

Insife
**How to run a
MedWatch Report**

Version 1.0, For HALOPV 5.0



About MedWatch

- MedWatch is a program by the FDA that allows health professionals and consumers to report serious problems that they believe may be associated with the medical products they use. These reports can help to identify safety concerns and improve the quality of the products.
- A **MedWatch Report** is a structured data published on MedWatch Form 3000A. The form contains information about the patient, the event or problem, the product availability, the suspect product, the suspect medical device, the other medical products, and the reporter.
 - You can learn more about MedWatch from this [website](#).
- HALOPV supports automatic generation of latest MedWatch Form 3000A.

Content

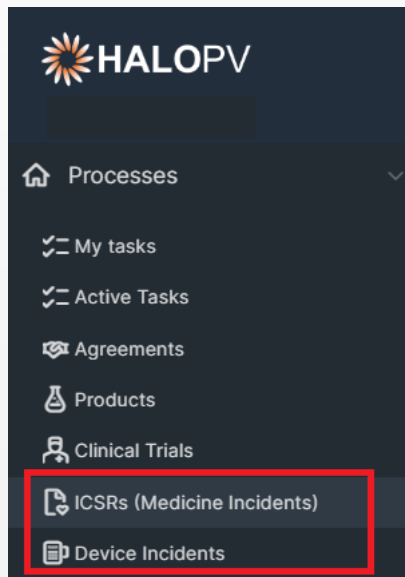
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Prerequisite

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

- How to enter an Incident - ICSR (Individual Case Safety Report)/ Device Incident using HALOPV.
- MedWatch Form 3000A needs to be configured at your HALOPV instance.
 - Please reach to HALOPV Support to configure this form at your instance.

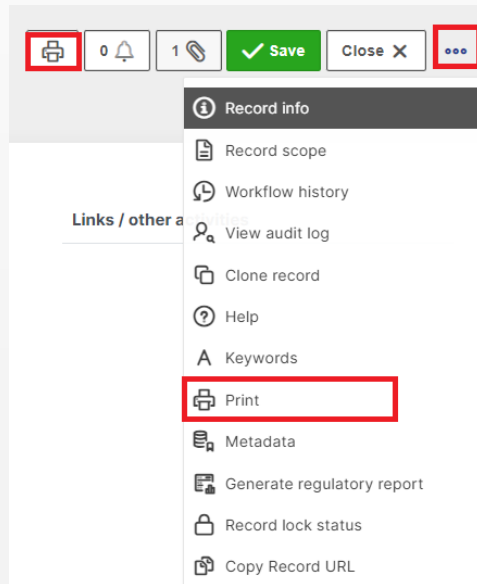
Getting to MedWatch Form



Incident Reporting

- On the left-hand side of the screen is a Deep Sea Blue Navigation Menu.
- On the navigation menu, under “Processes” parent menu there will be submenu’s -
 - ICSR (Medicines Incidents) – Used to report Medical Incidents related to Drugs/ Vaccines.
 - Device Incidents – Used to report Medical Incidents related to Devices.
- Click on the appropriate menu and select the workflow to proceed with incident reporting.

Getting to MedWatch Form



Incident Printing

After completing the Incident Reporting form you can generate the MedWatch Report form using below steps –

- Open the Incident Record by clicking on the respective link
- Click on Print Button –
 - As shown in the image, print Button is available at two locations on an incident form. You can use either of them.
- This will open HALOPV Print Document Page.

Getting to MedWatch Form

The screenshot shows a 'Print document' window with the following elements:

- Template:** A dropdown menu with 'FDA-3500A_medwatch_Sec' selected. Below it, a note says 'Leave blank to upload the generated document to the record'.
- Format:** A dropdown menu with 'WORD' selected.
- Interactive report (Optional):** A dropdown menu.
- Download locally?:** A checked checkbox.
- Buttons:** 'Generate' and 'Return' (with an external link icon).

Print Document Page

HALOPV Print Document page provides uniform interface to Print/ Generate various types of forms. You can follow the below steps to print MedWatch Form using this page -

- Click on “Template Dropdown” and Select the MedWatch Form (FDA-3000A medwatch_sec).
 - You can use the search functionality of the dropdown to filter the available list.
- Click on “Format” Dropdown and select the desired format.
- Use 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 go back to the record.
- Click on Close button to close the record.

Getting to MedWatch Form

Print document

Template Parameters to include

Selected parameters

EVENTDATE
REPORTDATE
NARRATIVE1
REPORTERCOMMENT
EVENTLIST
LABTEST
LABTEST2
REL HISTORY

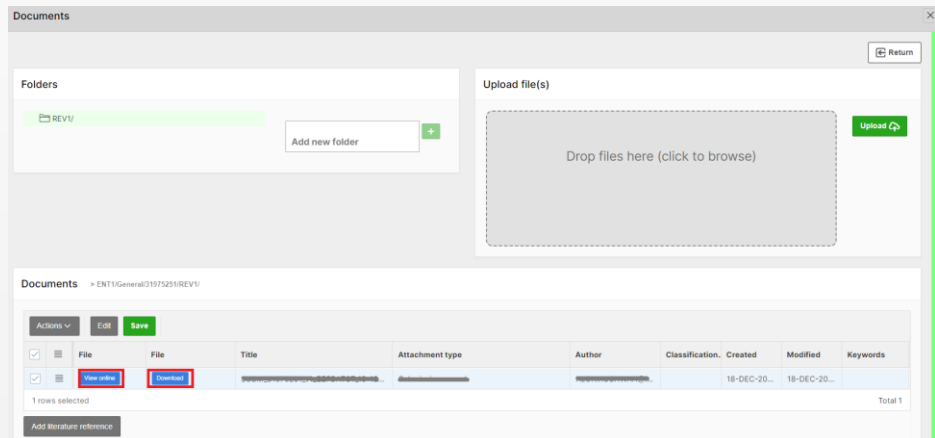
LABTESTDT

Template Parameters

HALOPV Print Document page provides uniform interface to Print/ Generate various types of forms. It also allows user to view/ select the parameters to be used while generating the form.


- You can use the “Parameters to Include” to include/ exclude certain parameters to include/ exclude printing of certain part of MedWatch 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” (Left list) will be used to generate the document.
 - Whereas the parameters in the Right list will be excluded while generating the document.

Getting to MedWatch Form



Accessing Uploaded Documents

HALOPV Print Document page provides uniform interface to Print/ Generate various types of forms. It also allows user either download the generated documents locally to their machine or upload the generated documents to HALOPV Cloud. You can follow the below steps to access the uploaded documents -

- All the uploaded documents are linked with their respective record -
 - Which means as a user you need to first open the record to view the documents.
- From the selected record click on attachment button 
- This will open “Document” Page, which will list all the uploaded documents of the record, identify the document you need to view/ download.
 - Use the View Online button to view the document.
 - Use the Download button to download the document to your machine.

NOTE : Describing other features of “Document” page is Out Of scope for this document.

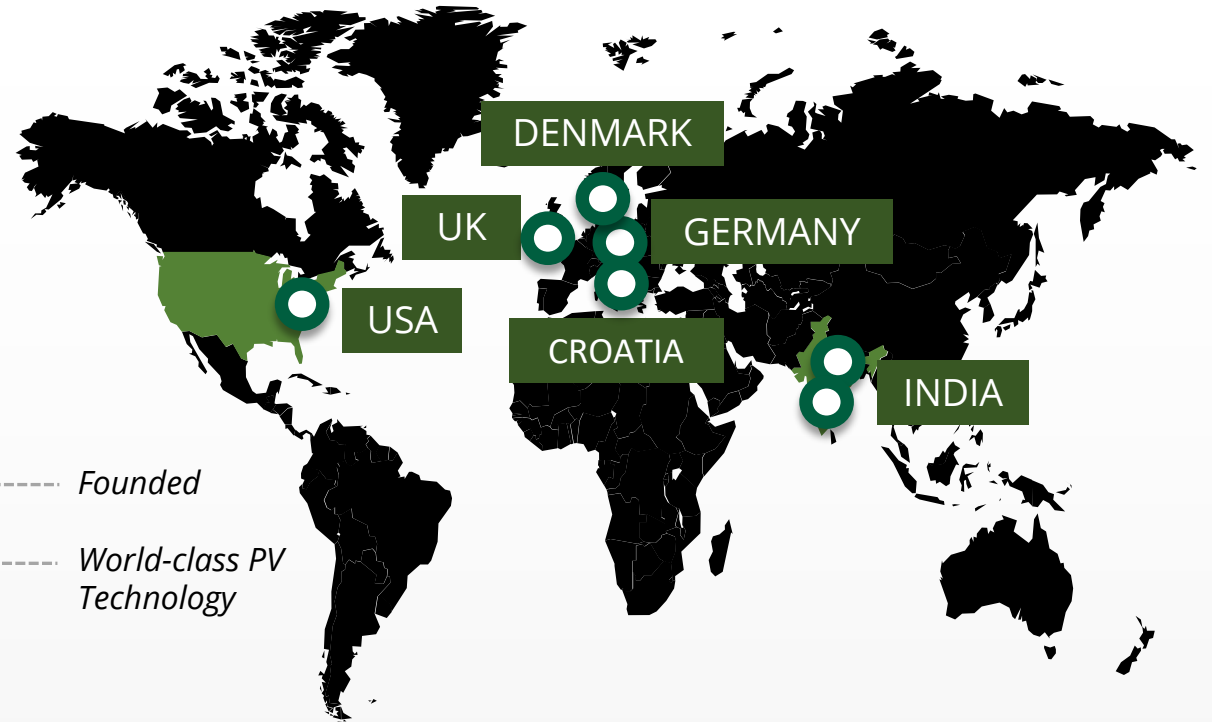
About Insife

Game-changing drug safety **technology** and consulting

Insife are supporting our clients with best-in-class technology and domain expertise from our global footprint

Insife consists of approx. 100 PV FTEs across the world, making us the biggest Europe-based company of its kind

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

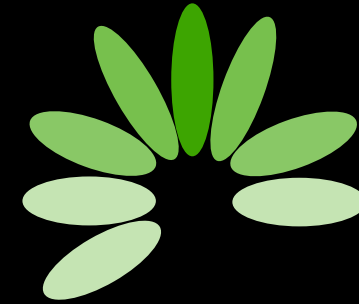


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Thank you



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