24 September 2026
EMA/178285/2026
Clinical Trials Transformation

Sponsor Guidance: New Safety Module on the Annual Safety Report

Clinical Trial Information System (CTIS) user guidance on the New Safety Module

This guidance is applicable to the New Safety Module on Annual Safety Report (ASR), which is now part of the Sponsor CTIS training environment and it is foreseen to be integrated in the CTIS Sponsor Workspace:

- Instructions on how to access the Sponsor CTIS training environment can be found in section 6.2.3. of the Sponsor Handbook
- Instructions on how to report blocking issues and suggestions are in section 4.
- the list of known issues and workarounds on the New Safety Module, can be found in Annex I: List of known issues and workarounds

Alignment between the Sponsors and the Member States is required in order to liaise on the training environment: Sponsors should contact the Member States using the List of National Contact Points. Since ASRs can be submitted only on authorised clinical trials, new clinical trials need to be submitted and authorised within the Sponsor CTIS training environment in order for them to them to be available for training on the New Safety Module.

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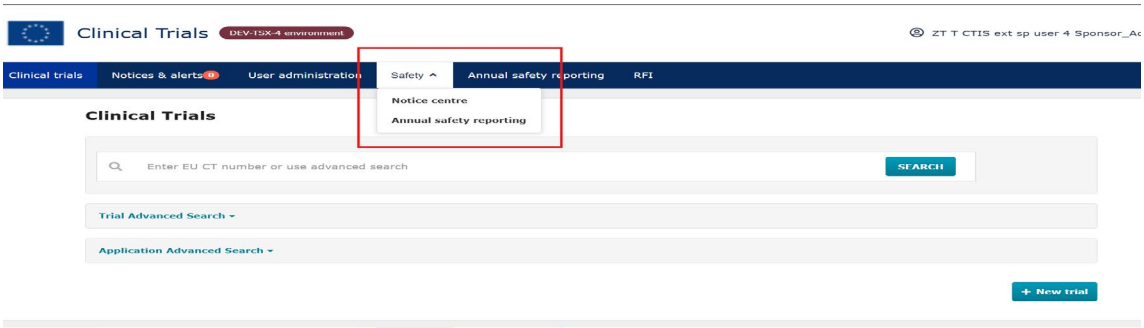
1. Introduction

In line with Article 43 of the Clinical Trials Regulation (EU) No 536/2014 , hereinafter 'CTR', sponsors shall submit annually a report on the safety of each Investigational Medicinal Product (IMP) used in a clinical trial (CT), other than placebo. The ASR (formerly known as the Development Safety Update Report, DSUR) is an annual report submitted by the sponsor to the relevant authorities that evaluates the evolving safety profile and benefit-risk balance of an IMP, including measures taken or proposed to mitigate potential risks and protect clinical trial participants. The obligation of submitting an ASR starts with the first European Union/European Economic Area (EU/EEA) authorisation of a trial and it ends with the end of the last trial conducted in EU/EEA by the sponsor with the concerned IMP. More information in section 7 of the CTR Q&A.

The Commission Implementing Regulation (EU) 2022/20 lays down the detailed rules and timelines for the coordinated assessment of ASRs submitted under Article 43 of the CTR. The New Safety Module on ASR supports the implementation of these requirements by enabling the harmonised submission, coordinated assessment, and management of ASRs in accordance with the procedures established in the Implementing Regulation.

The present document provides CT sponsors with the operational guidance they need to submit ASRs through the New Safety Module on ASR, including responding to the relevant Requests for Information (RFI). It is foreseen that this module will be integrated in the Clinical Trial Information System (CTIS). **During the two months before this date, the New Safety Module on ASR is implemented in the CTIS training environment: sponsors and authority users can train themselves through using the Sponsor CTIS training environment and Member State CTIS training environment. To request access to the CTIS training environment, refer to section 6.2.3. of the Sponsor Handbook.** Once access is granted, Sponsors can refer to the present document for detailed instructions on how to operate within the module.

A new 'Safety' tab is introduced in the Sponsor CTIS training environment, next to the existing 'Annual Safety Report' tab. As of October 2026, the new 'Safety' tab will be introduced in the CTIS Sponsor Workspace and all new ASRs must be submitted through the new Safety Module. The 'Annual Safety Report' tab will remain available for two months, to allow MSs to finalize the ongoing ASRs submitted through the old ASR submission functionality and during this period Sponsors will be able to access to the relevant RFIs through the old 'Annual Safety Report' tab; after this period, the tab will be removed: see section 2.1. on transition period.



The Authority Guidance: New Safety Module on the Annual Safety Report provides instructions to authorities on assignment of ASR and relevant assessment.

→ on this topic: watch also the CTIS bitesize talk: Annual safety report (ASR) new safety module

2. Submit an Annual Safety Report (ASR) and respond to ASR RFI

2.1. Transition period arrangements

The New Safety Module on ASR will fully replace the ASR submission functionality of CTIS. A **transition period of two months** is foreseen between the old ASR submission functionality and the New Safety Module on ASR where both will be used in parallel. As of go-live date, all new ASRs will be submitted by Sponsors through the New Safety Module on ASR and creation of new ASRs in the old ASR submission functionality will be disabled.

During the transition period of two months, the assessment of ASRs which are ongoing under the **old ASR submission functionality**can be finalised through accessing the old functionality: sponsors are able to respond to any RFI through accessing it via the 'RFI' and 'Notice & Alerts' CTIS tabs and check once the ASR is finalised when they receive a notice on it.

Once the transition period is over:

- **All ASRs for which the assessment is finalised under the old ASR submission functionality will be archived**, together with the relevant Final Assessment Reports, FARs (but not the Draft Assessment Reports, DARs) and the so-called 'saMS tracker'. The archive will be made available to EMA and Member States (MS), together with a report that will facilitate their search. Sponsor will not have access to those ASRs and FARs.
- **ASRs for which the assessment will still be ongoing under the old ASR submission functionality will not be transferred into the New Safety Module and will not be archived**. their assessment will need to be completed outside the new ASR workflow, under arrangements managed by the relevant Safety Assessing Member State (saMS) /Reporting Member State (RMS) (e.g., communication with sponsors, archiving of FARs, etc.).

Existing CTIS Safety role assignments to access the legacy ASR functionality remain available during the transition period. Assignment of a role that allows access to the new 'Safety' tab does not automatically create or update the corresponding role to view the legacy ASR functionality (refer to section 2.2. for more details).

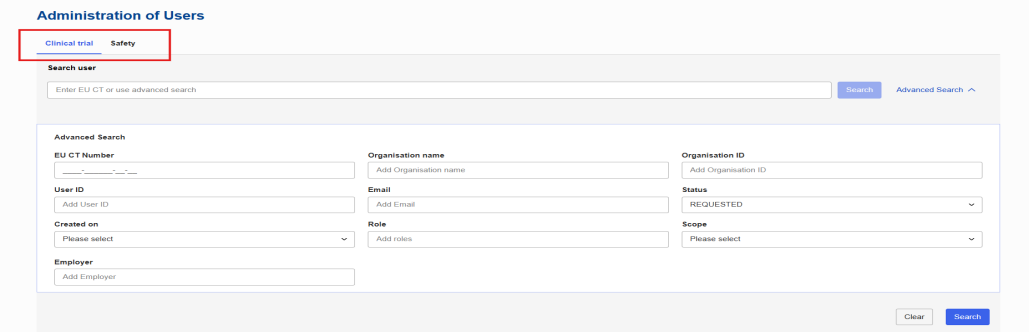
Any ASRs for which the assessment will remain incomplete at the end of the two-month transition period will no longer via accessible via CTIS. Before the end of the transition period, Sponsor users are advised to:

- Download any ASR submission (if the ASR is not already present in their archive)
- Download any RFI and RFI replies

The assessment will be managed outside CTIS by the already assigned saMS (or, where applicable, via the ad hoc assessment functionality). Once the assessment is finalised, the saMS will send ASRs and FARs to EMA for archiving purposes.

2.2. User Roles

A new subtab called 'Safety' is added in the 'User Administration' functionality of the Sponsor CTIS training environment, to allow the assignment of Sponsor Safety roles with access to the New Safety Module on ASR. The 'Clinical Trial' tab allows the management of Existing Clinical Trial related roles, including Safety roles to access the legacy ASR functionality: see section 1.6 of the Sponsor Handbook.



The same sub-tab appears in 'My roles' are under 'My Profile section' of every Sponsor user.

The subtab will be introduced in the Sponsor Workspace as of go live of the New Safety Module, in addition to the 'Safety' tab that will appear on the homepage to access the new Safety Module. For now, they are present in the Sponsor CTIS training environment.

CTIS Sponsor users which have a **Sponsor Admin role in CTIS can manage the access to the New Safety Module on ASR** to other Sponsor users through the Safety sub-tab; however, they **do not have any viewing or business permission** to the New Safety Module

The **Sponsor Safety Admin role** is a dedicated Safety administrator role used to manage Safety role assignments. It does not provide access to Safety Module business activities. Users assigned with the Sponsor Safety Admin role can assign the following roles to users from safety sub-tab within the limits of its own authorised scope (i.e. All' or 'Specific' trials):

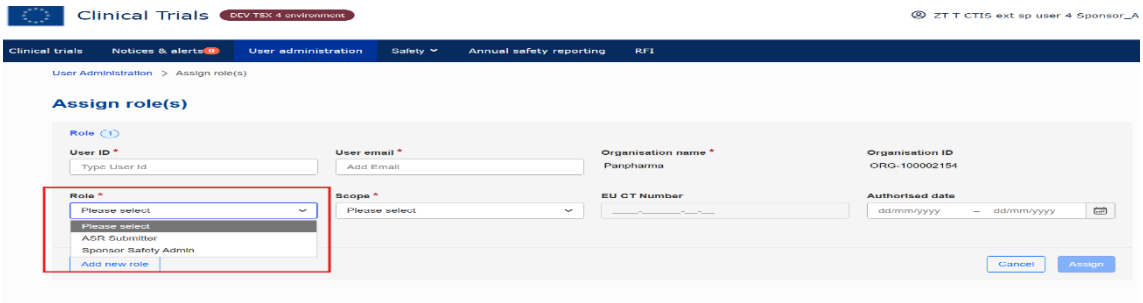
- ASR Submitter roles with scope 'All' or 'Specific' trials
- Sponsor Safety Admin role.

The Sponsor roles that can assign roles within the Sponsor workspace New Safety Module on ASR and roles that have access and can perform actions within the module are displayed below, together with modality of their assignment.

Roles type	Sponsor Workspace	Modality of assignment
Administrator Roles	Sponsor Admin	In the Sponsor CTIS training environment: N/A, all trials have a CT-centric approach In the CTIS Sponsor Workspace: EMA Account Management portal (refer to section of 1.5.1.1. Sponsor Handbook
	Sponsor Safety Admin	In the Sponsor CTIS training environment: automatically assigned upon authorisation of the initial clinical trial application In the CTIS Sponsor Workspace: assigned by the Sponsor Admin in CTIS from the safety-user management subtab *Note: If a trial was created under the **CT-centric approach**, the Sponsor Safety Admin role **is assigned automatically** to the user holding the CT Admin role for that trial, as soon as the trial is authorised. A user holding both CT Admin and Sponsor Safety Admin roles can assign either role to other users. Holding only the CT Admin role does not allow assigning the Sponsor Safety Admin role.*

Roles type	Sponsor Workspace	Modality of assignment
Business Roles & Scope	ASR submitter (All trials/Specific trials)	Assigned by the Sponsor Admin or the Sponsor Safety Admin in CTIS from the safety-user management subtab

Admin roles can assign roles within the CTIS User Management safety subtab:



The **ASR Submitter** is the business role within the CTIS Safety Module and is responsible for performing Annual Safety Reporting activities. Sponsor users with this role can access the Annual Safety Reporting and the Notice Centre tabs.

During the transition period, role assignments in the 'Clinical Trial' tab and the 'Safety' tab are not synchronised. Users requiring access to both the legacy ASR functionality and the new Safety Module must hold the required role assignment in both tabs e.g. the ASR Submitter role must be assigned to a user in both, the Clinical Trial and Safety tab, to enable that user to perform all activities in both the old and new Safety Module.

At go-live, CTIS will migrate existing Sponsor safety-related roles to the Safety tab in accordance with the defined migration matrix. **Existing CT Admin** roles will **automatically** inherit the **Sponsor Safety Admin** role while existing ASR Submitter roles will automatically inherit the corresponding ASR Submitter role, with their assigned scope preserved in both cases. The migration does not apply to the Sponsor Admin roles, as they are managed in EAM rather than assigned in CTIS.

Following go-live, any new user requiring safety roles must have those roles manually assigned or approved by a Sponsor Admin/CT Admin for the legacy ASR functionality and/or by the Sponsor Admin/Sponsor Safety Admin for the new Safety Module.

The ASR Submitter business permissions are detailed in the below table. The level of access available to an ASR Submitter is determined by the scope assigned to the role. **Users can only perform ASR activities for clinical trials that fall within their authorised scope.**

The table below ('Role Matrix') gives an overview of the permissions linked to the Sponsor workspace on the New Safety Module on ASR for the mentioned roles. For an explanation of the specific permissions, refer to the relevant sections in this guidance.

Permissions within the New Safety Module on Annual Safety Report		Sponsor Admin	Sponsor Safety Admin	ASR Submitter
Roles Admin	Manage role assignment: view roles & requests, and allocate roles and trials			
Notices	View safety notices (only notices where user is an explicit recipient)			
ASR View, Creation & Submission	View list of ASRs (draft, submitted, finalised) and ASR details (ASR Submission, RFI, Summary & Conclusion); Download ASR & attachments			
	Create / Edit draft ASR (search SG/CTs, populate form)			
	Save draft, Delete draft, Submit ASR			
RFI	View RFI Upload & Submit RFI response			

ASR Submitters can download documents from each individual document placeholder and from the general download, only the ASR submitted. The download functionality will be enhanced after go-live to facilitate the download of complete ASR packages, not only ASR submitted but also supporting documentation, RFIs, responses and assessment outcome information.

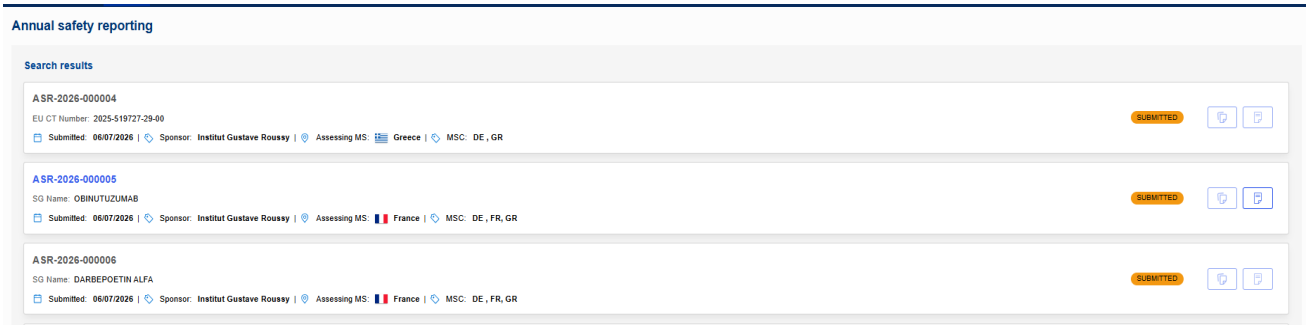
The user access to Safety information by the ASR Submitter role is determined by comparing the clinical trials included in the ASR with the clinical trials covered by the user's ASR Submitter role scope. CTIS evaluates whether the user's assigned scope covers none, some or all of the trials referenced in the ASR and grants access accordingly:

- Sponsor users with the ASR Submitter role but none of the CTs included in the ASR falling within the user’s role scope coverage are granted no access to view the ASR displayed in the ASR list view.
- Sponsor users with the ASR Submitter role and at least one CT included in the ASR falling within the user’s role scope coverage are granted access to view the ASR displayed in the ASR list view.
- Sponsor users with the ASR Submitter role and all CTs included in the ASR falling within the user’s role scope coverage are granted full access to the ASR. Full access comprises to view the ASR displayed in the ASR list view on top of the ASR detailed view screens (i.e. ASR Submission, RFI, Summary & Conclusion).

These access rules ensure that ASR information is only available to users whose role scope covers the clinical trials included in the ASR. As a result, two users holding the same ASR Submitter role may have different levels of access to the same ASR depending on the scope assigned to their role and the trials under the role scope.

Example: Consider an ASR that includes **Trial A**, **Trial B** and **Trial C**, while the user's ASR Submitter role scope includes only Trial A and Trial B. When CTIS evaluates access, it compares all clinical trials contained in the ASR against the user's authorised scope. Because at least one of the trials included in the ASR falls within the user's scope, the ASR is displayed in the Annual Safety Reporting list, and the

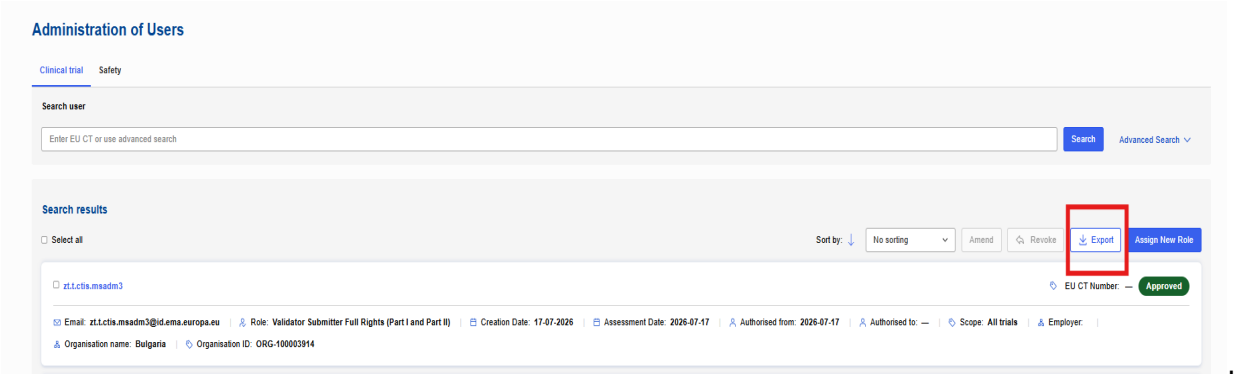
user receives List Access. However, the user does not receive full access because the scope does not cover all trials included in the ASR; Trial C remains outside the user's authorised scope. As a result, the ASR is visible to the user, but CTIS does not grant the full set of permissions available for users whose scope covers every trial included in the report.



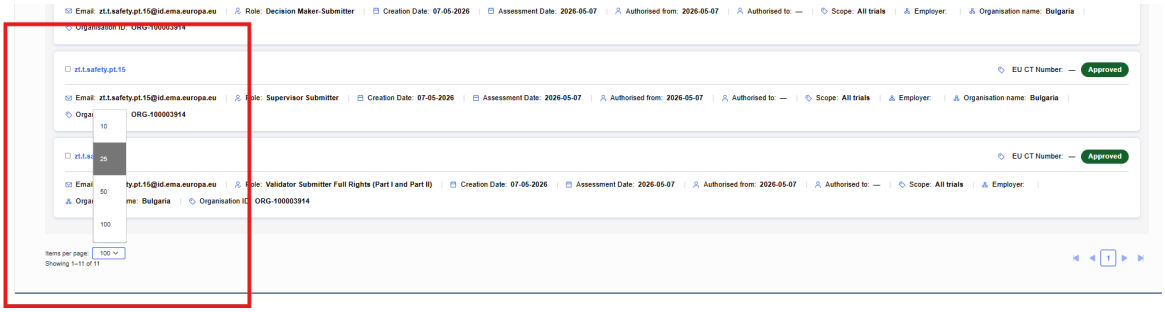
For more details on access permission refer to the Role Matrix above.

2.2.1. Exporting the list of Clinical Trial and Safety roles per Sponsor user

In User administration screen, from the clinical trial or safety sub-tabs, administrators can search and filter results using the existing criteria (e.g. User ID, Email, Status, Scope, Employer, etc.), and results retrieved can be exported through a new 'Export' button next to the 'Assign' role one.

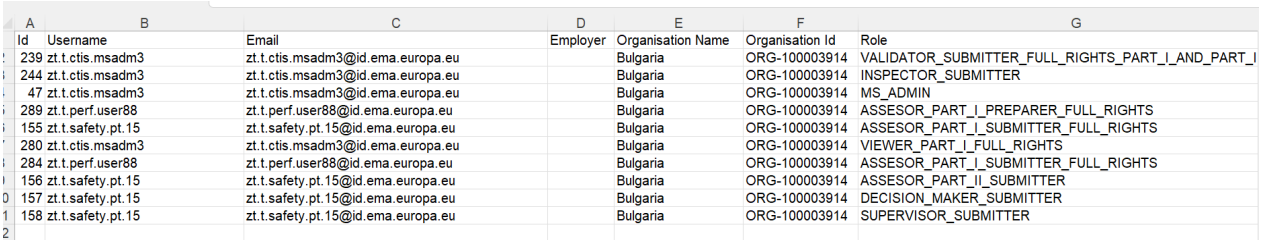


The export functionality is available to all administrators and the 'Export' button is always visible to administrator, however it appears disabled (greyed out) and it is only enabled when the current search returns at least one result. The export works per page and for this reason pagination is enhanced so that administrator can choose the page size, to display 10, 25, 50 or 100 results per page.



The selected page size defines how many records are exported, going from 10 if the selected page size is 10 to up the maximum number of 100 if the selected page size is 100: if an administrator manages more than 100 users, more than one Excel file needs to be downloaded and then combined.

When an administrator clicks 'Export', an XLS file is generated and downloaded: the exported file contains the records of a user per row with user ID on the first column and the rest of the fields in the remaining columns.



	A	B	C	D	E	F	G
	Id	Username	Email	Employer	Organisation Name	Organisation Id	Role
	239	zt.t.ctis.msadm3	zt.t.ctis.msadm3@id.ema.europa.eu		Bulgaria	ORG-100003914	VALIDATOR_SUBMITTER_FULL_RIGHTS_PART_I_AND_PART_I
	244	zt.t.ctis.msadm3	zt.t.ctis.msadm3@id.ema.europa.eu		Bulgaria	ORG-100003914	INSPECTOR_SUBMITTER
	47	zt.t.ctis.msadm3	zt.t.ctis.msadm3@id.ema.europa.eu		Bulgaria	ORG-100003914	MS_ADMIN
	289	zt.t.perf.user88	zt.t.perf.user88@id.ema.europa.eu		Bulgaria	ORG-100003914	ASSESOR_PART_I_PREPARER_FULL_RIGHTS
	155	zt.t.safety.pt.15	zt.t.safety.pt.15@id.ema.europa.eu		Bulgaria	ORG-100003914	ASSESOR_PART_I_SUBMITTER_FULL_RIGHTS
	280	zt.t.ctis.msadm3	zt.t.ctis.msadm3@id.ema.europa.eu		Bulgaria	ORG-100003914	VIEWER_PART_I_FULL_RIGHTS
	284	zt.t.perf.user88	zt.t.perf.user88@id.ema.europa.eu		Bulgaria	ORG-100003914	ASSESOR_PART_I_SUBMITTER_FULL_RIGHTS
	156	zt.t.safety.pt.15	zt.t.safety.pt.15@id.ema.europa.eu		Bulgaria	ORG-100003914	ASSESOR_PART_II_SUBMITTER
0	157	zt.t.safety.pt.15	zt.t.safety.pt.15@id.ema.europa.eu		Bulgaria	ORG-100003914	DECISION_MAKER_SUBMITTER
1	158	zt.t.safety.pt.15	zt.t.safety.pt.15@id.ema.europa.eu		Bulgaria	ORG-100003914	SUPERVISOR_SUBMITTER
2							

2.3. ASR drafting and submission

Since ASRs can be submitted only on authorised clinical trials, **new clinical trials need to be submitted and authorised** within the Sponsor CTIS training environment in order for them to them to be available for training on the New Safety Module on ASR: see instructions on Sponsor Handbook. Alignment between the Sponsors and the Member States is required to liaise on submissions and authorisations within the CTIS training environment: Sponsors should contact the Member States using the List of National Contact Points.

With the ASR new safety module, sponsors can submit an ASR in one of two ways:

- **Clinica Trial-centric ASR**: the ASR covers a single clinical trial. In this case, the assessing MS is by default the RMS of the trial concerned. CT-centric ASRs are identified by the EU CT Number displayed on the ASR.
- **Substance Group-centric ASR**: the ASR covers all clinical trials associated with a Substance Group (SG). In this case, the assessing MS is the saMS appointed for that SG. SG-centric ASRs are identified by the SG name displayed on the ASR. A SG-centric ASR may cover trials from more than one sponsor. Only authorised, temporarily halted and suspended trials can be part of a SG: if a trial is 'under evaluation', its authorisation is revoked or it is ended, it cannot be linked to a SG.

The choice between a CT-centric and a SG-centric submission lies with the sponsor. The CT-centric option is expected to be used mainly by academic sponsors, while SG-centric submissions are expected to be used more frequently overall.

An ASR is linked to one or more trials (see steps below) and to a SG, and it can involve more than one sponsor: refer to section 2.4 of the Authority Guidance: New Safety Module on the Annual Safety Report.

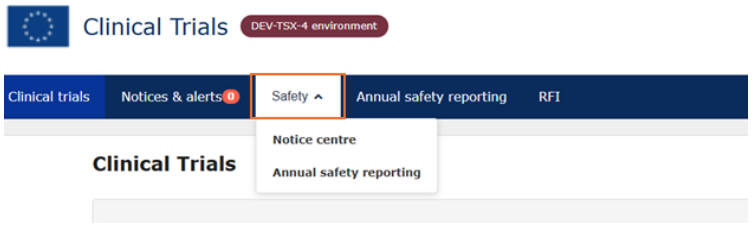
Any document submitted within the ASR New Safety Module, including ASR RFI, and their structured data are **never published**. However, all Member States (also those that are not MSCs for the trials that are in scope of the ASR) have access to the submitted ASR information.

The visibility of the ASR new safety module tabs is role-based: sponsor users only see the Safety functionality relevant to their assigned roles (see section 2.2.).

Within the Sponsor workspace, the new **Safety tab** is located nearby the old ASR functionality and provides access to the following options:

1. **Notice Centre**, used to view Safety notices
2. **Annual Safety Reporting**, used to create, manage and view ASRs.

Both options include **search and filtering capabilities** to help users identify and retrieve relevant information. The search criteria and column sorting are reflected in the results page URL, which can be bookmarked or shared to recreate the specific page. The Search Filters panel is available on the left-hand side of the screen and can be expanded or collapsed as needed.



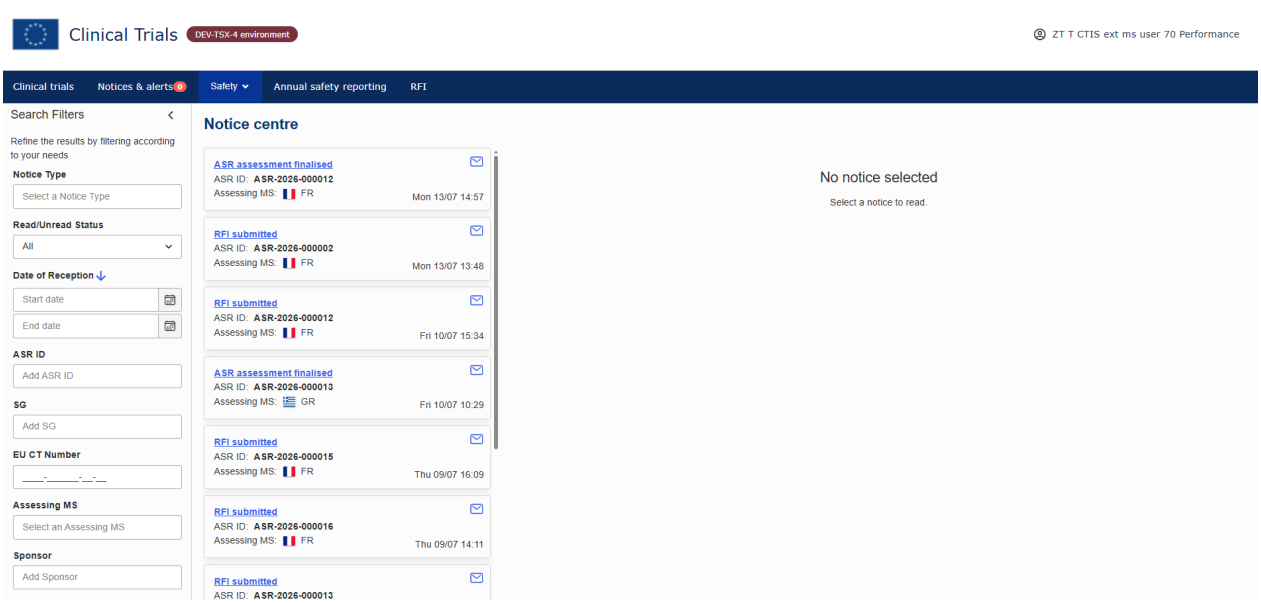
2.4. Notice Centre tab

The **Notice Centre** provides a location for viewing system generated notices of the New Safety Module on ASR, enabling users to **monitor changes affecting the ASR Assessment of any ASR they have a role for** (i.e. 'RFI submitted', 'ASR assessment finalised'). Notices are only related to the New Safety Module and an email notification is sent in case the user has opted in: other Notices and alerts that are related to the other functionalities of CTIS and not related to the New Safety Module are notified to users in line with section of 3.2 of the Sponsor Handbook.

Newly received notices are automatically marked as 'Unread', while notices that have been opened are identified by an open envelope icon, and unread notices are identified by a closed envelope icon.

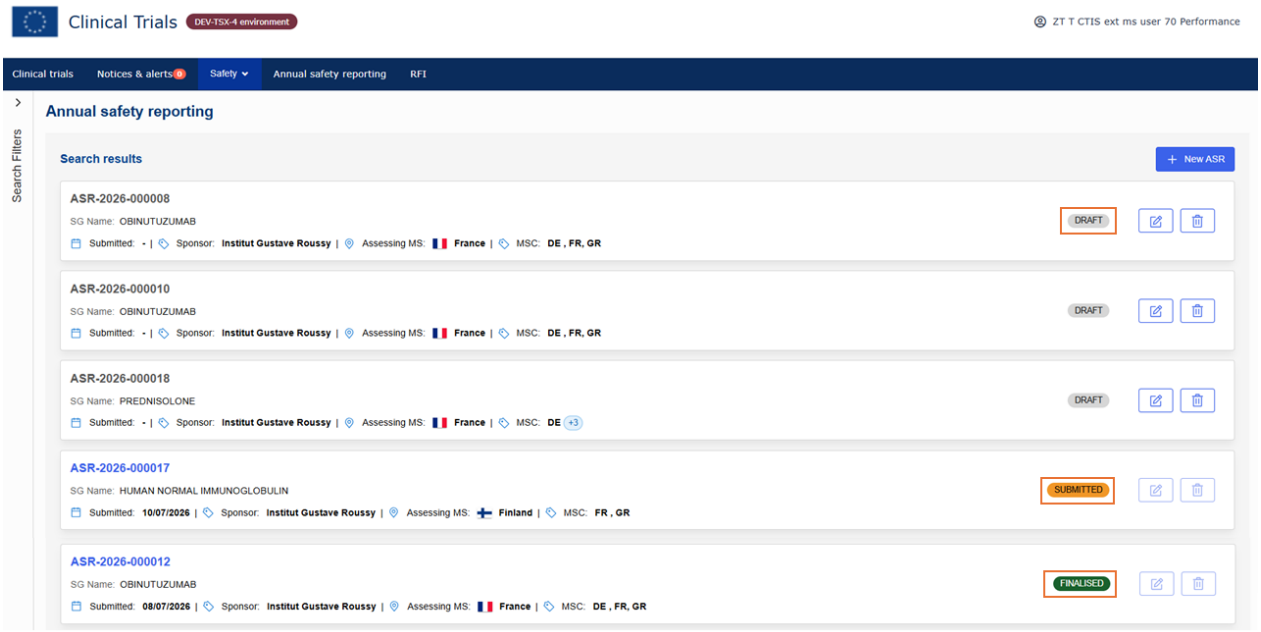
Note that notices remain available in the Notice Centre for 90 days from the date of receipt, after which they are automatically deleted.

Users can use the available **search filters** to locate specific notices and sort the results as appropriate. By default, notices are sorted by **Date of Reception** with the most recently received notice displayed at the top. The list of notices displayed in the Notice Centre cannot be exported (e.g. to an Excel file).

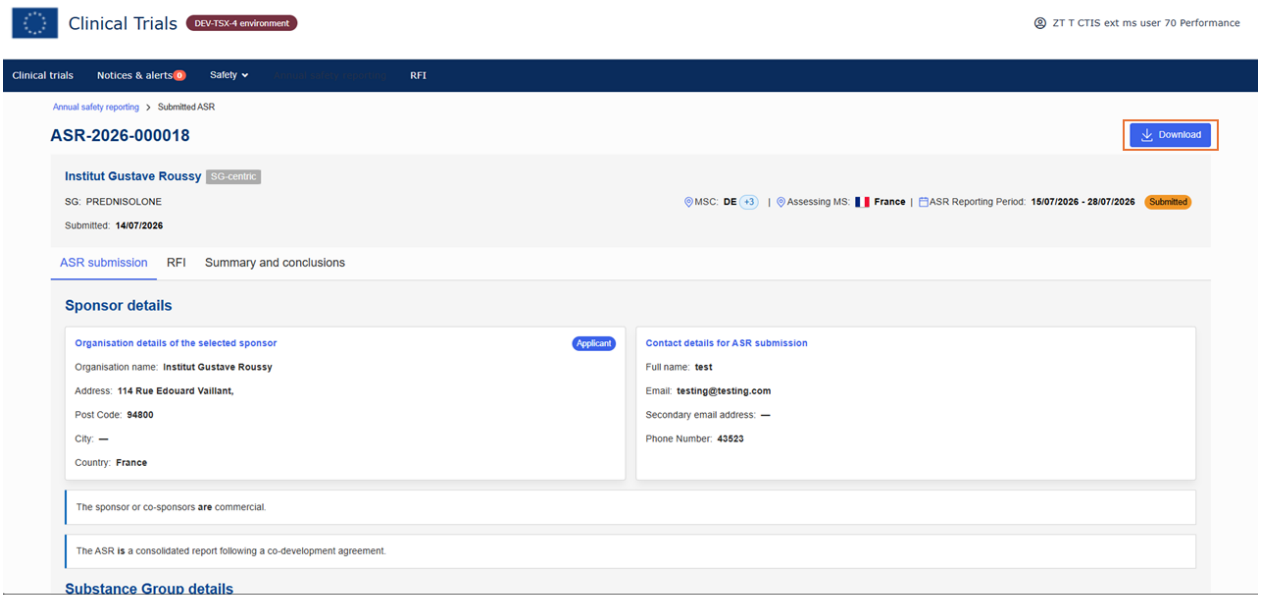


2.5. Annual Safety Reporting tab

The **Annual Safety Reporting** tab provides information related to ASRs. This tab provides a list of all ASRs by the sponsor, in 'Draft', 'Submitted' or 'Finalised' statuses.



Users can click on an ASR ID to open the relevant **ASR page,** where information related to the ASR Submission, RFIs and to the ASR Assessment/Conclusion can be viewed. In addition, it is possible to download the submitted ASR and all related documents from their placeholder or clicking on the 'Download' button at the top right corner. **Note**: the full ASR package download (i.e. ASR, supporting documentation, RFIs, responses and assessment outcome) from the 'Download' button will only be enhanced after go-live of the New Safety Module.



A user with **ASR Submitter role** can create/edit/delete/submit draft ASRs, and view submitted and finalised ASRs. Note that the level of access of a specific role depends on the scope assigned to that role. An ASR Submitter role may be assigned with:

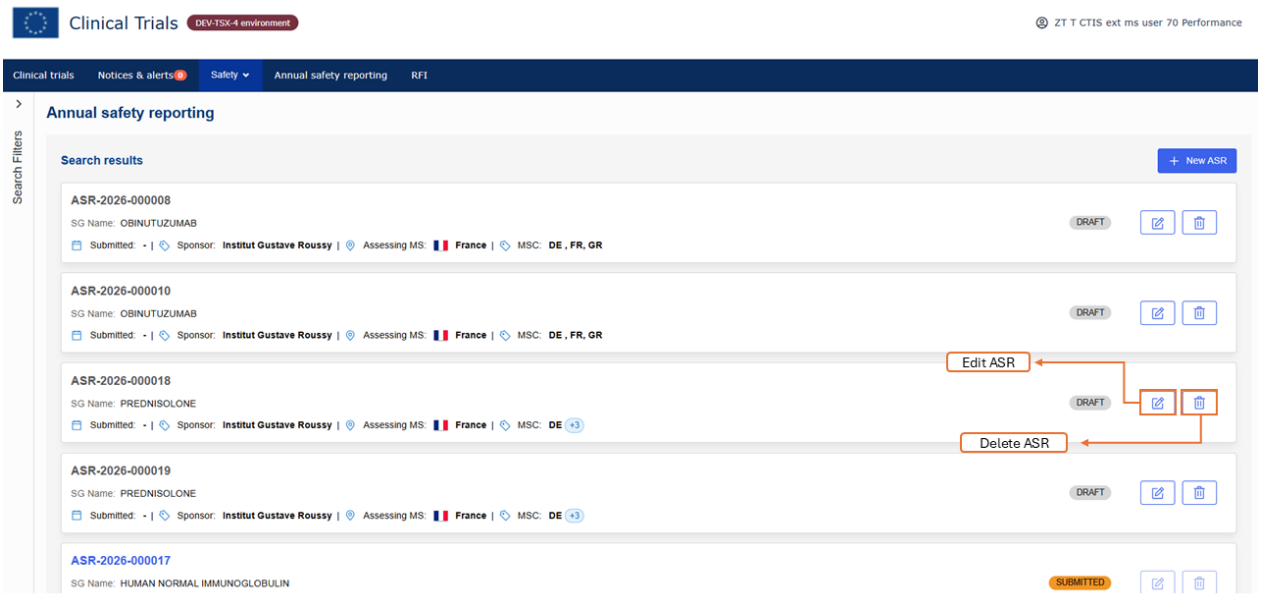
- **All Trials scope**, which provides access to all clinical trials covered by the organisation associated with the role assignment.
- **Specific Trial scope**, which provides access only to the clinical trial(s) specified in the role assignment.

Access to ASRs is determined by comparing the clinical trials included in the ASR with the clinical trials covered by the user's ASR Submitter scope:

- If at least one clinical trial included in the ASR falls within the user's scope, the ASR is visible in the Annual Safety Reporting list.
- If all clinical trials included in the ASR fall within the user's scope, the user has full access to the ASR, including the ASR Submission, RFI and Summary & Conclusions sections.
- If none of the clinical trials included in the ASR fall within the user's scope, the ASR is not visible to the user.

A user may hold multiple ASR Submitter role assignments with different scopes. In such cases, CTIS combines the clinical trial coverage from all ASR Submitter assignments when determining which ASRs can be accessed.

A CT Admin user does not have any ASR permissions to its role. To be able to perform ASR related activities, the CT Admin should assign the ASR Submitter role to him/herself (see section 2.2.)

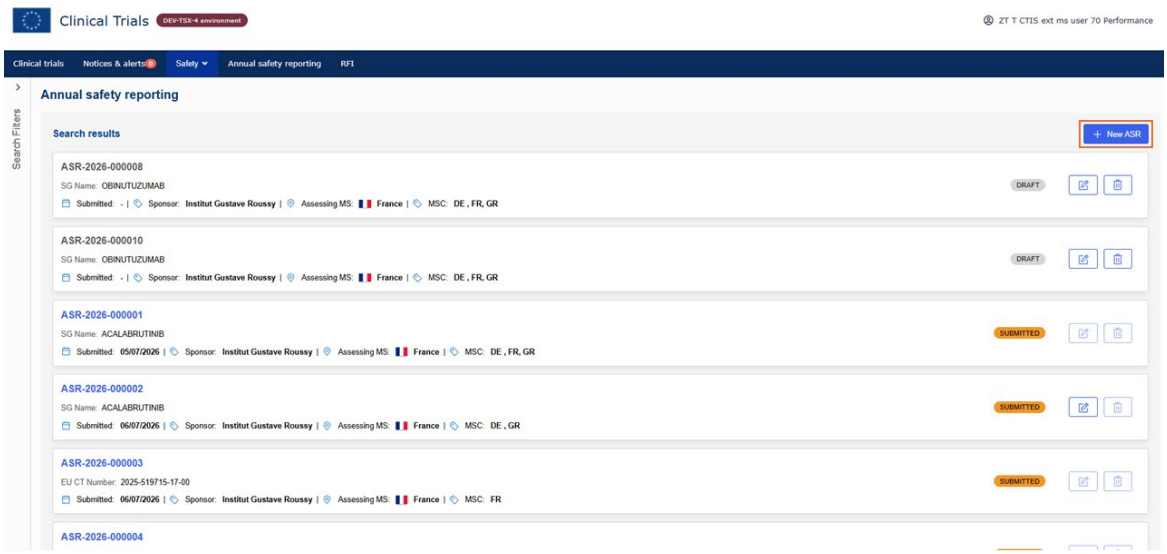


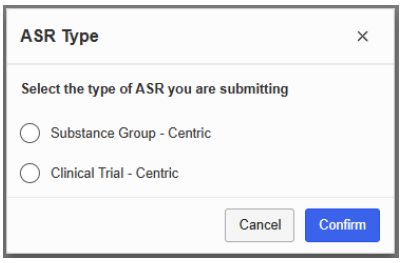
2.5.1. How to submit an ASR

Before proceeding, the ASR Submitter should **make sure that there is no ongoing assessment of a 'Change of sponsor' for the relevant trial(s)**: see section 4.4 of the Sponsor Handbook.

After having accessed the Sponsor Workspace, a sponsor user with the **ASR Submitter role**:

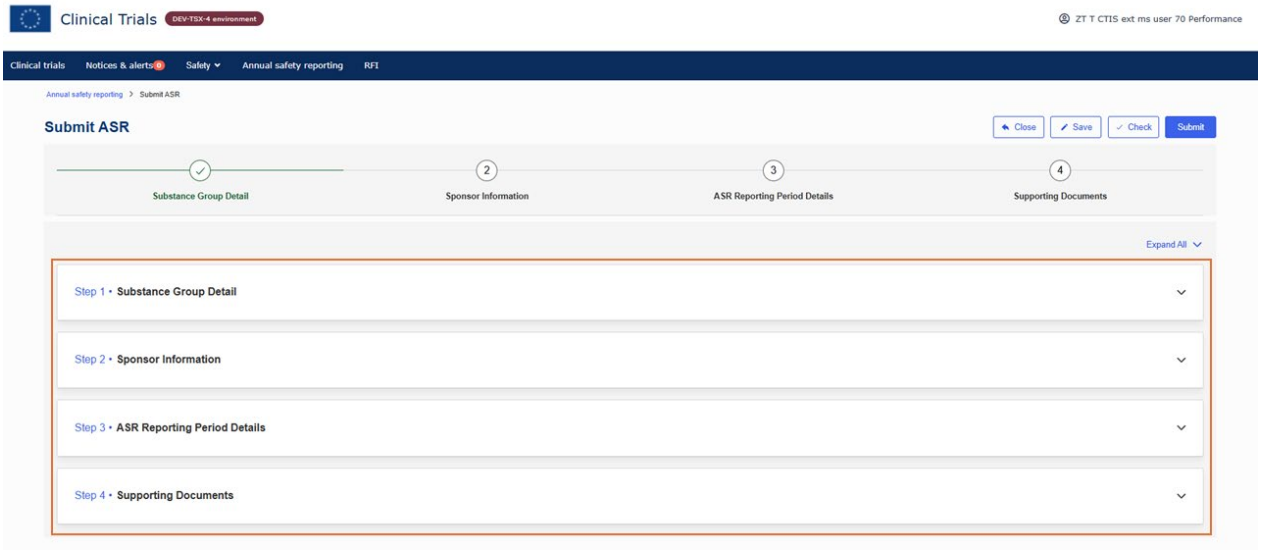
1. Navigate to the Safety tab and open the 'Annual safety reporting' tab. Click on the **'+ New ASR'** button and in the pop-up window, select whether your ASR should be 'Substance group – centric' or 'Clinical trial – centric'. Then click 'Confirm':





2. After selecting the ASR type, complete the mandatory fields of the ASR submission form. Those fields are grouped into four steps, see below image.

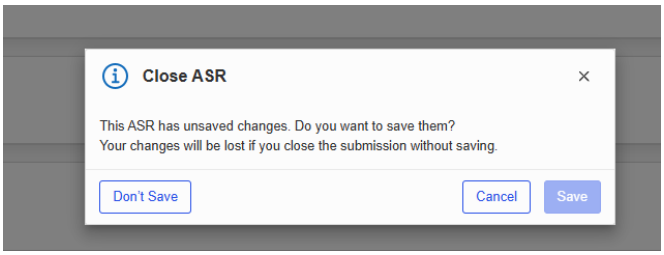
   As each section is completed successfully, CTIS automatically marks it as completed (green colour) in the navigation bar at the top of the page. This allows users to easily track their progress and identify which sections still require completion before submission. Users can either progress sequentially through the form using the **Next** button or navigate directly to another section by selecting the relevant step from the navigation panel. Refer to section 2.5.1.1. to see how to fill in each step of the Annual Safety Report.



At the top-right corner of the screen, four action buttons are available:

- Close: Closes the ASR and returns to the previous page. Unsaved changes will be lost.
- Save: Saves the ASR as a draft.
- Check: Validates that all mandatory fields and required documents have been completed.
- Submit: Submits the ASR for assessment once all validation checks have passed.

The button **'Close'** allows users to exit the form and return to the previous page. When selected, a confirmation dialog is displayed. The dialog warns that that any unsaved changes will be lost if the submission is closed without saving. Users can choose 'Don't Save' to discard the changes using or 'Cancel' to return to the form.



The '**Save' button is enabled only after 'Step 1 - Substance Group Details / Clinical Trial Details' has been completed.** Upon first time saving, the system automatically generates a unique **ASR ID**, which is an identifier consisting of a combination of unique elements: **ASR-YYYY-XXXXXX**, where the 'ASR' identifies the procedure type, the 'YYYY' represents the year in which the ASR was first saved and 'XXXXXX' is a sequential number generated by the system.

The first time an ASR is saved, the ASR status is set to 'Draft'. After saving, the draft ASR becomes available on the Annual Safety Reporting landing page together with other ASRs available within the user's access scope and can subsequently be edited, updated or deleted until they are submitted. An ASR can be kept as 'Draft': this means that the information entered can be saved and the user can keep working on them when logging in at a later moment. **Users do not need to complete an ASR in a single session**: the system allows sponsor users to save draft ASRs, edit draft ASRs and delete draft ASRs before submission. To continue working on a draft ASR:

1. Navigate to Safety → Annual Safety Reporting.
2. Locate the draft ASR on the landing page.
3. Select Edit ASR.
4. Update the required information.
5. Save the draft again or submit the ASR when completed.

If a draft ASR is no longer required, the user can select 'Delete ASR' to remove it. Deletion is available only for ASRs in 'Draft' status. Once the ASR is submitted, the status changes from 'Draft' to 'Submitted' and the ASR can no longer be edited as a draft.

Refer to section 2.5.1.2. for a description of buttons 'Check' and 'Submit' buttons.

2.5.1.1. Filling in the different sections of an Annual Safety Report

Step 1: Substance Group Detail/Clinical Trial details

As per section 2.5.1. , click on '+ New' and select 'Substance Group – Centric' / 'Clinical trial – Centric' within the Annual Safety reporting section, and click on 'Confirm'. Note that once this step is completed, the 'save' button is enabled.

Note that, irrespective of the approach followed (i.e. SG-centric or CT-centric), trials that are not authorised and trial with overall trial status 'Ended' and 'Revoked' will not appear in the list of trials for which an ASR is created.

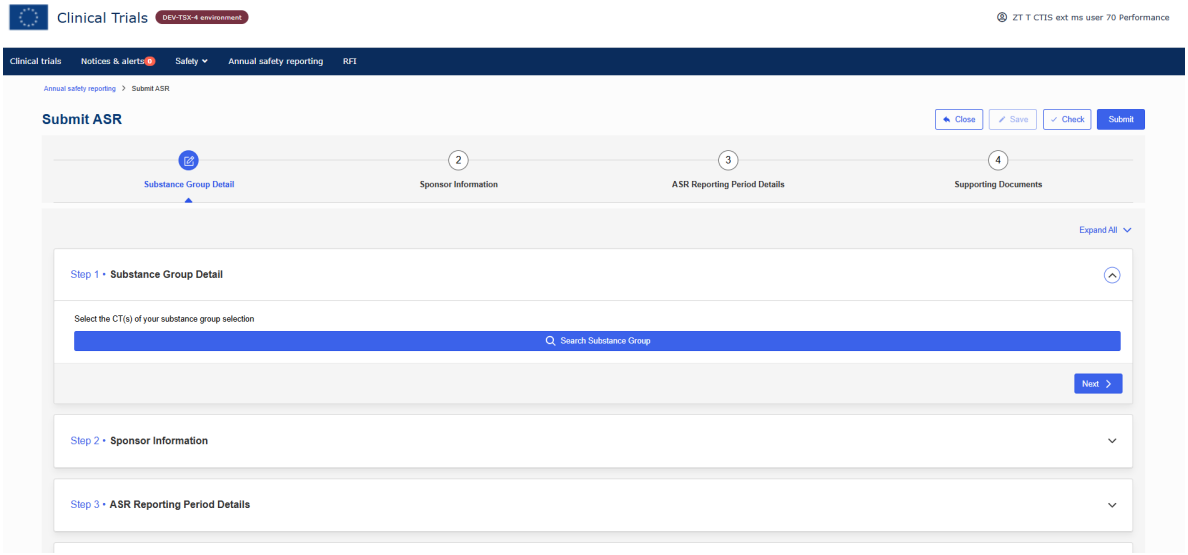
Step 1: Substance Group-centric ASR

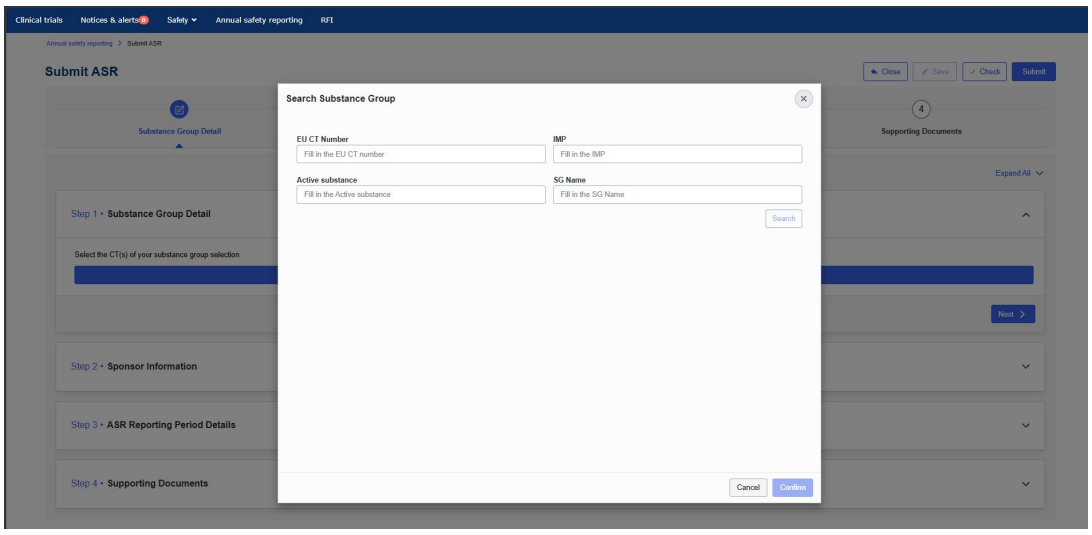
A **SG** is a grouping of clinical trials that are linked to the same active substance. Substance Groups are maintained within the CTIS Safety Module and support coordinated safety oversight and ASR

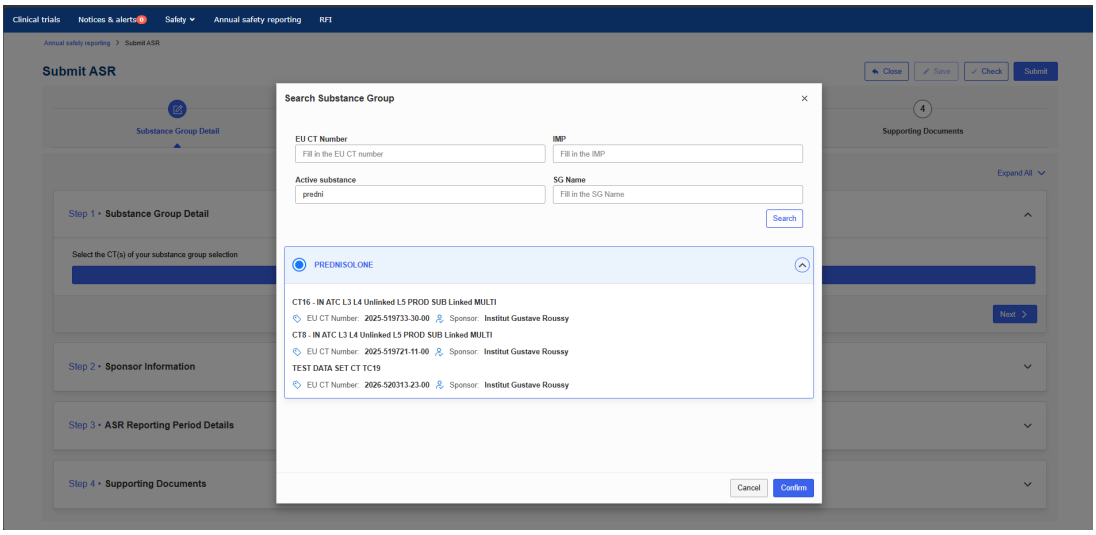
assessment across related clinical trials. A SG is created automatically when the first clinical trial associated with a specific active substance is authorised in CTIS.
Once the Substance Group-centric ASR is selected:

1. Click on '**Search Substance Group'** and search for the relevant SGusing one or more of the available search criteria (EU CT Number, IMP, Active Substance, SG Name)

2. Once the appropriate SG has been identified, review the list of clinical trials displayed by the system and **select the trials that should be included in the ASR**. Only authorised clinical trials that fall within the ASR Submitter role scope are available for selection. This means that the list of clinical trials displayed in CTIS may differ between users, depending on the scope assigned to their ASR Submitter role.
   Note: **an ASR Submitter does not necessarily need access to the relevant clinical trial application in order to submit an ASR**. Access to ASRs is controlled through the ASR Submitter role and its scope, independently of access to clinical trial records. As a result, a user may be authorised to prepare and submit an ASR for one or more trials without having access to those trials elsewhere in CTIS.





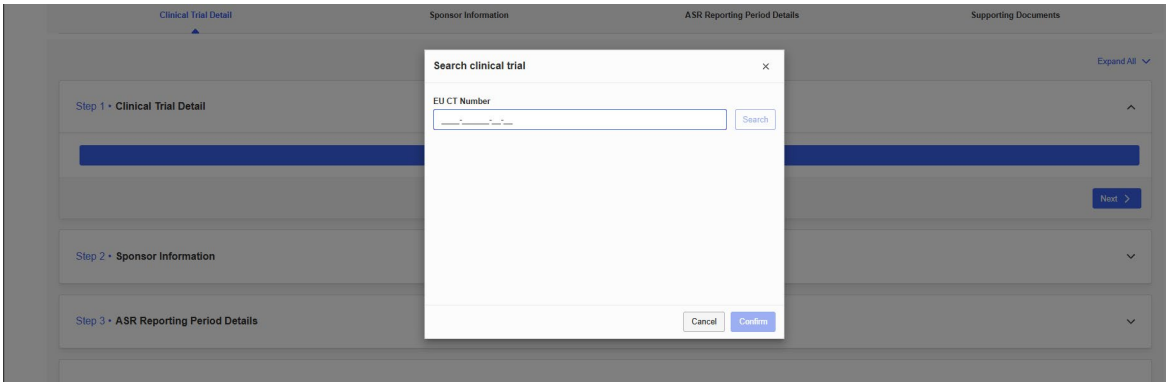


Step 1: Clinical Trial-centric ASR

Once the Clinical Trial-centric ASR is selected in section 2.5.1. :

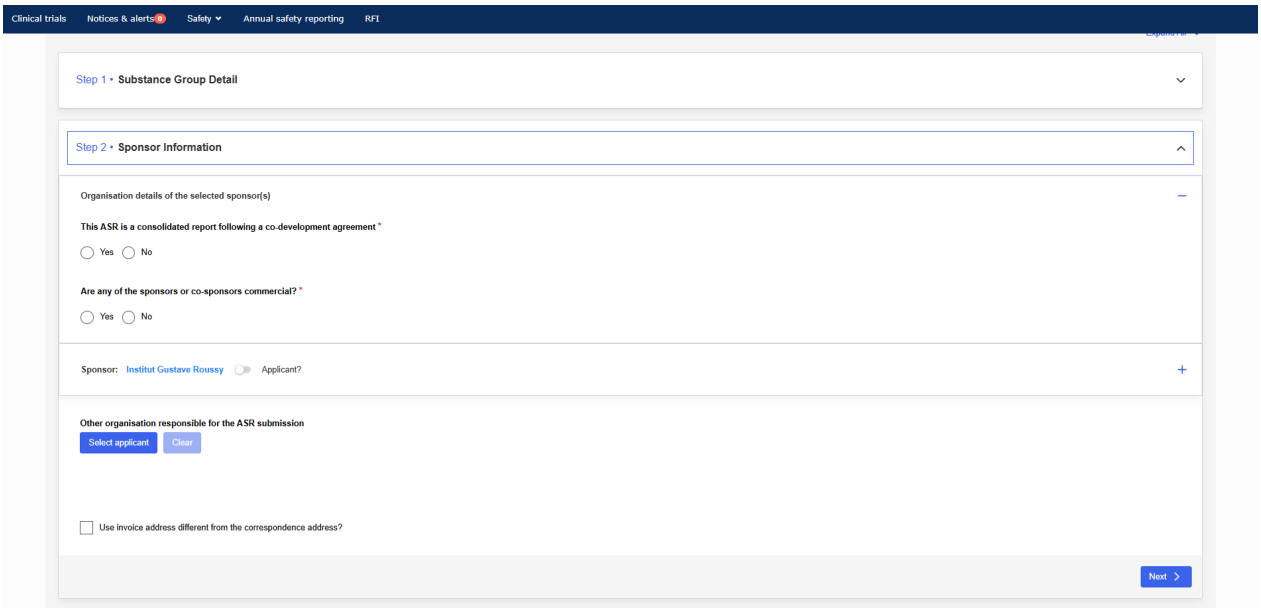
1. Select **Search Clinical Trial** and enter the relevant EU CT Number. Only clinical trials that fall within the user's ASR Submitter scope are available through the search functionality

2. Select the relevant trial and confirm: the system displays the trial details in the ASR form. Only one clinical trial can be selected for a Clinical Trial-centric ASR. Once selected, the clinical trial information is displayed in the form and cannot be replaced by adding additional trials.



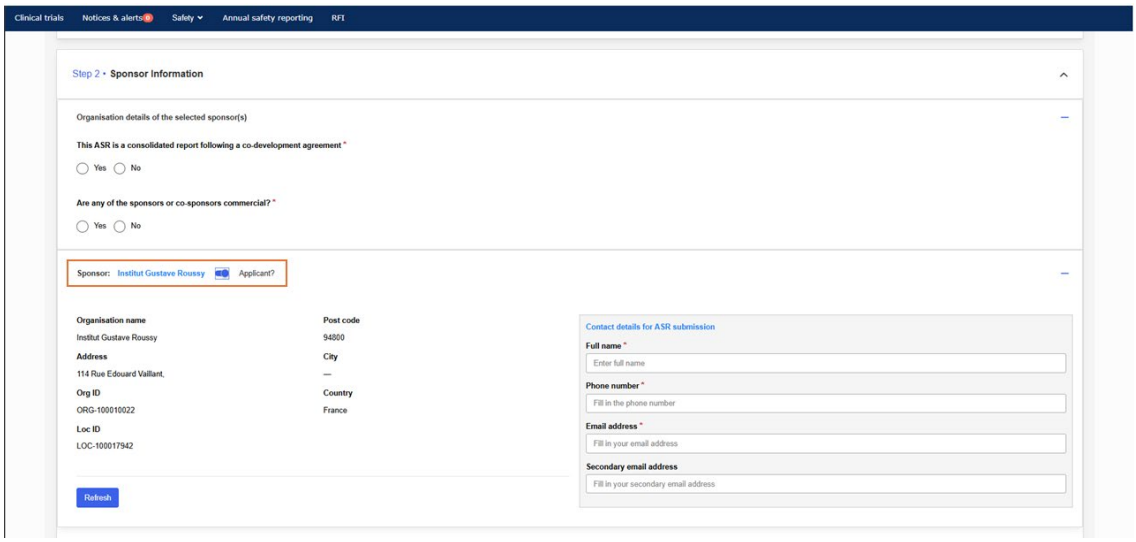
Step 2: Sponsor Information

Users must provide information about the sponsor(s) responsible for the ASR. This section contains mandatory sections that need to be completed before proceeding to the next step. The sponsors' information is automatically pre-populated for each clinical trial in linked to the ASR. Note that, **in case the sponsor changes during the ASR submission process, data needs to be refreshed** by clicking the appropriate 'Refresh' button and the new sponsor information will be updated in the draft ASR based on the newest information in Organisation Management Service (OMS).

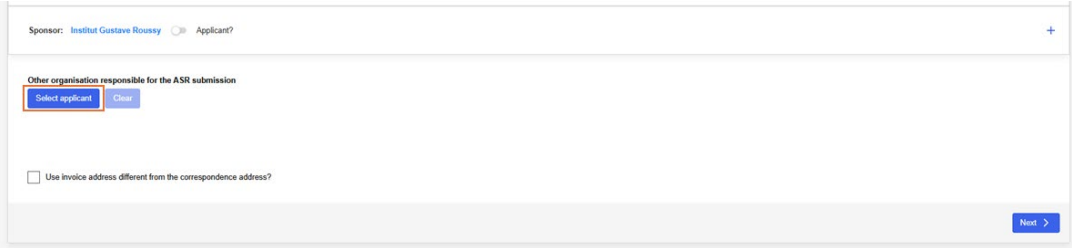


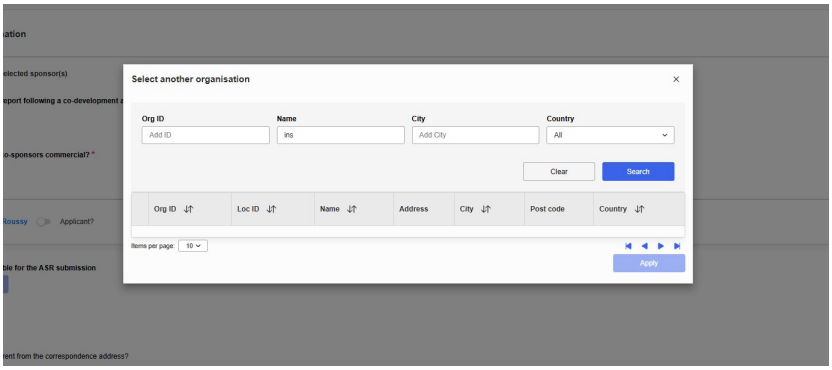
Steps to follow:

1. Reply on whether the ASR is a consolidated report following a co-development agreement (e.g. if two or more organizations are jointly developing an IMP) and on whether any of the sponsor(s) is commercial (e.g. pharmaceutical industry; hospitals and universities are classified as 'non-commercial')
2. Check that the displayed name of the sponsor responsible for the submission is correct. If applicable, you can also **identify the Applicant** which has the overall responsibility for the ASR submission, including the submission of responses to the RFI through the system, and will also be the recipient of all notices and email notifications related to the ASR:
    - If the **ASR includes multiple sponsors** and the applicant is one of the sponsors listed in the ASR: use the toggle button next to the sponsor to designate the relevant sponsor as the Applicant, and fill in the 'Contact details for ASR submission'

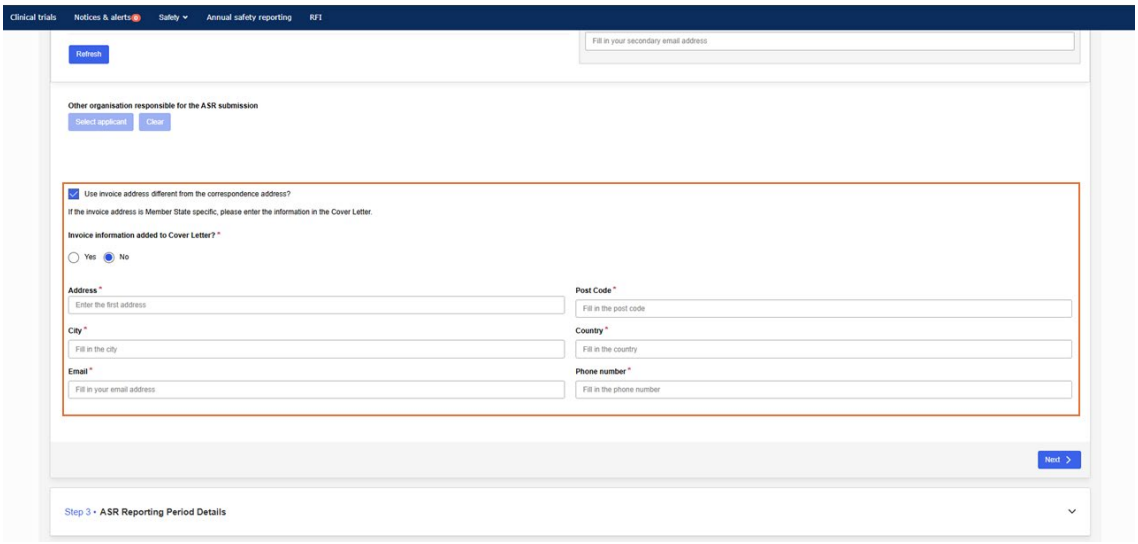


    - If the ASR is submitted **by another party**, such as Contract Research Organisation (CRO), the Applicant is not one of the listed sponsors, click on 'Select Applicant' and search for the organisation that is submitting the ASR on behalf of the sponsor(s)





3. Use the **checkbox** to indicate whether a different **invoice address** should be used instead of the applicant's correspondence address. If the invoice address is Member State specific, then this needs to be indicated in the cover letter and indicate whether it has been added by selecting Yes or No under 'Invoice information added to Cover Letter?'. If No is selected, the invoice address details must be entered in the fields below.

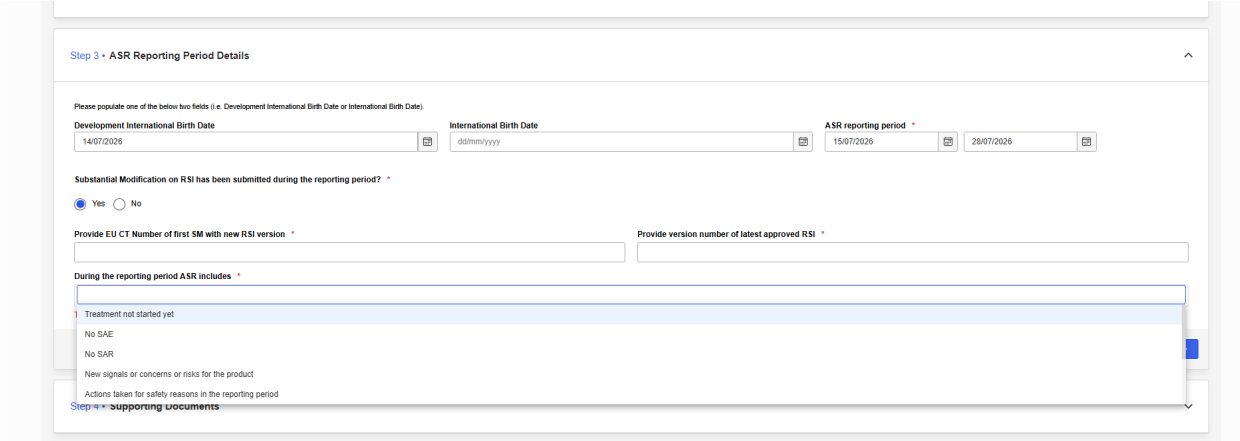


Step 3: ASR Reporting Period Details

In this section, the relevant reporting period information for the ASR need to be provided:

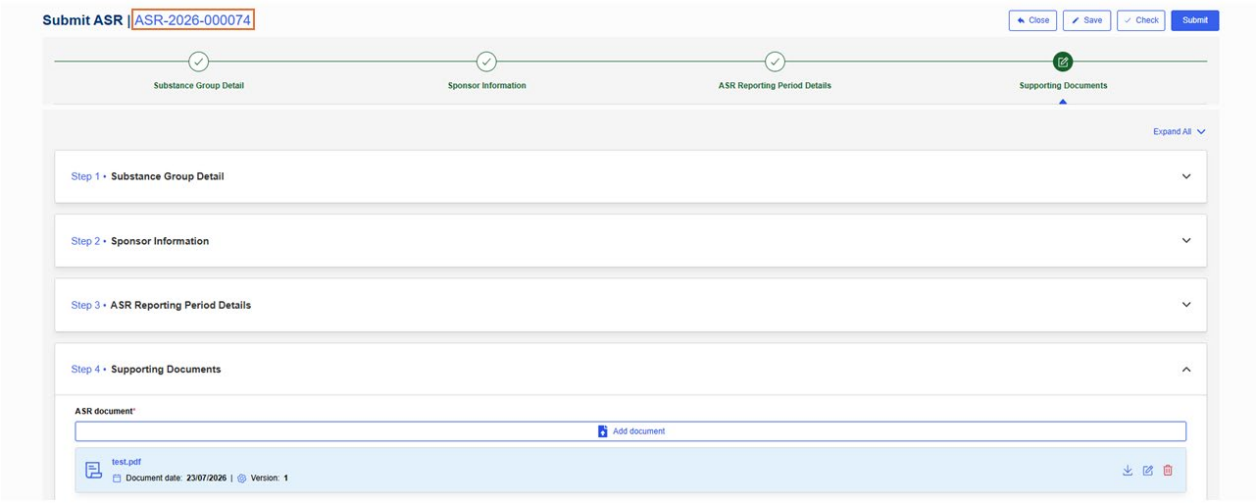
1. Enter either the **Development International Birth Date (DIBD)** or the **International Birth Date (IBD)** and specify the **ASR reporting period**.
2. Indicate whether a **Substantial Modification on the Reference Safety Information (RSI)** was submitted during the reporting period by selecting **Yes** or **No**. If yes is selected, additional fields will be displayed, requiring information on the relevant clinical trial and the version number of the latest approved RSI.

3. Use the **'During the reporting period ASR includes'** drop-down list to indicate whether any specific situations applied during the reporting period. Available options include scenarios such as 'Treatment not started yet', 'No SAE', 'No SAR', 'New signals or concerns or risks for the product', 'Actions taken for safety reasons in the reporting period', 'Vulnerable population (e.g. paediatric, pregnant, breastfeeding or incapacitated participants)', and 'First in class'. Select 'Other' when a safety relevant situation occurred during the reporting period, which is not represented by any of the options available in the list. Option 'None of the other options above' should be used when no safety related issue occurred during the reporting period.



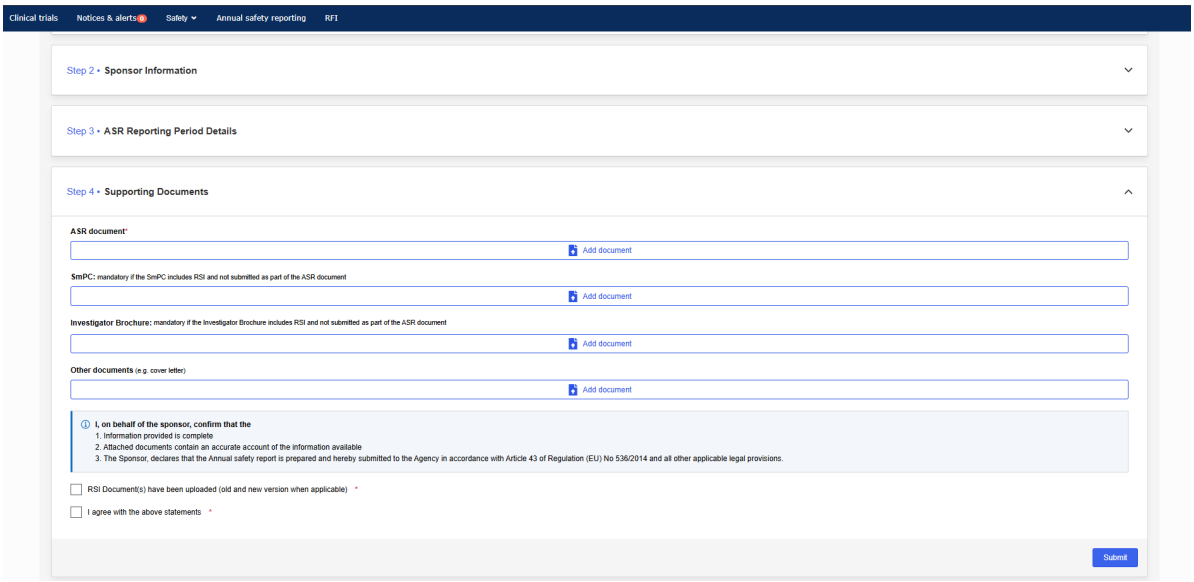
Step 4: Supporting Documents

In this section, users need to upload the ASR document, as well as any relevant supporting documents (i.e. Summary of Product Characteristics (SmPC), Investigator's Brochure (IB) etc.) **in PDF format.**

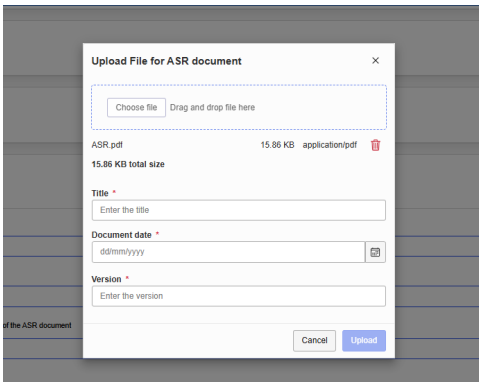


To prepare the ASR pdf document, a template for the ASR can be found in the 'Clinical Trial Safety' section in the CTCG Key Documents list. To correctly name it, see the 'Best practice guide naming of documents in CTIS', available in the 'Key document list' section on the CTCG page. The maximum allowed size per document is 50MB. None of the uploaded documents in this section is subject to publication. Steps to follow for the Sponsor user with **ASR Submitter** role to upload a document:

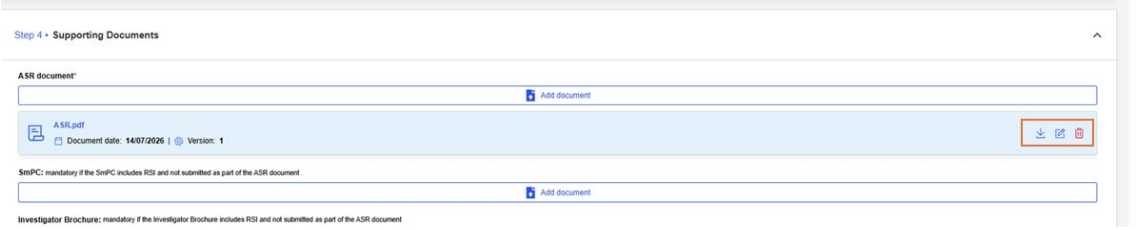
1. Click on '**Add document**' in the relevant document section and select the file to be uploaded.



2. For each uploaded document, complete the mandatory metadata fields and click on 'upload'.

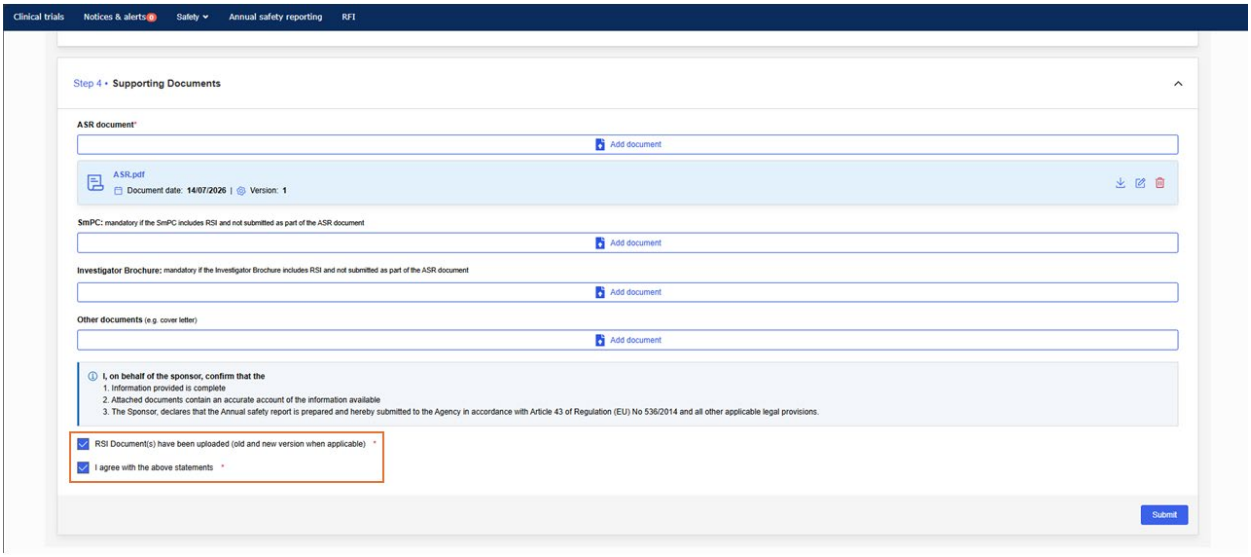


Once a document has been uploaded, it can be **downloaded**, **edited**, or **deleted** using the corresponding icons displayed on the right-hand side of the document entry. Additional documents may be uploaded at any time, where applicable.



3. Before submitting the ASR, ensure that all required documents have been uploaded and that the checkbox on whether the Reference Safety Information Document(s) have been uploaded is ticked.

4. Select 'I agree with the above statements' to confirm the declarations displayed on the screen.



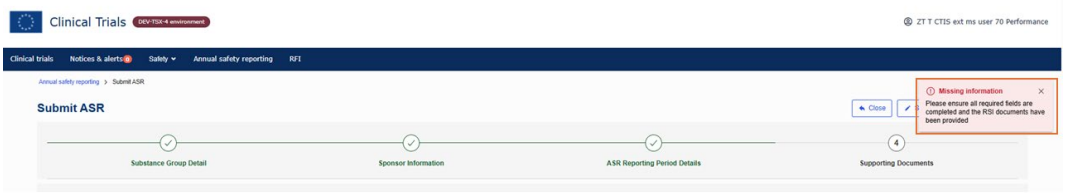
2.5.1.2. Check and submit the ASR

Once all steps are completed (i.e. all mandatory fields are filled in with the correct information and all required documents are uploaded in the right placeholders):

1. Scroll up to the top of the form and click on the '**Check'** button. The system verifies whether all mandatory sections of the ASR have been completed and whether all required information and supporting documentation have been provided. The validation includes checks on Substance Group Details / Clinical Trial Details, Sponsor Information, Applicant Information, Reporting Period Information, RSI-related information, Required declarations, Supporting Documents

    - If all required information has been provided, CTIS displays a confirmation message indicating that the ASR is complete and ready for submission:

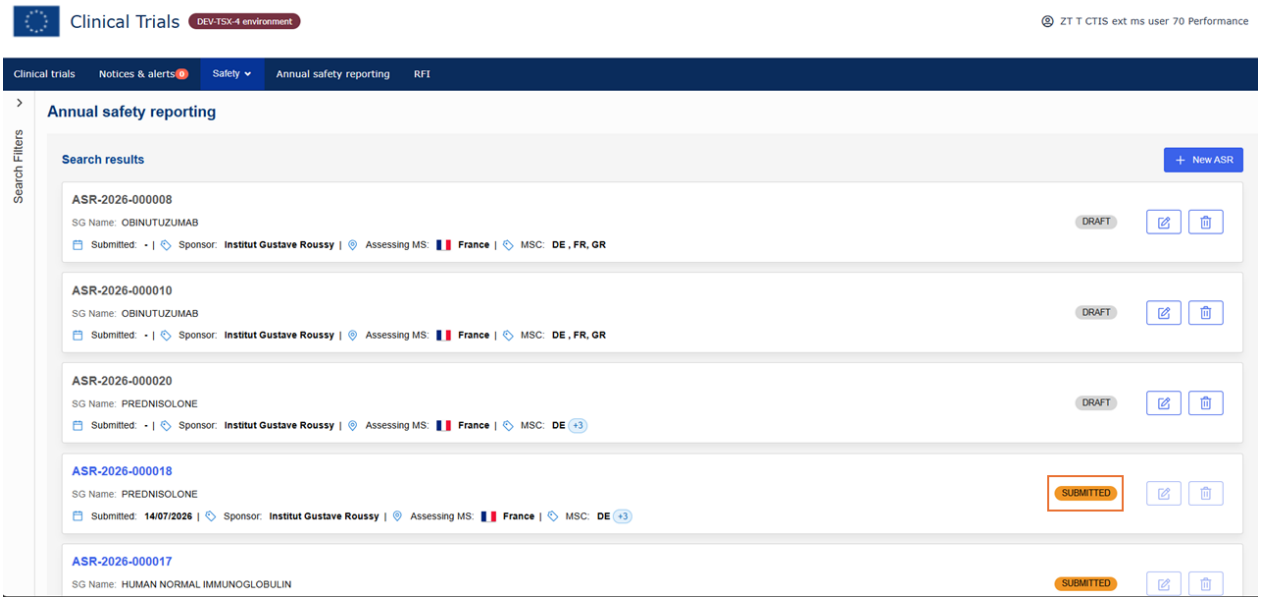
    - If mandatory information is missing or required documents have not been uploaded, CTIS displays a validation message identifying the section containing the missing or incorrect information so that the user can make the necessary corrections. The missing information must be completed before the ASR can be submitted.

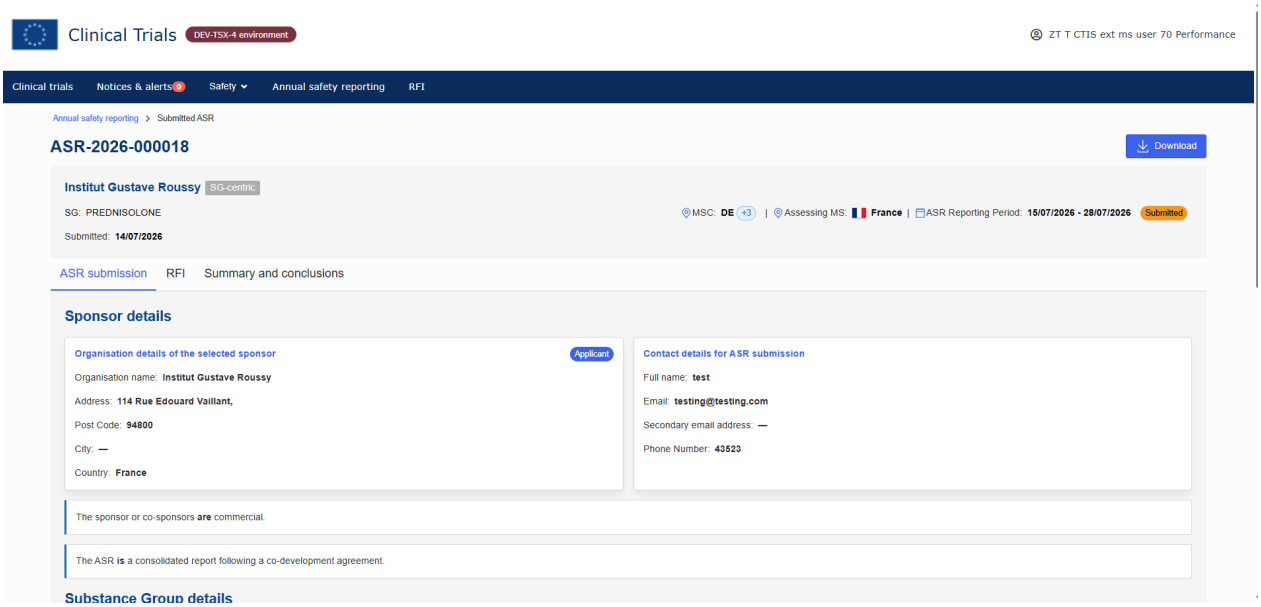


2. Once the validation is successful, select '**Submit'** to proceed with the ASR submission. Once the ASR is submitted, the submission date is recorded, and the ASR status changes from 'Draft' to 'Submitted'. **The sponsor can no longer modify the ASR** or **withdraw it.**

Once submitted, the submitted ASR becomes available for assessment and can be viewed from the Annual Safety Reporting page of the Safety tab. During this stage, sponsors can view the submitted ASR and any RFIs issued during the assessment process. Sponsors cannot modify an ASR also once the RFI is submitted but can only add supporting documents.

Once the assessment is completed (see section 3.), and the assessment outcome is available to sponsors in the Summary & Conclusions section, the ASR status will change to 'Finalised'.

- 



Note from the List of known issues and workarounds: CTIS users may encounter issues during the submission of ASRs for trials under those OMS ORG-IDs which were deleted in OMS (since they were identified as duplicates, see 22/12/2023 Newsflash). In this case you need to submit ASRs for trials under deleted ORG-IDs, you need to submit a substantial modification (SM) to change the sponsor of the trial to a valid ORG-ID. After the full authorisation of the change of sponsor SM, you can proceed with ASR submission.

3. Responding to an RFI raised during the ASR assessment

3.1. Assessment of the ASR by the assessing Member State

After submission, the Assessing Member State is assigned automatically according to the ASR type:

- For a **Substance Group-centric ASR**, the Assessing Member State is the saMS assigned to the relevant Substance Group.
- For a **Clinical Trial-centric ASR**, the Assessing Member State is the RMS of the selected Clinical Trial.

The assigned Assessing Member State is responsible for coordinating the assessment of the ASR.

Following submission, the Assessing Member State reviews the ASR and may consult the Member States Concerned (MSCs), where applicable. The assessment process may include:

1. Preparation of a Draft Assessment Report (DAR)
2. review of comments received from MSCs
3. if needed, creation of one or more RFIs, where clarification from the sponsor is required by the Assessing Member State
4. Preparation of a Final Assessment Report (FAR).

The DAR and FAR are internal assessment documents and are not visible to sponsors. According to the implementing regulation, Member States should conclude the ASR assessment within 42 days or, in case an RFI is raised, 84 days.

During the assessment process, sponsors can access the ASR details page and view:

- the **ASR Submission** section, containing the submitted ASR data and supporting documents;
- the **RFI** section, containing any RFIs issued by the Assessing Member State and the corresponding sponsor responses;
- the **Summary & Conclusions** section, which becomes available only after the assessment has been finalised.

The assessment outcome becomes available to sponsors once the ASR status changes to 'Finalised'. Sponsors also receive an 'ASR assessment finalised' notice when the assessment process has been completed and the Summary & Conclusions section becomes available. Users who have opted to receive CTIS email notifications will additionally receive these notices by email.

Refer to Authority Guidance: New Safety Module on the Annual Safety Report for more information on saMS selection and ASR assessment.

3.2. How to respond to RFIs raised by the assessing MS on an ASR

Once an RFI is submitted by the Assessing Member State (see step 3 of section 3.1.), an **RFI ID** is assigned to it. The RFI ID is a unique identifier composed of the acronym, year and sequential number of the ASR and RFI (for example: RFI-ASR-2026-00001-1).

Only one RFI can be active at a time. Once the RFI is submitted, it becomes visible to the sponsor, the RFI status changes to 'Pending', and the sponsor receives an 'RFI submitted' notice in the Notice

Centre. Following assessment of the sponsor response, if the information provided is considered insufficient, an additional RFI may be issued after closure of the previous RFI by the assessing MS.

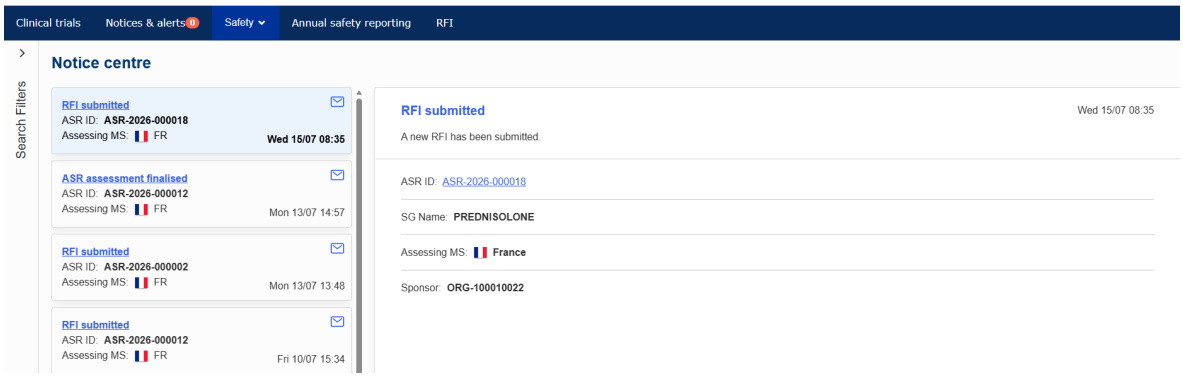
When the assessing MS creates an RFI, the **due date** for the sponsor to respond to the ASR RFI **is set automatically to 14 days**. However, before submitting the ASR RFI to the sponsor, **the assessing MS could also reduce this deadline**.

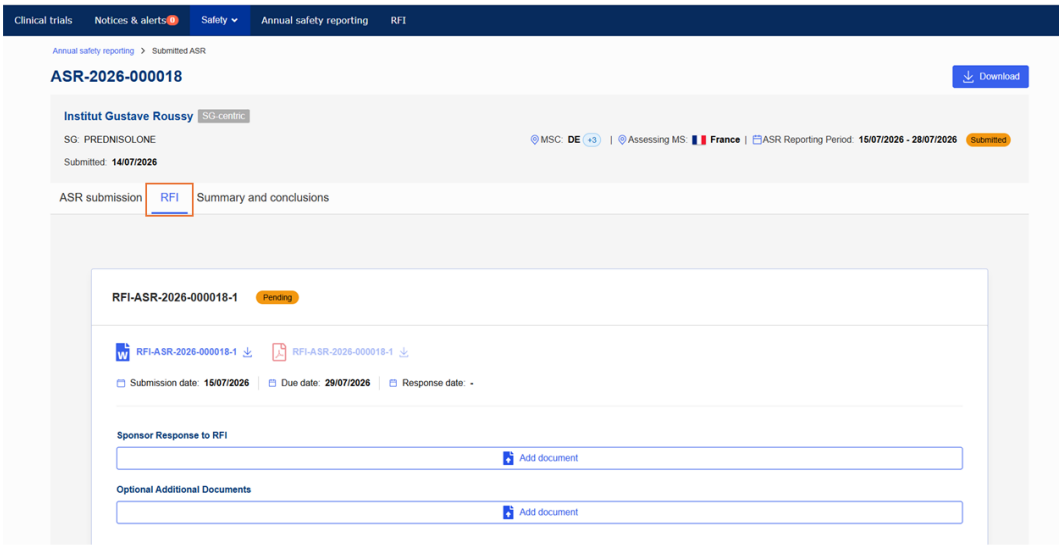
The ASR Submitter receives an **'RFI submitted' alert** for any RFI raised as part of an ASR assessment under the 'Notice centre' tab. The alert is also sent to the e-mail address registered in Identity and Access Management (IAM) for the specific user, if the user has opted in to receive e-mail notifications. The ASR Submitter should take note of **the due date** of the ASR RFI.

Below, there are the steps that sponsor user with **ASR Submitter** role should follow to access and submit responses to RFIs created by the assessing MS in the context of the ASR assessment. Note: the ASR Submitter is the only role that can view an ASR RFI and reply to it (not even the CT Admin can see if an RFI was submitted on one of their trial's ASRs), see section 2.2. .

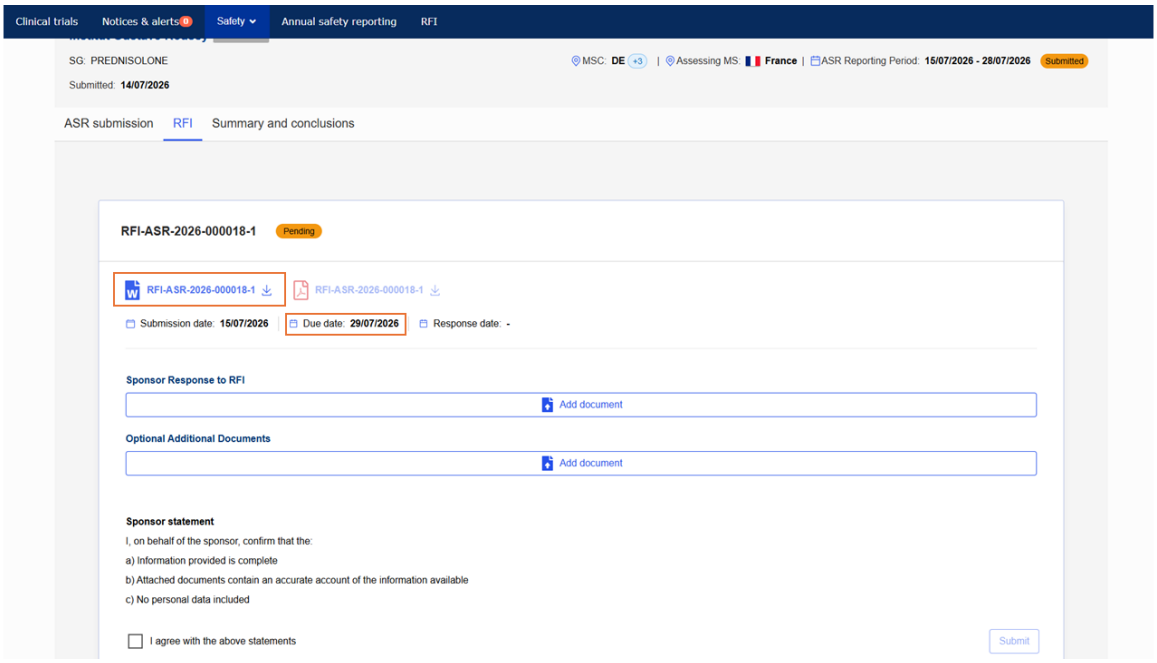
After having accessed the Sponsor workspace:

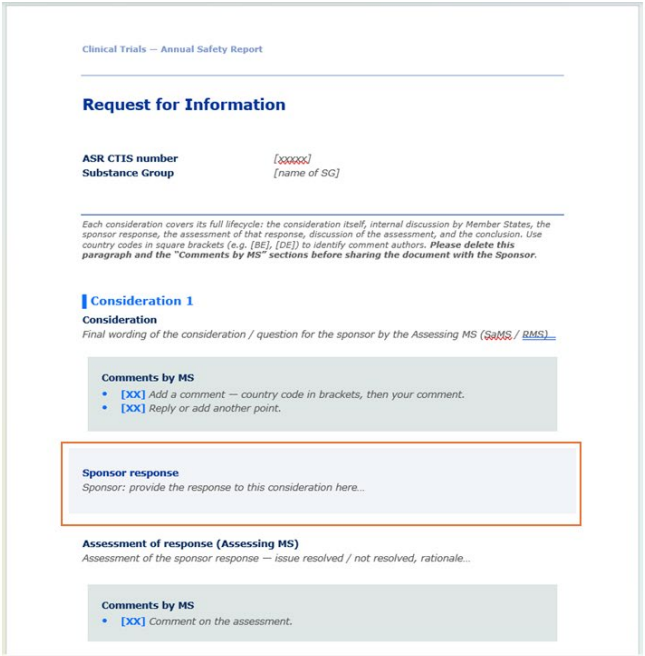
1. From the 'Safety' tab, access the RFI through either via the 'Notice Centre' by opening the corresponding 'RFI submitted' notice, and clicking on the ASR ID; in alternative, via the 'Annual safety reporting' tab by clicking on the relevant ASR ID and once on the ASR information page, navigate to the RFI tab. Once the ASR is opened, **the due date to answer the RFI is displayed**.





2. The RFI document, containing the list of consolidated considerations raised by the Member States, is available **in Word** (pdf is greyed out as it will be available after go-live) for review and download.

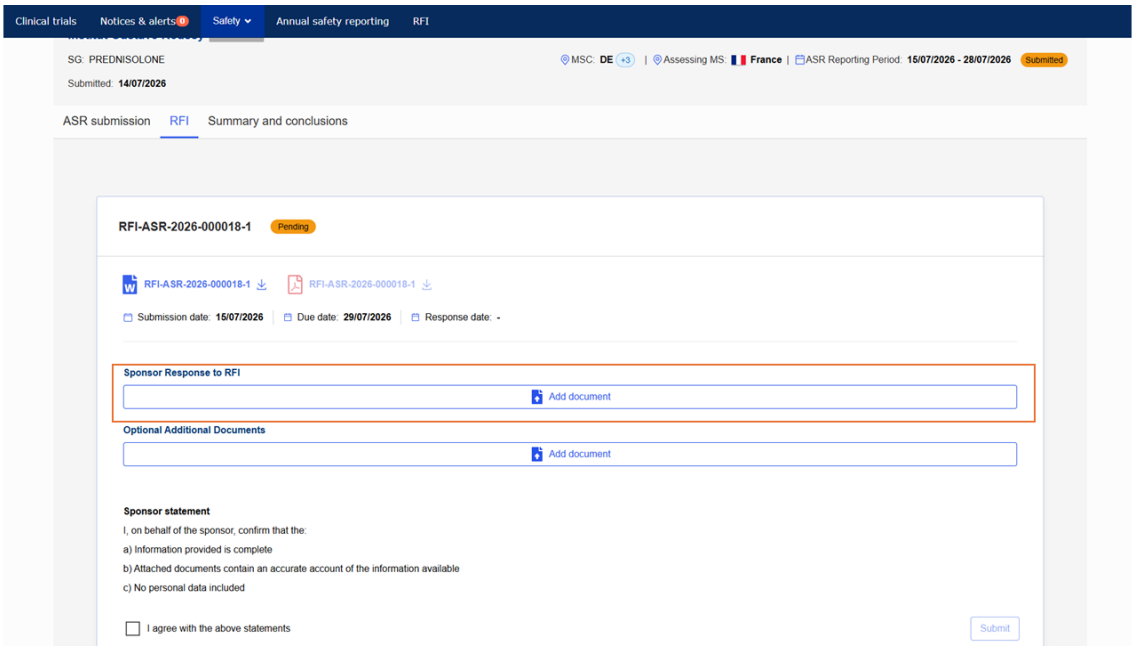


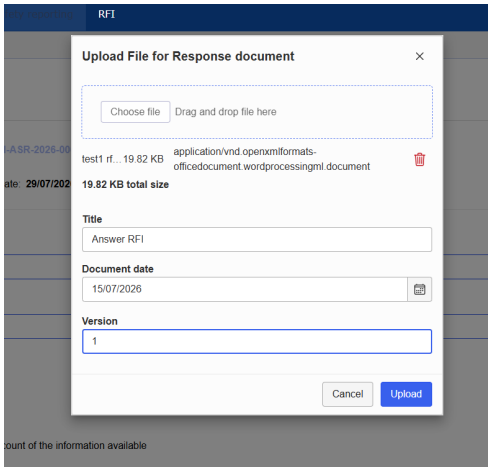


3. After downloading **the word document** respond to a**ll considerations** raised by the assessing MS,

4. Upload the RFI response document **as a Word document** under 'Sponsor Response to RFI' sub-section: click 'Add document' and complete the metadata fields: Title, Document date and Version. Once a document has been uploaded, it can be downloaded, edited, or deleted using the corresponding icons displayed on the right-hand side of the document entry. Note: **during the preparation of a response to an RFI, the only part that is possible to update in the ASR is the 'Contact information of the Applicant'.** If the contact information needs to

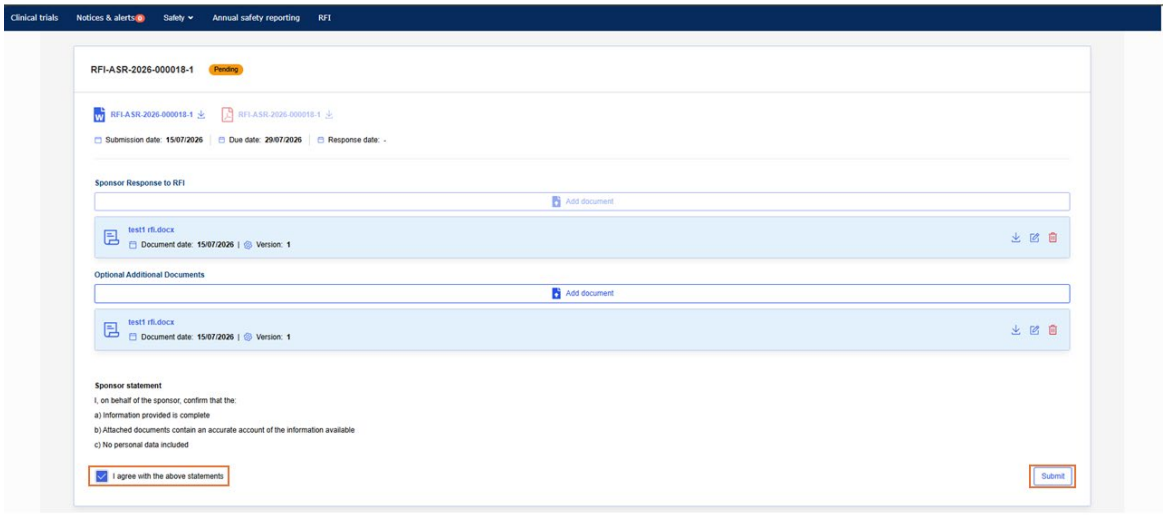
be updated in the ASR, the ASR can only be saved (submission is disabled). Once saved, the updated information is reflected in both sponsor and authority workspace. In the RFI response, please indicate that the contact details have been updated.

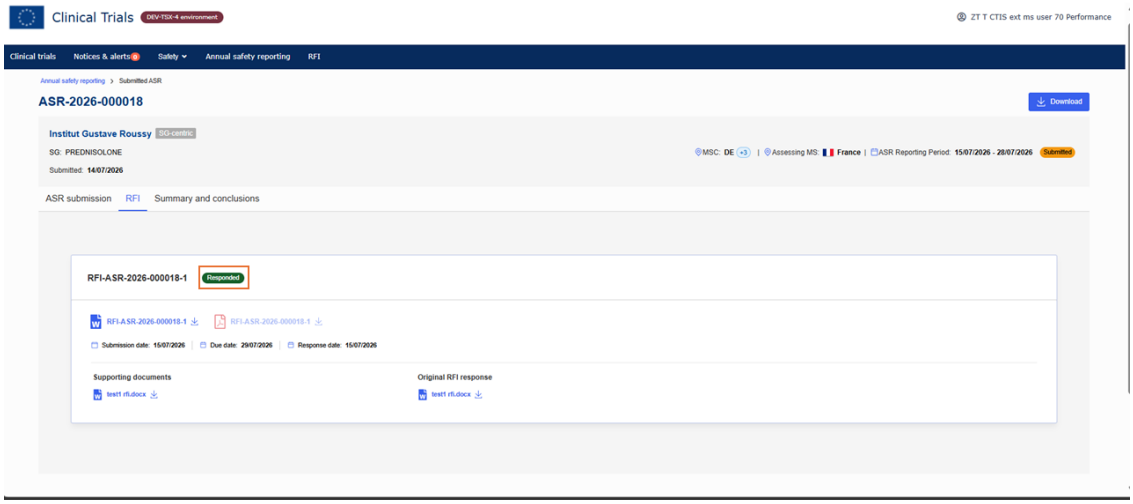




3. Upload any supporting document through clicking on '**Add document**' It is possible to add more than one document, if necessary. To name the document, the Sponsor user should consult the 'Best practice guide naming of documents in CTIS', available in the 'Key document list' section on the CTCG page. Note: **submitting a new document (e.g. a new ASR document) as an ASR RFI supporting documentation does not replace the original document, neither create a new version of it.**

4. Tick the checkbox to agree with the ASR RFI response submission statement and click 'Submit'. **Note:** submission will only be possible after the Sponsor has uploaded the RFI response document and the sponsor statement has been acknowledged, at which point the 'Submit' button will be enabled to submit the RFI response. Once the RFI response is submitted, the RFI status changes to 'Responded'.





The ASR RFI response follows an assessment process similar to the responses to other types of RFIs (see section 3.3 of the Sponsor Handbook). An ASR RFI response is assessed by the assessing MS , which has the responsibility to **perform an assessment of the ASR RFI response**. The assessing MS can reply to each sponsor response individually and after the assessing MS has assessed the response, the MSCs can comment on the assessment of the ASR RFI response made by the assessing MS. In case the **RFI response is deemed insufficient**, a **new RFI** can be created. The flow will be the same as for the first RFI described above.

If the RFI response is accepted by the assessing MS, no notification is sent to the sponsor.

3.3. ASR Assessment finalisation by the Assessing MS

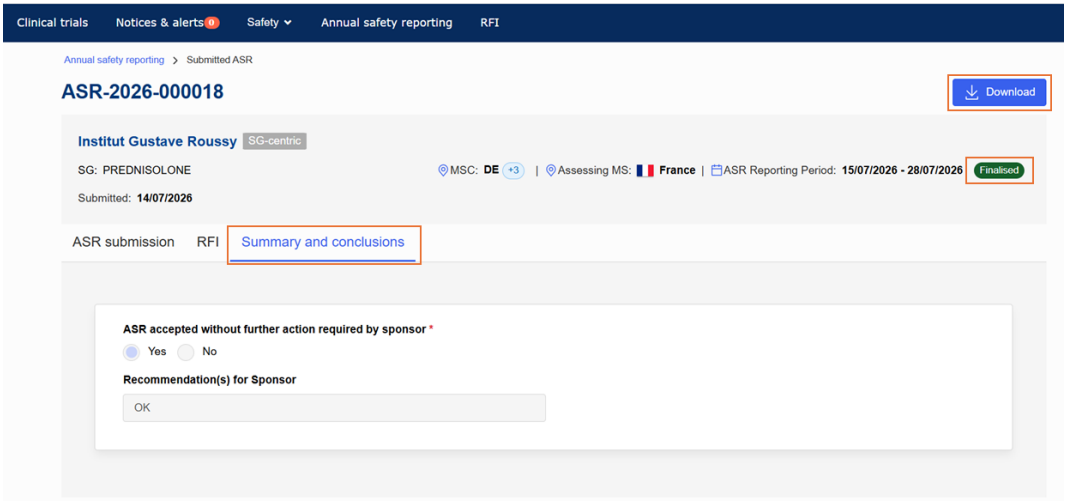
Once the Assessing Member State shares the final assessment outcome and the ASR status changes to Finalised, the sponsor receives an 'ASR assessment finalised' notice in the Notice Centre. Users who have opted to receive CTIS email notifications also receive an email notification.

The Summary & Conclusions section contains the final outcome of the assessment. Depending on the assessment outcome, it may:

- confirm that the ASR has been accepted without further action from the sponsor;
- identify specific follow-up actions requested from the sponsor;

- provide deadlines for completion of those actions;
- provide recommendations, guidance or observations from Member States.

Sponsors should review the Summary & Conclusions section carefully and ensure that any requested actions are completed within the specified timelines.



The sponsor will be able to download after go-live all information related to a finalised ASR by clicking the 'Download' button located in the top-right corner of the ASR page. Currently, only the ASR submitted will be downloaded. The downloaded package will contain:

- the ASR submission and supporting documents;
- all RFIs and RFI responses exchanged during the assessment process;
- the Summary & Conclusions section available to sponsors.

This allows sponsors to retain a complete record of the ASR procedure and its outcome.

4. CTIS Support

If the behaviour of CTIS training environment in relation to the New Safety Module differs from what is described in this guidance or demonstrated during the Bitesize talk, users **should first carry out the following checks:**

- For a specific issue such as missing tabs, timeouts or empty warning messages, consult the Annex I: List of known issues and workarounds to determine whether the issue has already been identified and whether a workaround is available.
- For login-related issues, check whether the issue can be solved following the guidance provided for EMA account management.

If none of the above applies, and the issue **cannot be solved internally or by using an available workaround**, users may contact EMA via EMA CTIS Service Desk or submit feedback via Slido, depending on the severity and impact of the issue.

4.1. Reporting blocking issues and questions

To support efficient triage and resolution of issues and questions, **blocking issues and blocking questions should be reported via EMA CTIS Service Desk**. An issue or question is considered blocking when it:

- **prevents the completion of a training activity**
- has no reasonable workaround
- prevents access to essential functionality, data or services, and
- requires resolution before the affected process can continue

When submitting a ticket through the Service Desk, users should:

1. Use the Request form for questions and the Incident form for technical issues.
2. Indicate in the '**Subject'** field that the issue concerns the **'CTIS training environment – New Safety module'** and Select **'CTIS training environment'** in the '**CTIS Request type'** field.
3. Provide a detailed **description** of the issue or question, including:
    - The affected screen or area (e.g. ASR drafting, notice centre etc)
    - The steps performed (e.g. created a new ASR and attempted to submit it)
    - The expected result (e.g. successful submission of ASR)
    - The actual result observed (e.g. an error message displayed and submission failed)
    - The impact on the training activity (e.g. prevents completion of the training exercise)
    - Any supporting screenshots showing the full view from the user's perspective

4.2. Reporting non-blocking issues and feedback

Non-blocking issues/observations, minor defects and general feedback should <u>not</u> be reported to the CTIS Service Desk. The following instructions apply to **a Sponsor user that needs to report non-blocking issues/questions/feedback** on the New Safety Module on ASR:

1. Access **Slido** using code #sponsors or by scanning the QR code below:

2. Check whether the same or a similar observation/issue has already been submitted. If so, upvote the existing entry rather than submitting a duplicate.
3. If no similar issue/question/feedback appears on the Slido, proceed with submitting it

This channel will be monitored and used for observations and feedback that may be considered during the finalisation of the development of the New Safety Module on ASR.

For further information on CTIS training and support, see section 6 of the Sponsor Handbook.

Annex I: List of known issues and workarounds

The purpose of this Annex is to describe issues known to occur in the Sponsor CTIS training environment upon implementation of the New Safety Module on ASR. Relevant workarounds to apply are described. Each issue is numbered and connected to a number (‘[ADO-xxxxxx]’): this number is unique and is used internally by EMA to identify and track the issue from reporting to resolution.

1. Overarching issues affecting CTIS and New Safety Module

This section covers known issues that cut across both the Access and User Management screens (User Administration, My Roles and the Personal Profile) and the Safety module.

1. Issue: Due to intermittent technical issues, screens related to access and user management, as well as safety may fail to load: results may not appear, may keep loading indefinitely, or may return a generic error message. [ADO-331900].

> **Workaround:** Refresh the screen or retry after a short interval. If the problem persists, contact the EMA CTIS ServiceDesk.

2. Access and User Management

This section covers known issues related to user account management, role assignment and access control, including the User Administration and My Roles screens across the Clinical Trial and Safety tabs, and the Person Profile screen.

1. Issue: When a user is on the 'My Roles' page or the 'User Administration' tab and refreshes the browser, the system redirects to the Clinical Trials homepage, and the current page context is lost. [ADO-318624].

> **Workaround:** Navigate back to the intended page after refreshing. Avoid using browser refresh on these screens.

2. Issue: When a browser tab is duplicated and the user logs out in the duplicate, the original tab refreshes and returns to the login screen, but the duplicated tab shows the logout message without automatically refreshing. [ADO-320212].

> **Workaround:** Manually refresh or close the duplicated tab after logging out.

3. Issue: When adding or deactivating a location, the attachments section does not yet follow the required behaviour (PDF-only, multiple documents, per-file size limit and document actions). [ADO-326258].

> **Workaround:** Perform changes in OMS directly.

4. Issue: A user with the MAH Admin role cannot see the Safety tab in My Roles. [ADO-332111].

> **Workaround:** There is no workaround until the issue is fixed. Contact the EMA CTIS ServiceDesk for urgent assignments.

5. Issue: Attempting to deactivate a trial site (location) via the Personal Profile returns an error. [ADO-332294].

> **Workaround:** Perform changes in OMS directly.

6. Issue: In My Roles (Sponsor workspace, Safety tab), the Advanced Search does not work properly. [ADO-332702].

Workaround: Use basic search fields until the issue is fixed.

7. Issue: In User Administration, the Clinical Trial tab is visible to Sponsor Safety Admin users when it should be hidden from them. [ADO-334264].

Workaround: Sponsor Safety Admin users should disregard the Clinical Trial tab until the issue is fixed.

8. Issue: In both User Administration and My Roles, the search results are clickable when they should not be, upon clicking an error is displayed. [ADO-334293].

Workaround: There is no workaround until the issue is fixed.

9. Issue: In the Clinical Trial tab of both My Roles and User Administration, roles fail to load from time to time. [ADO-334294].

Workaround: Search button needs to be clicked first.

10. Issue: In the Personal Profile, the 'My Employer' information is displayed incorrectly. [ADO-334295].

Workaround: Update the 'My Employer' information to the correct organisation.

11. Issue: In the User Administration Safety tab, legacy Enterprise roles are displayed when they should not be. [ADO-334297].

Workaround: Disregard the Enterprise roles shown until the issue is fixed.

12. Issue: When assigning a role, the expected confirmation pop-up window does not appear. [ADO-334300].

Workaround: Verify the assignment before confirming.

13. Issue: When the User Administration screen has many results across many pages, clicking a page number can lead to an error instead of showing the selected page. [ADO-334637].

Workaround: Retry the navigation or narrow the search criteria to reduce the number of result pages.

14. Issue: In the User Administration screen and My Roles screen, the Authorised Date is not consistently formatted (all dates should be DD-MM-YYYY). [ADO-334640].

Workaround: There is no workaround until the issue is fixed.

15. Issue: There is a typographical error in the error message shown when a role search fails during role assignment. [ADO-335105].

Workaround: No action required; cosmetic text issue.

16. Issue: In My Roles, both in the Safety tab and the Clinical Trial tab, no check is currently performed when requesting a role that has already been requested or approved. [ADO-332721] [ADO-333310].

Workaround: There is no workaround until the issue is fixed.

17. Issue: Across the User Administration and My Roles screens, several advanced-search filters and sort options do not work correctly. The affected fields vary by tab and workspace (e.g. email, role, organisation name/ID filters, and sorting by role, status, employer or 'authorised from'). [ADO-332298] [ADO-332301] [ADO-333301] [ADO-332702] [ADO-333155] [ADO-328836].

Workaround: Use the filters and sort options that are working for the relevant screen, and narrow results with basic search until the issue is fixed.

18. Issue: In the Personal Profile, when a user updates their employer via 'My Employer', the employer name changes but the address does not update to match the selected employer. [ADO-332307].

Workaround: After changing the employer, manually verify and correct the address until the issue is fixed.

3. New Safety Module on ASR

This section contains known issues related to the Safety module, including ASR and Notice centre screens.

1. Issue: When a document upload exceeds the maximum 50 MB limit, the file-size message displayed to the user is misleading. [ADO-315216].

Workaround: Ensure uploaded files are within the 50 MB limit; split large documents if necessary.

2. Issue: Documents that are downloaded lose their original file name. [ADO-316527].

Workaround: Rename downloaded files manually if needed.

3. Issue: Occasionally, a notification can take an unexpectedly long time before it is displayed in the Notice centre. [ADO-319019].

Workaround: Wait a couple of minutes and refresh the Notice centre if an expected notification is not shown.

4. Issue: During ASR submission, an empty Country field is incorrectly accepted by validation as successful, when it should be flagged as a required field. [ADO-326731] [ADO-328405].

Workaround: Ensure the Country field is completed before submitting the ASR.

5. Issue: When an ASR is saved without a selection in the Organisation Details radio buttons for the sponsor(s), reopening it in Edit mode causes the system to pre-populate those buttons with 'No', although no selection had been made. [ADO-326867].

Workaround: Review and correct the Organisation Details radio-button values each time the ASR is reopened in Edit mode before submitting.

6. Issue: After opening an ASR-related notice via its hyperlink, the user is taken to the ASR detail screen and cannot navigate back to the Notice Centre using the menu (the user stays on the assessment screen). This occurs only when arriving via the hyperlink. [ADO-327621].

Workaround: Refresh the page and navigate to the Notice Centre directly rather than via the hyperlink.

7. Issue: When creating a new SG-centric ASR and searching for a Substance Group by EU CT Number, the system returns the SG with only the single CT matching the number, rather than all linked CTs the user can access. Searching by SG name works correctly. [ADO-327848].

Workaround: Search using the Substance Group name (rather than an EU CT Number) to display all linked accessible CTs.

8. Issue: In the ASR Detail view, the active substance name is shown instead of the product name for IMPs whose product name is not null, and the IMP string is split incorrectly, inflating the apparent number of products. [ADO-327925].

Workaround: Consult the original CT application for accurate IMP product-name information.

9. Issue: A mandatory field is indicated only by text and not by the standard red-box highlight, making the requirement less visible. [ADO-328198].

Workaround: Ensure all mandatory fields are completed regardless of highlighting.

10. Issue: In the 'Select another organisation' pop-up, the City field appears empty even though a value is present in the underlying organisation record. [ADO-327928].

Workaround: Verify the city value in the organisation record; the data is present despite the empty display.

11. Issue: When uploading a document, the document version of type x.yy is incorrectly not allowed. [ADO-328274].

Workaround: Record the document version differently.

12. Issue: When a valid, existing EU CT Number is entered in the Safety Issue Tracker, it should act as a hyperlink to the CT summary page, but the link does not currently work. [ADO-295613].

Workaround: Navigate to the CT summary page manually via the Clinical Trials search.

Annex II: Acronyms and definitions

Acronym	Definition
ASR - Annual Safety Report	Report submitted annually by the sponsor in accordance with Article 43 of Regulation (EU) No 536/2014 to provide an evaluation of the evolving safety profile and benefit-risk balance of the investigational medicinal product(s).
CRO - Clinical Research Organisation	A service organisation that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services. It is also called a clinical research organisation.
CT - Clinical trial	Refer to Article 2(2)(2) of the CTR.
CTCG - Clinical Trials Coordination Group	The CTCG is a European Heads of Medicines Agencies (HMA) working group of experts in the classification, assessment and oversight of clinical trials from National Agencies. This working group also promotes harmonisation of clinical trial assessment decisions and administrative processes across the national competent authorities (NCAs). More information here.
CTIS - Clinical Trial Information System	The single-entry point for sponsors and Member States for the submission, assessment, authorisation, supervision and transparency of clinical trials in the European Union and European Economic Area.
CTR - Clinical Trial Regulation (EU) 536/2014	EU pharmaceutical legislation aiming to harmonises the processes for assessment and supervision of clinical trials throughout the EU. On 31 January 2022, the Regulation repealed the Clinical Trials Directive (EC) No. 2001/20/EC and national implementing legislation in the EU Member States, which regulated clinical trials in the EU until the Regulation's entry into application. More information here.
DAR - Draft Assessment Report	Preliminary assessment report prepared by the saMS and shared with the MSC the coordinated ASR assessment.
DIBD - Development International Birth Date	The date of first authorization by a regulatory authority anywhere in the world for a clinical trial with the investigational medicinal product.
DSUR - Development Safety Update Report	ICH E2F annual safety report on which the Annual Safety Report submitted under the Clinical Trials Regulation is based.
EEA - European Economic Area	Economic area composed of Member States of the EU and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway; excluding Switzerland).
EMA - European Medicines Agency	Agency of the EU responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU, as well as for the maintenance and further development of the CTIS. More information here.
EU - European Union	Supranational political and economic union of 27 member states that are located in Europe.
FAR - Final Assessment Report	Final report adopted by the Safety Assessing Member State following the coordinated assessment of an Annual Safety Report.

Acronym	Definition
IAM - Identity and Access Management	User registration system that provides individuals with access to the applications that are managed by the EMA, including CTIS, XEVMPD, OMS, EV.
IB - Investigator Brochure	A multifunctional regulatory document essential for the conduct of clinical tri als that summarises the physical, chemical, pharmaceutical, pharmacological, and toxicological characteristics of an investigational medicinal product (IMP) as well as any clinical experience.
IBD - International Birth Date	First marketing authorisation anywhere in the world for the product. Typically, relevant after authorisation/post-marketing safety reporting.
ICH - International Council for Harmonisation	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use is an organisation responsible for developing internationally harmonised guidelines for the development, registration, and lifecycle management of medicinal products.
IMP - Investigational Medicinal Product	Medicinal product being tested or used as reference in a clinical trial.
MS - Member State	A Member State of the European Union/European Economic Area.
MSC - Member State Concerned	Member State in which the clinical trial concerned is authorised.
OMS - Organisation Management Service.	EMA management system managed providing a single source of organisation data, such as their names and addresses. More information here.
RFI - Request for Information	Request issued during the assessment process requiring the sponsor to provide additional information or clarification.
RMS - Reporting Member State	Member State leading the assessment of a clinical trial application.
RSI - Reference Safety Information	The approved safety information for an investigational medicinal product used as the reference for the assessment of expectedness of adverse reactions and for ongoing safety monitoring during a clinical trial.
SAE - Serious Adverse Event	Any untoward medical occurrence that results in death, is life-threatening, requires hospitalisation or prolongation of hospitalisation, results in significant disability or incapacity, is a congenital anomaly/birth defect, or is otherwise considered medically important.
saMS - Safety Assessing Member State	Member State that assesses the information contained in ASRs submitted in accordance with Article 43 of the CTR, leading the safety assessment of a Substance Group.
SAR - Serious Adverse Reaction	A serious event for which a causal relationship with the investigational medicinal product is at least reasonably possible.
SG - Substance Group	Grouping of related active substances for the purpose of safety assessment.
SM - Substantial Modification	A substantial modification as defined in Article 2(13) of Regulation (EU) No 536/2014.
SmPC – Summary of Product Characteristics	This is the product information document which is made available to all prescribing physicians in the EU for marketed products.