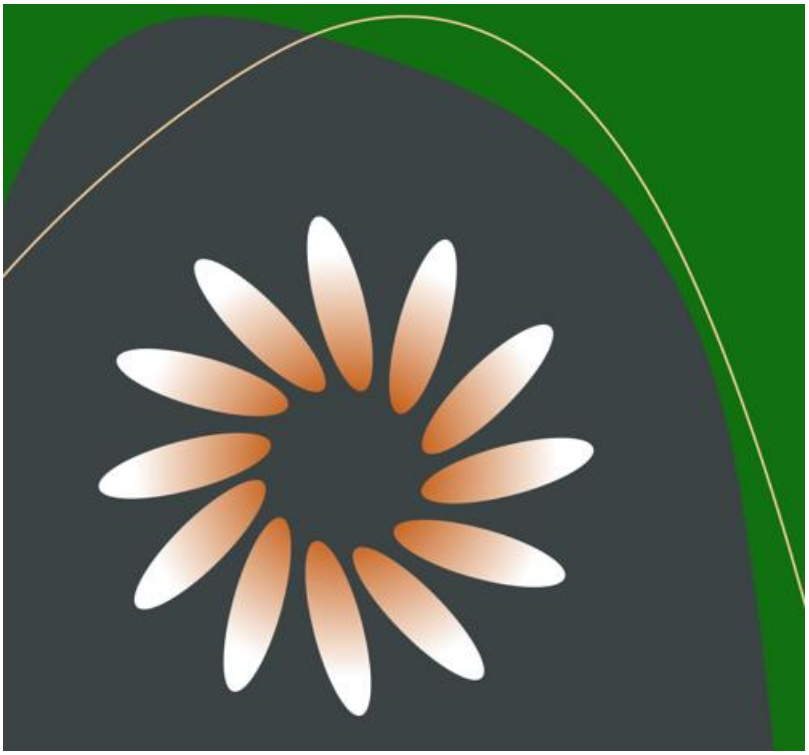
HALOPV PROHALO

Requirements Intelligence Module



HALOPV / PROHALO 4.X USER MANUAL

This is an end-user manual for the Requirements Intelligence module of the drug safety solution HALOPV / PROHALO.

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1. HALOPV / PROHALO Requirements Intelligence Module User Manual

User Manual - Release 4.X (4.2 released March 2023)

2. Preface

The latest product information, including release notes for HALOPV and multi-tenant HALOPV (branded as PROHALO) is available at

https://www.halopv.com or

https://insife.com/halopv

2.1. Insife Support

The Insife Support team can be reached at support@insife.com 24/7, depending on the agreed terms. Furthermore, the Insife Support team handles upgrades related to Modules that require MedDRA codes, EDQM codes, WHO Drug dictionary, etc.

3. Introduction

3.1. Purpose of this document

This User Manual describes the Requirements Intelligence module features of HALOPV. It is intended as a module guide, which should be considered in relation to one of general manuals. You will find a manual for each Module separately at https://insife.com/halopv-user-guides-tutorials.

The overall guide for using general features is available online on General features (insife.com)

3.2. Modules of HALOPV

At the time of writing of this manual, the modules comprise of:

- Aggregate Reporting
- Agreement
- Clinical Trials
- Complaints
- Data Collection Programs
- Device Incidents Processing
- Entities
- ICSRs (Medicines and Vaccines Incidents)
- Labelling
- Literature Monitoring
- Medical Information and Communications
- Pharmacovigilance System Master File (PSMF)
- Products
- Quality
- Requirements Intelligence
- Risks
- Signals
- Submissions
- Training

Besides the modules, you will also find a separate manual for application administration and user administration in Admin Guide (insife.com)

3.3. About HALOPV (incl. PROHALO)

HALOPV is a cloud-based system. Internet connectivity is required, but you can use your computer, tablet, or smartphone to access the system. Your organization should have provided you with the correct link to access your instance of HALOPV.

4. Navigating the Requirements Intelligence module

Once you log into HALOPV with your user credentials, on the left Menu, you will find the list of Modules to which your user has access. To review HALOPV access and general features, please refer to our **General Features User Manual** and **User Guide Introduction and Main Features.**

The **Requirements Intelligence module** will appear if your user profile has access to the Module.

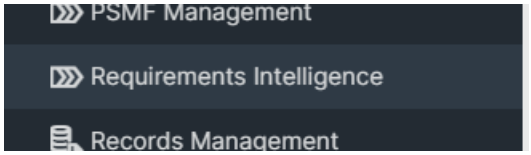

Figure 1 Left menu, Requirements Intelligence is available for users with the appropriate access role

4.1. Module Main Screen

The main screen for the Module lists all available *workflows* as well as *functionalities* (if any, per default the **"Whom and When report"** is available)

It is important to note that the workflows may be configured to local requirements in your HALOPV setup. Hence the workflows may look different from the standards, and some workflows and menus might not be available to the user view.

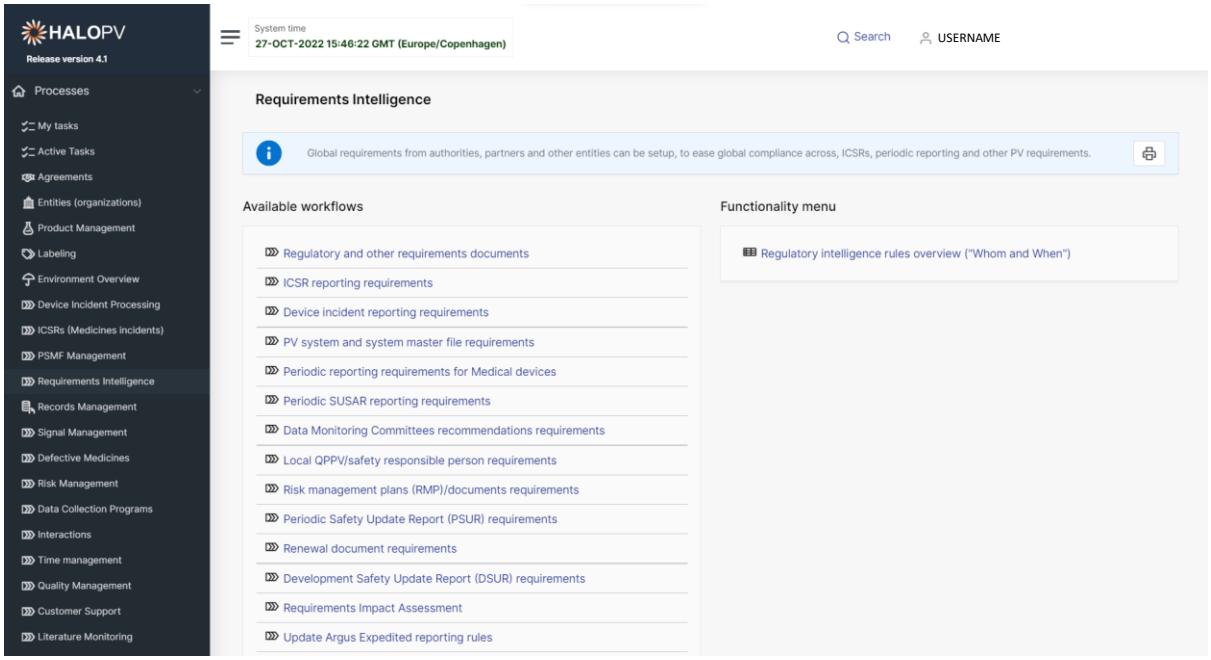

Figure 2 The standard list of Workflows and Functionality Menu items for the Requirements Intelligence Module

Simply click on a workflow or functionality to access it.

4.2. User roles relevant to the Requirements Intelligence module

Users must be assigned roles to access the relevant modules. Furthermore, user roles can allow access or editing rights for a record in a specific workflow task step. Please consult the table below for standard user roles provided by the system. Your administrator may have configured other user roles. For a description on how to administer users and user roles, please refer to the Admin Guide (insife.com)

User role	Description
Requirements Intelligence module	Provides access to the Requirements Intelligence module in the navigation.
Requirements Intelligence processing	Main processing role for the Module. The role can create records and assign a due date.
Requirements Intelligence reviewer	Users with this role can review the information/data available in the relevant workflow step.
Requirements Intelligence approval	Users with this role approve the information/data available in the relevant workflow step.

Table 1 User roles for the Requirements Intelligence module

4.3. Standard Workflows

The Module comes pre-configured with several standard workflows. These are described in the following sections, including tasks and associated actions.

You can access a record worklist by clicking on one of the available workflows: **E.g., Regulatory and other requirements documents Records**. The view will display the record(s) created in the process workflow.

The Records worklist may have different columns, depending on the selected workflow. However, the principle is the same for all workflows. You will have a ***Record ID, Title of the record, the Type, Current task, Overall Due date*** *(the date the task is due to comply with set timelines),* etc.

It is important to note that the workflows may be configured to local requirements in your HALOPV / PROHALO setup; hence the workflows may look different to the standards.

Clicking on a workflow takes you to the worklist of the workflow, with all the records in the workflow at the current time. See also Figure 2 The standard list of Workflows and Functionality Menu items for the Requirements Intelligence .

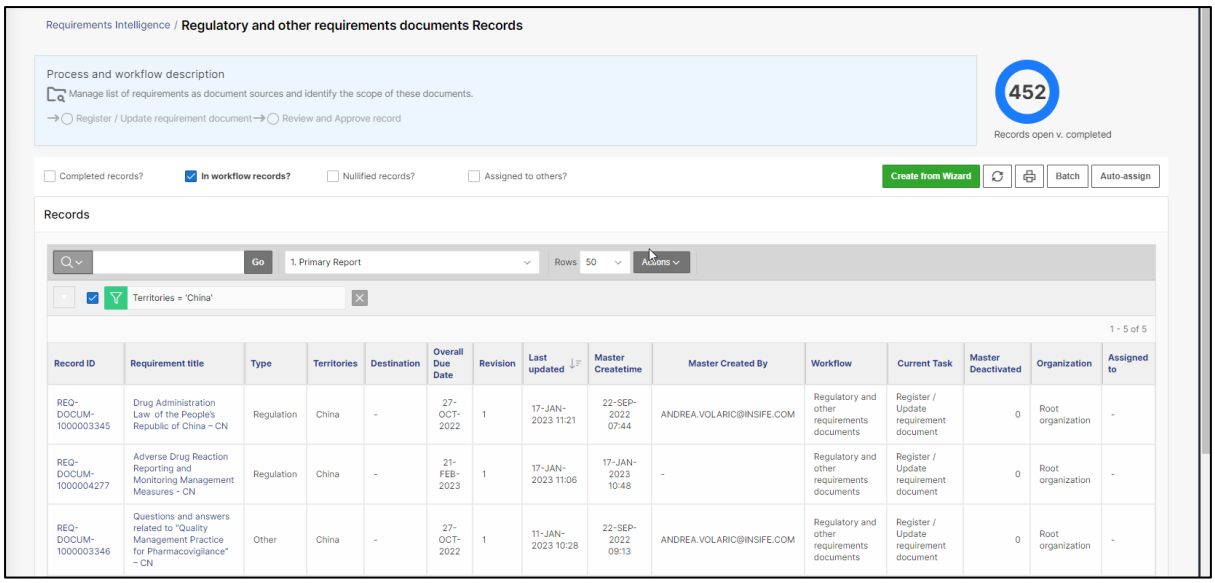

Figure 3 When clicking on a workflow, the following screen displays the Process workflow description, current tasks (if configured,) and a worklist of records, where the Record ID or Title/Identifier can be clicked to access the individual record.

End users can update reports using the **Actions** button**.** Please consult the User Guide on Interactive Reports.

Please note that access to Records is restricted to the user role assigned to you, e.g., 'You have read-only access to the current workflow' means that the user cannot create or nullify a record but can execute the task(s) assigned within the record if the role has been assigned.

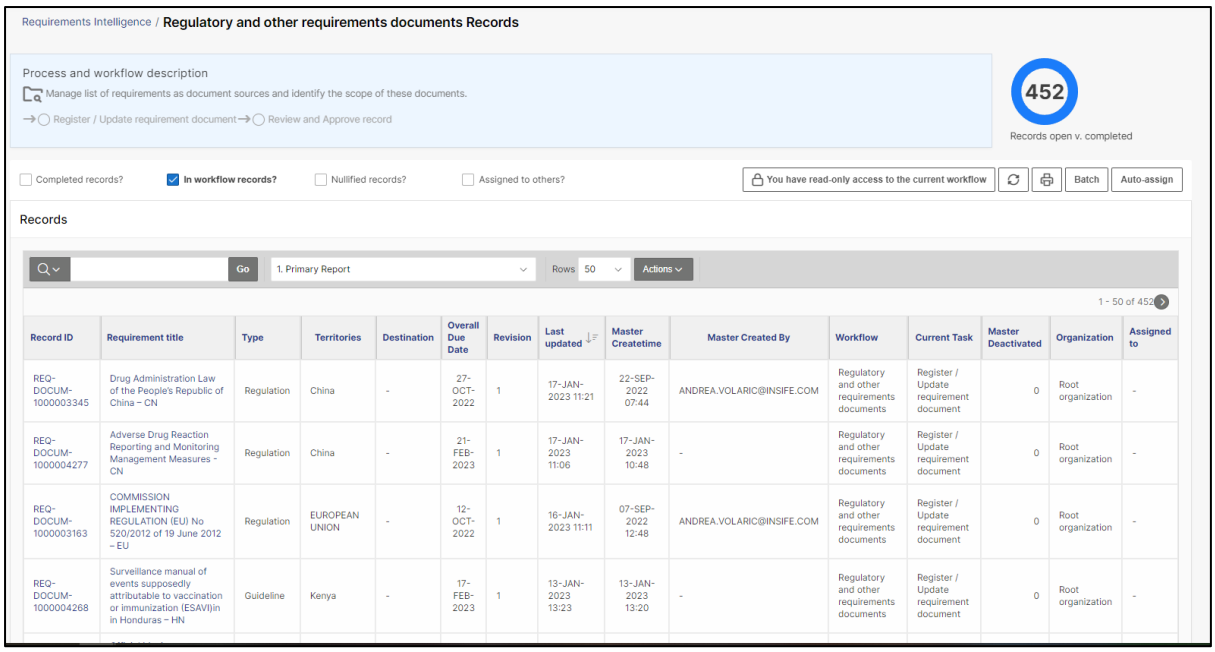

Figure 4 The screen displays the user's restriction to create new records.

4.4. Workflows Structure

Clicking on the **"Record ID"** or **"Title/Identifier"** takes you to the individual record, as shown below.

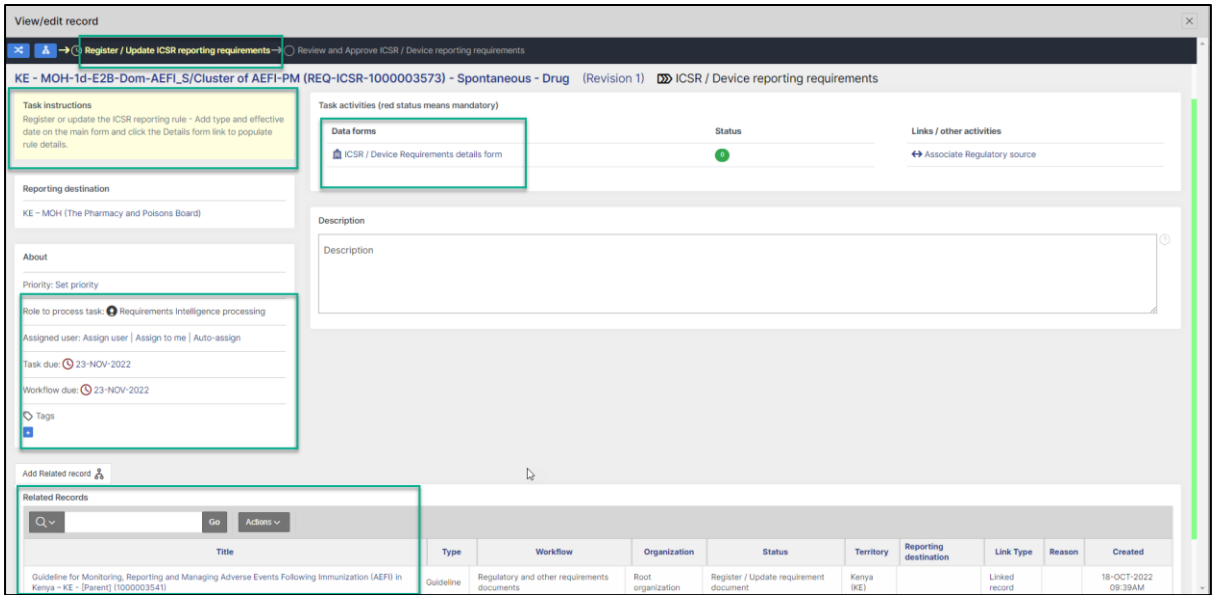

Figure 5 The screen displays an example of a user with the role of accessing the first step.

A Workflow shows a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.

When a user has a record open, no other user can perform activities in the record. The record will be in a locked state.

The **Task instructions** are shown in the application on the left side of the screen, highlighted in yellow. Follow the task instruction for further information about the step.

The **About section** shows the role requires to access the step, the due task date, and the overall due date of the workflow.

The record view also displays the current user in the step. This means no other user can perform any task in the current step.

The **Task activities** and **Link/other activities** sections contain all required tasks buttons to execute in the step.

The top part of the view shows a link to the parent record **'Regulatory and other requirements documents'**. The current process step is highlighted in bold.

A workflow step may have task actions. The status is marked with colors:

- **Green mark:** the task is not mandatory.
- **Red mark:** the task action is mandatory, and the task cannot be completed before it is done.
- **Pending actions:** the task has activated validation rule(s). This is usually linked to a mandatory task (red mark) that requires your attention.

If an existing record should be moved to a further step, **e.g.,** from **Register / Update ICSR reporting requirements** to **Review and Approve ICSR / Device reporting requirements**, the user can use the *change*

Workflow  standard functionality located on the left corner of the record view. This applies to workflows that have more steps.

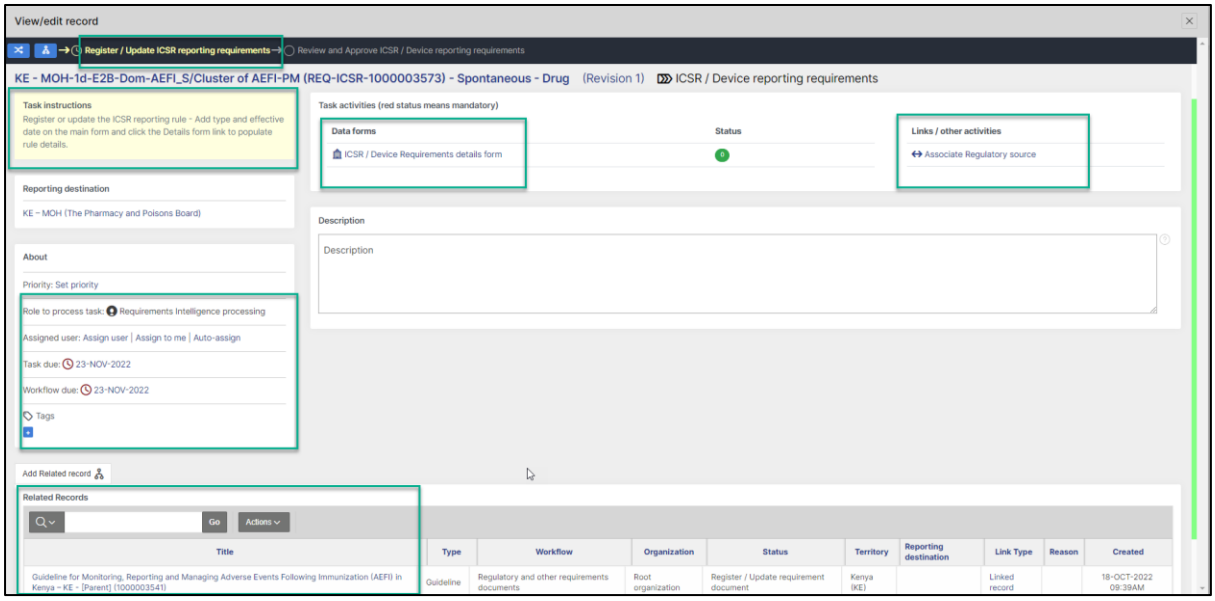

Figure 6: Example of a workflow with two steps

To link a child record or create a linked record; First click "**Associate Regulatory source"** in the **Links/other activities** section *(see figure above).* Then click on the **Document process scope** and select the relevant process from the dropdown list. On **Selected record,** choose the relevant record.
In the 'Linked details' section, select the **Type of link** and press 'Save link'.
Once the linked record is saved, it will be displayed in the **Related Records** section (*see figure above)*.

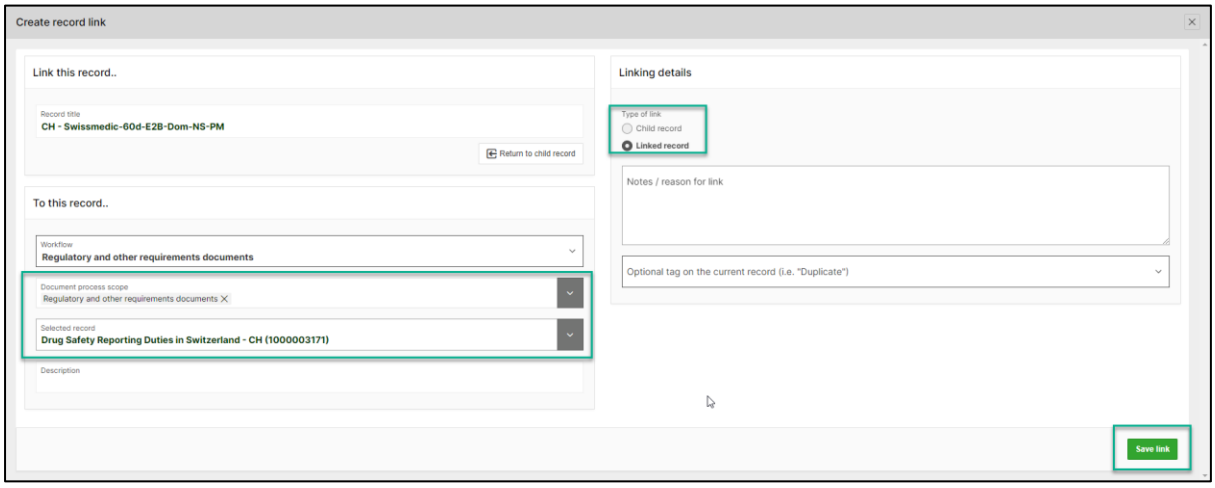

Figure 7: Example of how to link a record

The Related Records section will display linked, parent, or child records. It is possible to remove the link by clicking Linked record. A new box opens, and the user press the "**Remove link."**

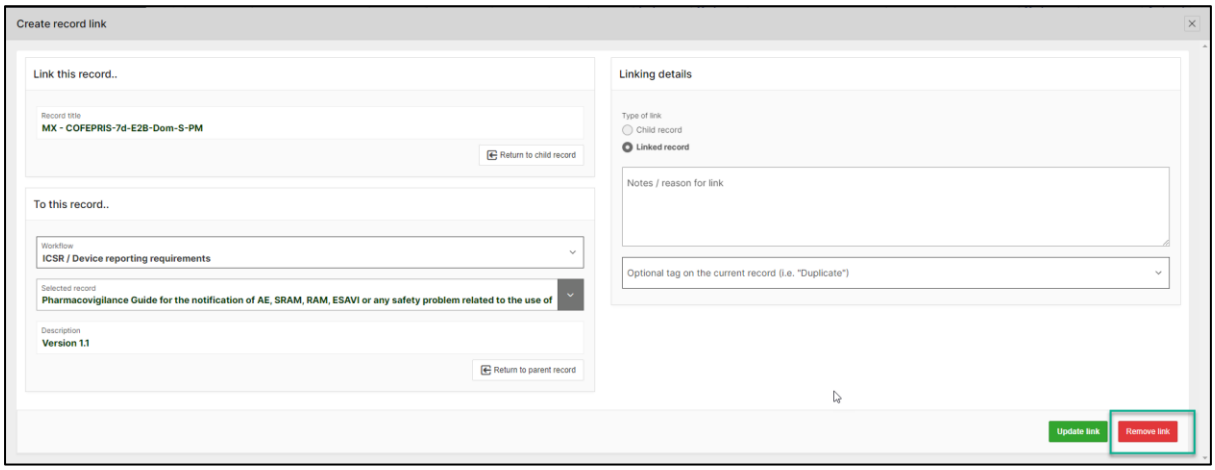

Figure 8: Example of how to remove a linked record

4.5. Regulatory and other requirements documents workflow

Register / update requirements document → Review and approve record

The purpose of the workflow is to manage the list of requirements as records with document sources and identify the scope of these documents.

The workflow consists of two task steps:

- *Register / update requirement document (4.5.1)*
- *Review and approve record 4.5.2)*

The following sections will explain the tasks in further detail:

4.5.1. Register / update requirement document task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Register or update a requirement document such as legislation or guideline from a regulatory source.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains two actions:

Data form action	Description
Regulatory documents form	This form allows for capturing information about the regulatory document, including its Source URL, Territory (country),

	Effective date, Published date, Requirement in text, and Implementation notes. Click the action to open the form. Please see the Form reference section (**Error! Bookmark not defined.**) for details about the form elements.
Links / Other activities	Description
Associate Regulatory Source	This action allows associating the impact assessment record with a parent document in the **Regulatory and other requirements documents form**. This is important in order to be able to trace back the impact assessment record to the document that is causing the impact. Click the action to open the linking window, select a record by clicking **Select recor**d, choose **Child record** as the Type of link and finally, click the **Save link** button to complete the action.

4.5.2. Review and approve record task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Review and approve the provided requirements documents information. Once the Task Activities are completed, please click on the Complete Task button to finalize the registration.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains one action:

Data form action	Description
Regulatory documents form	This form allows for capturing information about the regulatory document, including its Source URL, Territory (country), Effective date, Published date, Requirement in text and Implementation notes. Click the action to open the form. Please see the Form reference section (**Error! Bookmark not defined.**) for details about the form elements.

4.6. ICSR / Device reporting requirements workflow

The purpose of the workflow is to maintain a list of reporting requirements of ICSRs and Devices and their rules to third parties.

The workflow consists of two task steps:

- *Register / update ICSR/Device reporting requirements (4.6.1)*
- *Review and Approve ICSR/Device reporting requirements (4.6.2)*

The following sections will explain the tasks in further detail:

4.6.1. Register / update ICSR/Device reporting requirements task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Register or update the ICSR/Device reporting rule - Add type and due date on the main form and click the Details form link to populate rule details.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains two actions:

Data form action	Description
ICSR / Device Requirements details form	This form allows for capturing information about the ICSR/Device reporting requirement or a combination of both (for drug-device combination product rules) – *please note that you must choose a Combination product record type to enable both drug and device tabs for editing*. It includes tabs for different sections: **Reporting criteria**, **Drug specific criteria**, **Device specific criteria**, **Time, format and content**, **Territories**, **Implementation details**. Click the action to open the form. Please see the Form reference section (6.2) for details about the form elements.
Links / Other activities	Description
Associate Regulatory Source	This action allows for associating the impact assessment record to a parent document in the **Regulatory and other requirements documents form**. This is important in order to be able to trace back the impact assessment record to the document that is causing the impact. Click the action to open the linking window, select a record by clicking **Select recor**d, choose **Child record** as the Type of link and finally click the **Save link** button to complete the action.

4.6.2. Review and Approve ICSR/Device reporting requirements task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Review and approve the provided requirements form information. Once the Task Activities are completed, please click on the Complete Task button to finalize the registration.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains one action:

Data form action	Description
ICSR / Device Requirements details form	This form allows for capturing information about the ICSR/Device reporting requirement or a combination of both (for drug-device combination product rules) – *please note that you must choose a Combination product record type to enable both drug and device tabs for editing*. It includes tabs for different sections: **Reporting criteria**, **Drug specific criteria**, **Device specific criteria**, **Time, format and content**, **Territories**, **Implementation details**. Click the action to open the form. Please see the Form reference section (6.2) for details about the form elements.

4.7. PV system and System Master File Requirements workflow

The purpose of the workflow is to maintain an overview of relevant documents needed at each territory to fulfill PSMF, and local responsible person.

The workflow consists of two task steps:

- *Register PV system and System Master File requirements (4.7.1)*
- *Review and Approve PV system and System Master File requirements (4.7.2)*

The following sections will explain the tasks in further detail:

4.7.1. Register PV system and System Master File requirements task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Requirements for PV system and system master file are captured in the form. Please click on the Complete Task button to progress the registration to the next task step.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains two actions:

Data form action	Description
PV Systems / PSMF details form	This form allows for capturing information about any PV System requirements and/or PSMF requirements in a territory It includes tabs for different sections: **PV System / PSMF**, **Implementation details**. Click the action to open the form. Please see the Form reference section (6.3) for details about the form elements.
Links / Other activities	**Description**
Associate Regulatory Source	This action allows for associating the impact assessment record to a parent document in the **Regulatory and other requirements documents form**. This is important in order to be able to trace back the impact assessment record to the document that is causing the impact. Click the action to open the linking window, select a record by clicking **Select recor**d, choose **Child record** as the Type of link and finally click the **Save link** button to complete the action.

4.7.2. Review and Approve PV system and System Master File requirements task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Review and approve the provided requirements information. Once the Task Activities are completed, please click on the Complete Task button to finalize the registration.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains one action:

Data form action	Description
PV Systems / PSMF details form	This form allows for capturing information about any PV System requirements and/or PSMF requirements in a territory It includes tabs for different sections: **PV System / PSMF**, **Implementation details**. Click the action to open the form. Please see the Form reference section (6.3) for details about the form elements.

4.8. Requirements Impact Assessment workflow

The purpose of the workflow is to Investigate and document the potential impact of changes in requirements.

The workflow consists of four task steps:

- *Analyze Impact (4.8.1)*
- *QC/Review Impact Assessment (4.8.2)*
- *Prioritize implementation / schedule (4.8.3)*
- *Conclude Impact Analysis - actions implemented / handled (4.8.4)*

The following sections will explain the tasks in further detail:

4.8.1. Analyse Impact task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

The impact of the changed or new requirement or requirement document is analyzed. Supporting documentation can be uploaded as attachments. Please click on the Complete Task button to progress the registration to the next task step.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains one action:

Links / Other activities	Description
Associate Regulatory Source	This action allows for associating the impact assessment record to a parent document in the **Regulatory and other requirements documents form**. This is important in order to be able to trace back the impact assessment record to the document that is causing the impact. Click the action to open the linking window, select a record by clicking **Select recor**d, choose **Child record** as the Type of link and finally click the **Save link** button to complete the action.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

4.8.2. QC/Review Impact Assessment task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Perform Quality control / Review the impact assessment as entered in the record or it's attachments. Once the Task Activities are completed, please click on the Complete Task button to progress the registration to the next task step.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains no additional actions.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

4.8.3. Once task actions are completed, click on Complete task. And remember to click on Close X; otherwise, the user role in the next step will not be able to perform any actions. Prioritize implementation / schedule task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Consider the prioritization and schedule of the impacted element(s) of the PV system, as entered in the record or it's attachments. Once the Task Activities are completed, please click on the Complete Task button to progress the registration to the next task step.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains no additional actions.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

4.8.4. Once task actions are completed, click on Complete task. And remember to click on Close X; otherwise, the user role in the next step will not be able to perform any actions. Conclude Impact Analysis - actions implemented / handled task step

The task step instructions are shown in the application on the left side of the screen in yellow highlight. Please follow the task instruction for further information about the step.

Task instructions (as shown in the application):

Conclude on the impact analysis, it's prioritization and schedule of the impacted element(s) of the PV system and if relevant add notes and attachments to support the conclusion(s). Once the Task Activities are completed, please click on the Complete Task button to finalize the registration.

As with any other task in the application, you must have the corresponding role assigned in order to be able to process the record in the task step. The first task step contains no additional actions.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

5. Functionalities

The functionalities of the Module are found on the module main screen (see also 4.1). The following section(s) list the available functionalities and describe their use. Typically, the functionalities add value to the Module by providing dashboarding, reporting or associated features.

5.1. Whom and when report

The **Whom and when report** is allowing users to search out a list of relevant ICSR requirements by filling in ICSR case filters. The requirements that would match the case by the filtered attributes will show up in the **Matching expedited reporting rules** interactive report in the bottom part of the screen, see Figure 9: Whom and when report. The filter options are further described in section 18.

After filling in the desired filters, simply click the Search button to see the resulting list.

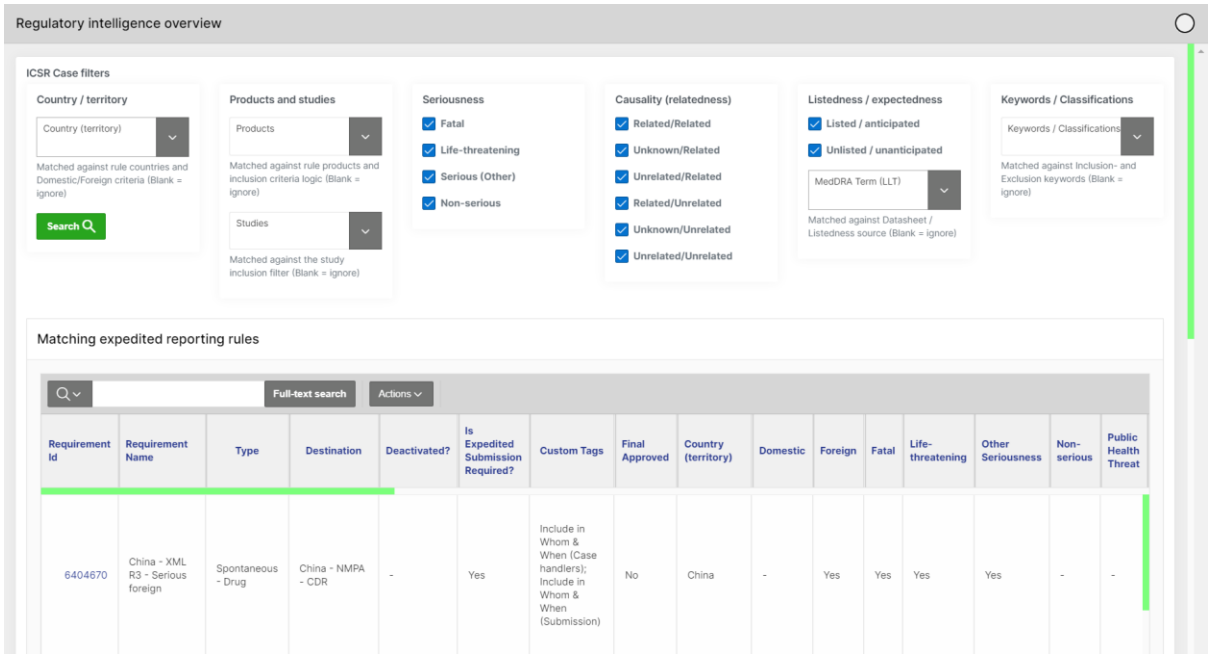

Figure 9: Whom and when report

For further instructions on how to work with the **Matching expedited reporting rules** result list, please consult the separate Guide - Interactive Reports.

5.1.1. Whom and When report filters

The report filters are as follows:

Filter	Description
Country / territory	Select a territory in the filter. Only rules with this territory (if domestic rule) or foreign to the territory (if foreign rule) will be matched. It can be left blank, which will ignore the filter.
Products	Select one or more products to be matched with the products configured in a specific rule. It can be left blank, which will ignore the filter.
Studies	Select one or more studies to match the studies configured in a specific rule. Can be left blank, which will ignore the filter.
Seriousness	Select one or more seriousness criteria to match the seriousness criteria configured in a specific rule. Note that this must be filled in to get a match
Causality	Select one or more causality/relatedness criteria to match the seriousness criteria configured in a specific rule. Note that this must be filled in to get a match
Listedness	Select one or more listedness / expectedness criteria to match the listedness criteria configured in a specific rule. Note that this must be filled in to get a match Furthermore, a specific MedDRA term can be added to be matched against a configured datasheet (SmPC). It can be left blank, which will ignore this part of the filter.
Keywords	Select one or more keywords / classifications criteria to match the keyword criteria configured. It can be left blank, which will ignore this part of the filter.

6. Forms reference

This section explains data elements for the various forms in use for the Module as a reference.

6.1. Regulatory and other requirements documents form

6.1.1. Requirement verbatim and notes tab

Requirement verbatim and notes tab		
Requirement verbatim and notes	Territory (country) Add country	Dropdown list of all available countries configured in the system. It's possible to do a multiple select e.g. Viet Nam, Malaysia etc.
Requirement verbatim and notes	Requirement text in original language	Free text box
Requirement verbatim and notes	Requirement text in English	Free text box
Requirement verbatim and notes	Notes	Free text box
Requirement verbatim and notes	URL of source	Free text box
Requirement verbatim and notes	Effective date	Date Picker
Requirement verbatim and notes	Published date	Date Picker
Requirement verbatim and notes	Document process scope	Shuttle

6.1.2. Implementation details tab

This form captures internal information about Implementation, Agreements e.g., between affiliate and HQ, and links to QMS Documents in implementation scope.

Implementation details tab		
Implementation details	Implemented	Tick box:
Implementation details	Agreements between affiliate and HQ	Free text box
Implementation details	QMS Documents in implementation scope	Shuttle

6.2. ICSR / Device reporting requirements form

The ICSR / Device requirement details form consists of 5 or 6 tabs depending on the type of reporting rule.
Type is a selectable dropdown list:

- Post-marketing – Device
- Solicited – Drug
- Spontaneous - Drug
- Clinical – Drug
- Drug – Device combination
- Clinical – Device

Type selected defines which tabs in the form are visible.
** Type = "Drug" populates the Drug specific criteria tab*
** Type = "Device" populates the Device specific criteria tab*
**Type = "Drug - Device" populates both the Drug and Device tab*

6.2.1. Reporting criteria tab

Reporting criteria tab		
Basic Info	Is submission of expedited reports required?	Yes No
Basic Info	Destination	Selectable dropdown list of all configured Entities which is a sender/receiver of E2B reports
Domestic / Foreign	Include Domestic cases	Against the selected territory(ies)
Domestic / Foreign	Include Foreign cases	Against the selected territory(ies)
Domestic / Foreign	Only Inside EEA?	Populated if Foreign is ticked
Domestic / Foreign	Only outside EEA?	Populated if Foreign is ticked
Initial / Follow-up?	Initial	Initial report
Initial / Follow-up?	Follow-up	Follow-up report
Causality (Relatedness)	Causality as reported by reporter / Causality as determined by Company	Values to select: Unrelated/Unrelated Unknown/Related Unknown/Unrelated Related/Unrelated Unrelated/Related Related/Related
Causality (Relatedness)	Exclude Unknown/unrelated reports from study source	Exclusion of Unknown/Unrelated cases from study sources i.e., solicited cases

Case Type	Schedule if destination is the same as the original sender or authority?	This tick box should be ticked if an ICSR should be reported back to the Sender/Authority
Case Type	Include non-valid cases?	This tick box should be ticked if the rule should include Non-valid ICSRs
Case Type	Select the TAG (keyword) which defines a case as non-valid	To be selected if "Include non-valid cases" is ticked Predefined dropdown list
Case Type	Only schedule if the following tag (keyword) is present *Tags - or keywords - can be added to records in order to do classification of the contents, e.g., black triangle or AESI*	Predefined dropdown list
Case Type	Do not schedule if the following tag (keyword) is present *Tags - or keywords - can be added to records in order to do classification of the contents, e.g., black triangle or AESI*	Predefined dropdown list
Product Criteria	License matching logic	Default (match rule country on license country)
Product Criteria	License matching logic	Schedule on licenses with same ingredient
Product Criteria	License matching logic *Per default HALO auto-schedules submissions for countries with a license for the suspect products in the ICSR. If this box is ticked, HALO will also consider other products if they share same ingredient list as the suspect product.*	Ignore licenses (do not check if a license is present in the rule country)
Product Criteria	Include/Exclude specific products	List values: Ignore Do NOT schedule on the select product(s) Only schedule on the select product(s)
Product Criteria	Families (Groups)	Select list from the configured Product Families
Product Criteria	Products	Select list from the configured Products
Product Criteria	Other Product criteria*	Configurable I.e.: Only for products marketed in country Only if products are used in a trial conducted in country

Only report on the following studies	Study cross reporting*	List values: All local/domestic studies with the same IMP All studies with same protocol (EUDRACT number in EU) All studies with same IMP Concerned study only
Only report on the following studies	Include Non-Clinical Trials?	Tick box
Only report on the following studies	Limit to studies	Selectable list of all configured studies
Other reporting criteria	Other reporting criteria	Free text box

6.2.2. Drug specific criteria tab

Drug specific criteria tab		
Seriousness / Event terms	Fatal	Tick box
Seriousness / Event terms	Life threatening	Tick box
Seriousness / Event terms	Other seriousness	Tick box
Seriousness / Event terms	Non serious	Tick box
Seriousness / Event terms	Other reporting criteria*	Tick box
Seriousness / Event terms	Other criteria (please specify)	Free text box to add i.e., internal other reporting criteria
Seriousness / Event terms	Query on term collection*	Dropdown list of SMQs/MedDRA term collections configured in the Labelling module – i.e., Lack of Effect SMQ
Seriousness / Event terms	Rule	Dropdown list – either include or exclude a selected rule: Do NOT schedule on the select SMQ Only schedule on the selected SMQ
Seriousness / Event terms	Follow up by CIOMS I report	Tick box
Seriousness / Event terms	Literature cases	Dropdown list: Ignore No, exclude Yes, include ignoring other criteria Yes, only include this type
Seriousness / Event terms	Literature cases – if “Yes” is selected	Tick boxes becomes available: Yes No

		Yes (if literature is not already known by LHA – Local Health Authority)
Listedeness (expectedness) / anticipatedness	Listed / anticipated	Tick box
Listedeness (expectedness) / anticipatedness	Unlisted / unanticipated	Tick box
Listedeness (expectedness) / anticipatedness	Listedness assessed according to	Dropdown list: *Possible to configure multiple Summary of Product Characteristics (SmPC) datasheet which listedness should be assessed against – i.e., CCDS datasheet, IB datasheet or US PI datasheet*
Case Type (drug specific)	Only include if Medically confirmed?	*Tick box*
Case Type (drug specific)	Include if drug not administered?	Dropdown list: Ignore No, exclude Yes, include ignoring other criteria Yes, only include this type
Case Type (drug specific)	Include lack of efficacy cases?	Dropdown list: Ignore No, exclude Yes, include ignoring other criteria Yes, only include this type
Case Type (drug specific)	MedDRA term collection - if "Include lack of efficacy cases?" is selected with "Yes"	Use MedDRA term collection to select the configured MedDRA SMQ
Case Type (drug specific)	Include Placebo-cases?	Dropdown list: Ignore No, exclude Yes, include ignoring other criteria Yes, only include this type

6.2.3. Device specific criteria tab

Device specific criteria tab		
Seriousness / Health Impact	Public health threat	Tick box
Seriousness / Health Impact	Fatal / Death	Tick box
Seriousness / Health Impact	Unanticipated seriousness deterioration state of health	Tick box

Seriousness / Health Impact	Malfunction or all other reportable incidents *"Device deficiency that could have led to serious deterioration"*	Tick box
Seriousness / Health Impact	Non-serious	Tick box
Seriousness / Health Impact	Follow up by MIR report	Tick box

6.2.4. Timelines, format and content tab

Timelines, format and content tab		
Submission timelines	Do you have local regulatory reporting timelines?	Tick Box: Yes No
Submission timelines	Timeline *When tick is set in "Days" it auto-populate the Reporting timelines*	Tick box: When case is closed (only SAE) Days
Submission timelines	Reporting timeline (days)	Enter number of days i.e., 10 or 15 etc.
Submission timelines	Local date of receipt ("Day 0") *Select when Day 0 should count from*	Dropdown list: First org. employee When received from HQ Other Not defined
Submission timelines	*How are days defined?* *Select how days are defined*	Dropdown list: Calendar days Business days Not defined
Submission timelines	Other definition – specified *Auto-populates when "other" is selected in Local date of receipt ("Day 0")*	Free text box
Submission format and content	Format *The format of the report the reporting rule uses i.e., rule schedules an E2B XML R3 report or a CIOMS report etc.*	Tick boxes: CIOMS E2B XML (R2) PSUR E2B XML (R3 KOREA) Local Format US FDA MedWatch 3500A Drug CIOMS and EU MIR (Combination products only) E2B XML (R2-CP) E2B XML (R3)

		MedWatch 3500A Device (eMDR) E2B XML (R2) E2B XML (R3 CHINA) EU MIR Other
Submission format and content	Other format requirements	Free text box
Submission format and content	Clinical reference type *Included in the integration*	Configurable dropdown lists: I.e., EUDRACT No. EU TRIAL Number EUDRAMED ID IND
Submission format and content	Message type *Auto-scheduling in HALO is currently hardcoded to ICHICSR for E2B reports* *Included in the integration*	Configurable dropdown lists: I.e., ichicsr psur backlog
Submission format and content	Letter template *Included in the integration*	Configurable Letter templates
Submission format and content	Should Personal identifiable information be included in the report?*	Tick box: Yes No
Submission format and content	Will cases be submitted electronically by Head quarter to external receiver?	Tick box: Yes No
Submission format and content	Is submission done by investigator? *This is available when the type of the rule is Clinical* *Included in the integration*	This only auto-populates if destination selected in rule contains "Ethic".
Submission format and content	Is providing of unblinded information required? *This is available when the type of the rule is Clinical* *Included in the integration*	Tick box: Yes No NA Unknown

6.2.5. Territories (scope) tab

Territories (scope) tab		
Countries	Add country	Dropdown list of all available countries configured in the system. It´s possible to do a multiple select. I.e., Viet Nam, Malaysia etc.

6.2.6. Implementation details tab

Implementation details tab		
Implementation details	De-activated *If rule is deactivated*	Tick Box:
Implementation details	Custom tags *Configurable custom tags*	Tick box: Include in Whom & When (*Regulatory Intelligence Overview*) Reporting Rule Implemented
Implementation details	Start workflow (auto-scheduling)	Dropdown list - configurable
Implementation details	Internal Timeline (days)	Enter number of days
Implementation details	Implementation Notes	Free text box
Implementation details	QMS Documents in implementation scope	Dropdown list of all available QMS documents configured in the system. It´s possible to do a multiple select.

6.3. Local QPPV/safety responsible person requirements form

6.3.1. Qualified Person tab

Qualified Person tab		
Qualified Person	Country Add country	Dropdown list of all available countries configured in the system. It´s possible to do a multiple select.

		I.e., Viet Nam, Malaysia etc.
Qualified Person	Is a Qualified person required? If "Yes" is selected *Please remember to add the name of the local QPPV under the information of the persons in the affiliate in the entities and agreement (internal) sub-module*	Dropdown list: Yes No
Qualified Person	Qualified person required location This is only appearing if "Yes" is selected in "Is *a Qualified person required"*	Configurable dropdown lists: Country EEA No location requirements Region

6.3.2. Requirement verbatim and notes tab

Requirement verbatim and notes tab		
Requirement verbatim and notes	Requirement text in original language	Free text box
Requirement verbatim and notes	Requirement text in English	Free text box
Requirement verbatim and notes	Notes	Free text box
Requirement verbatim and notes	URL of source	Text Field or Free text box
Requirement verbatim and notes	Effective date	Date Field
Requirement verbatim and notes	Document process scope	Configurable dropdown list: It´s possible to do a multiple select. i.e., Local QPPV / Safety responsible person (LQPPV) requirements.

6.3.3. Implementation details tab

Implementation details tab		
Implementation details	Implemented	Tick box
Implementation details	Agreements between affiliate and HQ	Free text box

Implementation details	QMS Documents in implementation scope	Dropdown list of all available QMS documents configured in the system. It´s possible to do a multiple select.

6.4. Requirement impact assessment form

6.4.1. Impact assessment details

Impact assessments details tab		
Impact assessments details tab	Describe the impact	Free text box
Impact assessments details tab	Impact on internal procedures	Free text box
Impact assessments details tab	Impact notes	Free text box
Impact assessments details tab	QMS Documents in implementation scope	Dropdown list of all available QMS documents configured in the system. It´s possible to do a multiple select

6.4.2. Territories (scope) tab

Territories (scope) tab		
Countries	Add country	Dropdown list of all available countries configured in the system. It´s possible to do a multiple select I.e., Viet Nam, Malaysia etc.

6.4.3. Implementation details tab

Implementation details tab		
Implementation details	Implemented	Tick box
Implementation details	Implementation notes	Free text box
Implementation details	Date for planned implementation	Date field
Implementation details	Actual date of implementation	Date field

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