

Insife

How to import An E2B R3

Version 1.0, For HALOPV 5.0



Content

- › About E2B R3
- › Prerequisite
- › Import E2B R3 - Upload E2B File Workflow
- › Import E2B R3 – Enter Basic Information
- › Import E2B R3 – E2B Intake and Auto-code Workflow
- › Import E2B R3 – Manual Verification Workflow
- › About Insife

About E2B R3

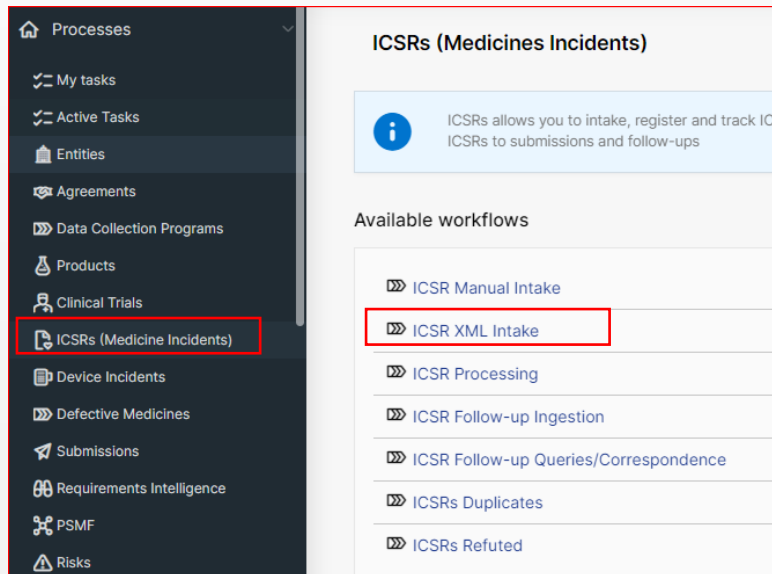
```
<?xml version="1.0" encoding="UTF-8" ?>
<ns1:INVESTIGATIONEVENT xmlns="urn:h17-org:v3" xmlns:fo="http://www.w3.org/1999/XSL/Format" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:mif="urn:h17-org:v3/mif"
  ITSVersion="XML_1_0" xsi:schemaLocation="urn:h17-org:v3 http://eudravigilance.ema.europa.eu/XSD/multicacheschemas/HCCI_IN2001000V01.xsd"
  <id root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <creationTime value="20240117133145+0100"/>
  <responseModeCode code="D"/>
  <interactionId root="2.16.840.1.113883.1.6" extension="HCCI_IN2001000V01"/>
  <name code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.1" codeSystemVersion="2.0"/>
  <PORR_IN049016UV/>
  <id extension="DK-ORX100003918-32492376" root="2.16.840.1.113883.3.989.2.1.3.11"/>
  <creationTime value="20240117133145+0100"/>
  <interactionId root="2.16.840.1.113883.1.6" extension="PORR_IN049016UV"/>
  <processingCode code="P"/>
  <processingModeCode code="T"/>
  <acceptAckCode code="AL"/>
  <receiver typeCode="RCV"/>
  <device classCode="DEV" determinerCode="INSTANCE"
    <id extension="ORX100003918" root="2.16.840.1.113883.3.989.2.1.3.12"/>
  </device>
  <sender typeCode="SND"/>
  <device classCode="DEV" determinerCode="INSTANCE"
    <id extension="ORX100003918" root="2.16.840.1.113883.3.989.2.1.3.11"/>
  </device>
  <sender/>
  <controlActProcess classCode="CACT" moodCode="EVN"/>
  <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
  <effectiveTime value="20240117133145+0100"/>
  <subject typeCode="SUBJ"/>
  <investigationEvent classCode="INVSIG" moodCode="EVN"/>
  <id root="2.16.840.1.113883.3.989.2.1.3.1" extension="DK-ORX100003918-32492376"/>
  <id root="2.16.840.1.113883.3.989.2.1.3.2" extension="DK-ORX100003918-32492376"/>
  <code code="PAT_ADV_EVENT" codeSystem="2.16.840.1.113883.5.4"/>
  <textTest Case/text>
  <statusCode code="active"/>
  <effectiveTime>
  <time value="20240117"/>
  </effectiveTime>
  <availabilityTime value="20240117"/>
  <component typeCode="COMP"/>
  <adverseEventAssessment classCode="INVSIG" moodCode="EVN"/>
</ns1:INVESTIGATIONEVENT>
```

- An **E2B** is an electronic transmission of adverse event information to stakeholders through the International Conference on Harmonisation (ICH) which is a crucial element in global drug safety and pharmacovigilance operations.
- The latest version of these requirements is **E2B R3**, which both the pharmaceutical industry and designated organizations facilitating safety information reporting must adhere to.

Prerequisite

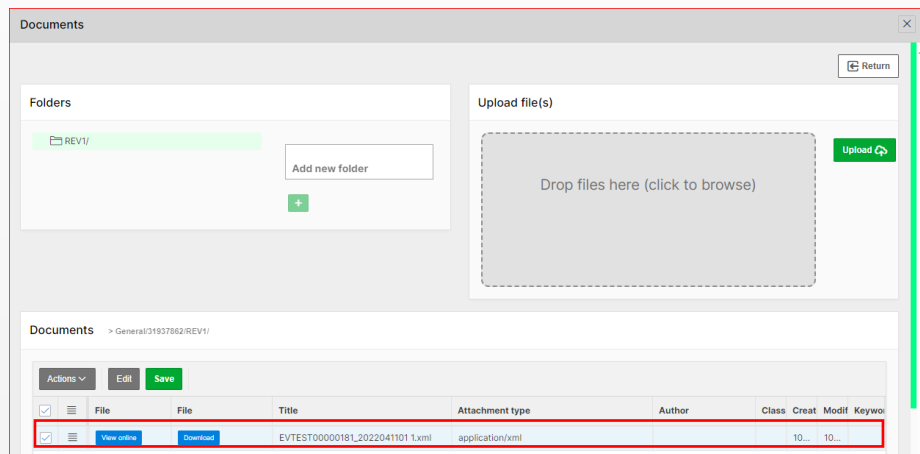
To be able to import an E2B R3 from HALOPV, you need to have access to:

- ICSRs (Medicine Incidents) module
- ICSR XML Intake Workflow



The screenshot displays the Insite application interface. On the left is a dark sidebar with a list of navigation items: Processes, My tasks, Active Tasks, Entities, Agreements, Data Collection Programs, Products, Clinical Trials, ICSRs (Medicine Incidents) (highlighted with a red box), Device Incidents, Defective Medicines, Submissions, Requirements Intelligence, PSMF, and Risks. The main content area is titled 'ICSRs (Medicine Incidents)' and contains an information box stating: 'ICSRs allows you to intake, register and track ICSRs to submissions and follow-ups'. Below this is a section titled 'Available workflows' with a list of options: ICSR Manual Intake, ICSR XML Intake (highlighted with a red box), ICSR Processing, ICSR Follow-up Ingestion, ICSR Follow-up Queries/Correspondence, ICSRs Duplicates, and ICSRs Refuted.

Upload E2B File Workflow



On the ICSR XML Intake record page:

- Click on 'Create New'. The system opens a View/edit record page.
- Click on the 'Attachment Icon'. The system opens the Document page.
- Drop the E2B R3 XML in the 'Upload file(s)' section. Click on Upload button.
- The files is uploaded into HALOPV and the record is created under Documents section (highlighted).
- The record currently is in 'Upload E2B File' workflow state.
- Click on Return. The system returns to View/edit record page.

Enter Basic Information

[Enter title] (ICSR_INX-31937840) - [Select type] (Revision 1) ICSR XML Intake

Basic information

Calculated due date for this task Due date for completion of workflow
 Set manually

On the View/edit record page:

- Click on the title of the record, it will open the Basic information page. This page allows users to provide a Title and the Type of the record along with Task due date and priority of the record.

E2B Intake and Auto-code Workflow

On the View/edit record page:

- Click on Save.
- Click on Complete Task. The E2B Automator shall verify the E2B file for errors.
- The record is then automatically pushed through the E2B Intake and Auto-code Workflow states into Manual Validation. The system populates information from the file into various fields within the ICSR form.
- The system displays various validation errors on each of the tab of the ICSR form.

View/edit record

Upload E2B file → E2B Intake → Auto-code → **Manual Validation** → Duplicate search → Transfer record

Pending actions

Send back task

SANCHITA.KHANDURI@INSIFE.COM

1 Save

Close X

ICSR Sample 1 (ICSR_INX-31937840) - Spontaneous Report (Revision 1) ICSR XML Intake

Task instructions
Click on the data forms to manually complete the validation warnings that were not captured in E2B Intake.

Task activities (red status means mandatory)

Data forms	Status	Links / other activities
Sender(s) and Case Info	1	
Reporter(s)	1	
Patient / Parent	1	
Drug(s)	1	
Event(s)	1	
Drug(s)-reaction(s) / Event(s) Matrix	0	
Narrative / Summary	0	
Event listedness and datasheets	0	

About

Priority: Set priority

Role to process task: ICSR Case Processing

Assigned user: Assign user | Assign to me | Auto-assign

Tags

Non-Serious ICSR

Manual Validation Workflow

On the View/edit record page:

- The user can investigate each validation error message.
- Once the validation messages are resolved, Click on Complete task to push the record through workflow states Duplicate Search and Transfer Record into Process ICSR information.
- The user can process the record through submission.

View/edit record

Process ICSR Information → Quality Control → Medical Review → Submission

Complete task

ICSR Sample 1 - Spontaneous Report (Revision 1) ICSR Processing

Task instructions
Assessment of essential ICSR information following ICSR Intake. Use the link to the case forms to add/assess data to be entered in the case.

About
Priority: Set priority
Role to process task: ICSR Case Processing
Assigned user: Assign user | Assign to me | Auto-assign
Task due: 12-JAN-2024
Tags

Task activities (red status means mandatory)

Data forms	Status
Sender(s) and Case info	●
Reporter(s)	●
Patient / Parent	●
Drug(s)	●
Event(s)	●
Drug(s)-reaction(s) / Event(s) Matrix	●
Narrative / Summary	●
Event listedness and datasheets	●
Event Adjudication	●

Links / other activities

- Create Submission (manual) record
- Task relocation (Refuted ICSR)

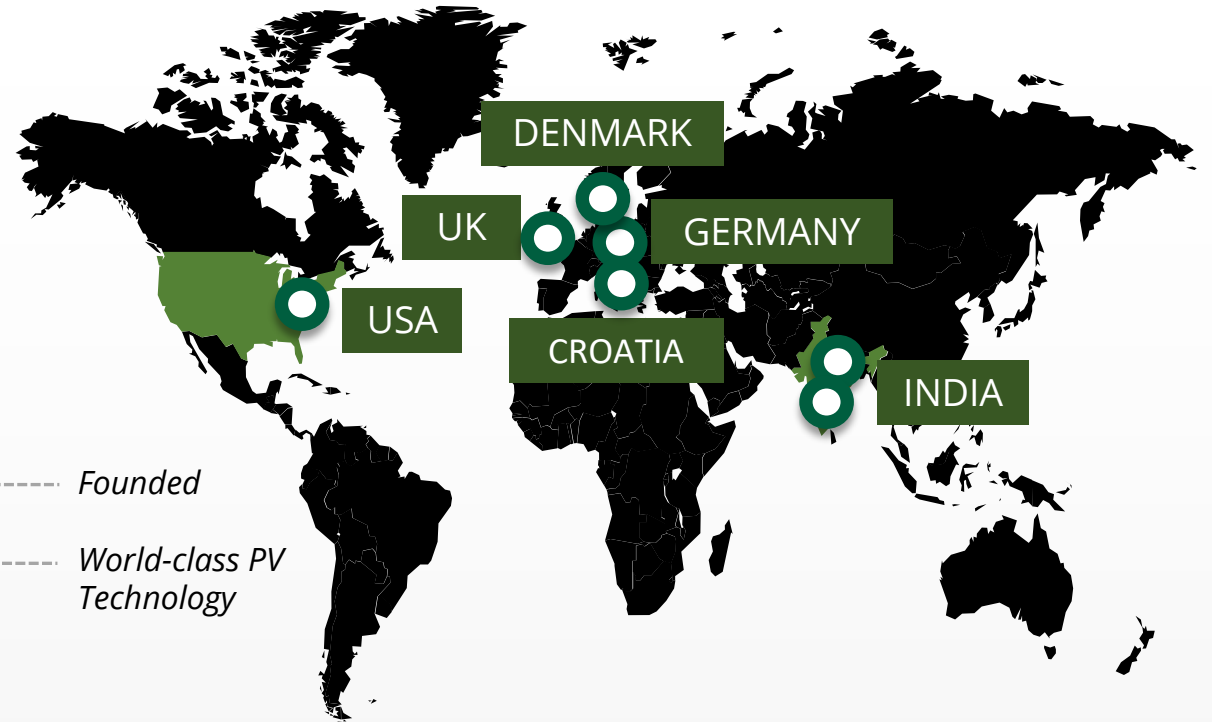
About Insife

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

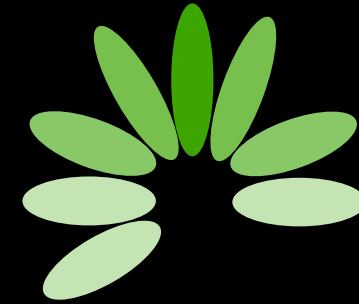


0%
**carbon footprint on
insife.cloud***

* 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



Thank you



Game-changing drug safety
technology and consulting

Headquarters

Insife ApS
Copenhagen
Denmark

North America

Insife Inc.
Jersey City
USA

Germany

Insife Germany GmbH
Cologne
Germany

Asia

Insife India Private Ltd.
Noida / Bangalore
India

Croatia

Insife d.o.o
Zagreb
Croatia

United Kingdom

Insife UK Ltd.
Milton Keynes
United Kingdom

Contact us at hello@insife.com