icon. This opens a Print Document page.
- To generate CIOMS, repeat the steps mentioned in the slides ‘Print Document Page – Template’ and ‘Print Document – Parameters’.

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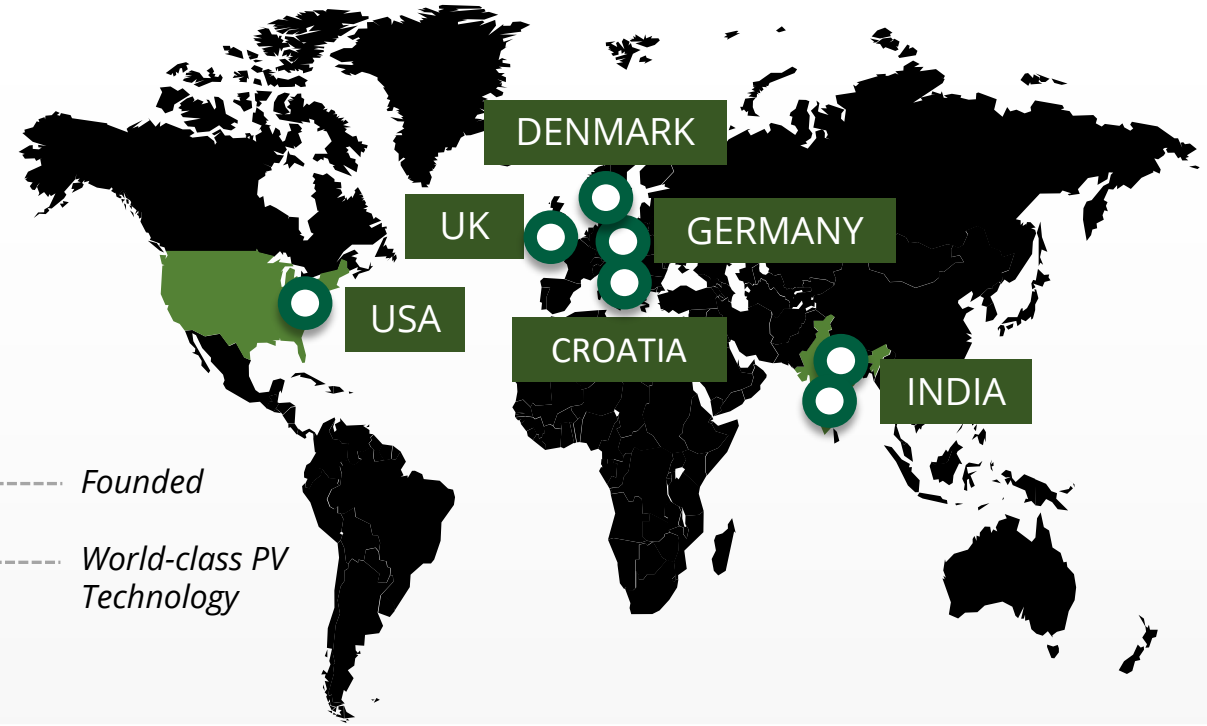
We are ISO 9001, ISO 27001, ISO 14001 and GDPR certified



2017 --------- *Founded*

2023 --------- *World-class PV Technology*

Who are using our technologies?

5
Tier-1 Pharma companies

2
Tier-1 Regulatory Agencies

20+
SME pharma /biotechs

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THE FUTURE IS GREEN

0%

carbon footprint on insife.cloud*

* all our hosting services are based on data centers that are operating entirely on sustainable energy and has been so since the beginning of 2022

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Thank you

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