

1 September 2025

EMA/283849/2025

European Medicines Agency

Helpdesk for non-commercial sponsors: 6-month report

1. Background

The Accelerating Clinical Trials in the EU (ACT EU) priority action on the implementation of the Clinical Trials Regulation (EU) No 536/2014 (CTR), aims to promote clinical trial research by supporting non-commercial sponsors (NCSs) in using the Clinical Trial Information System (CTIS) and navigating the clinical trials landscape.

An important part of this activity has been the establishment of a dedicated helpdesk with the intention to facilitate dialogue and reduce the gap between NCSs and regulators.

The NCS helpdesk offers dedicated and expedited support from the moment a request is submitted; the whole process is managed through ServiceNow: a centralized support system that provides assistance to users requiring technical support and service requests while using CTIS. It offers tailored guidance and training to help NCSs strengthen their capabilities for successfully submitting clinical trial applications, while also allowing EMA to better understand their challenges and adapt its support accordingly.

2. Participants:

A dedicated team responsible for managing enquiries submitted and following a defined process flow was established within EMA; National Competent Authorities (NCAs) play an active role in the helpdesk by collaborating in responding to queries that require joint solutions or are complex in nature, particularly those not directly related to CTIS functionalities. In addition, NCAs may provide direct support to NCS users, following consultation with the helpdesk, when queries concern specific national requirements.

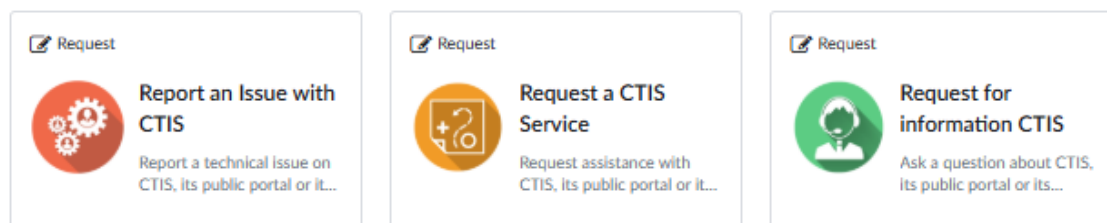
3. Process for CTR/CTIS helpdesk:

Entry points are identified for requests of support on CTR and CTIS use via ServiceNow where the user needs to select the request among three possible options (**Fig. 1**):

- **“Report an Issue with CTIS”** for technical issues; the so-called “incidents”,

- **"Request a CTIS Service"** for assistance (e.g. for support regarding the system functionalities),
- **"Request for information CTIS"** for the use of CTIS and regulatory questions.

Fig. 1: The image shows the three options available in ServiceNow to request support on CTIS.



After the request of interest is selected, the user needs to fill in the following fields and the affiliation where it is possible to specify that the request is raised by a NCS:

* Indicate required information

* Raise this request on behalf of

* Subject

* Description

* CTIS Request Type

* User affiliation

-- Please Select --

-- Please Select --

National Competent Authority

Commercial Sponsor

Ethics Committee

Non-commercial Sponsor

Other

Once the form is completed and submitted, the request is received and validated by the ServiceNow dedicated team. Validation process confirms the CTR/CTIS scope and affiliation of the submitter.

If the question is within the scope, the team provides a reply in writing within the timelines assigned based on the priority of the topic; these timelines are defined as SLAs (Service Level Agreements).

The user may require additional clarifications; in which case further support is provided accordingly. In case the issue persists, a virtual meeting can be organised with NCS representatives and CTIS experts, technical team, NCA members, as applicable.

After fulfilling the request, a satisfaction survey is submitted, and the process is closed.

4. Analysis of the first 6-months of activity of the helpdesk

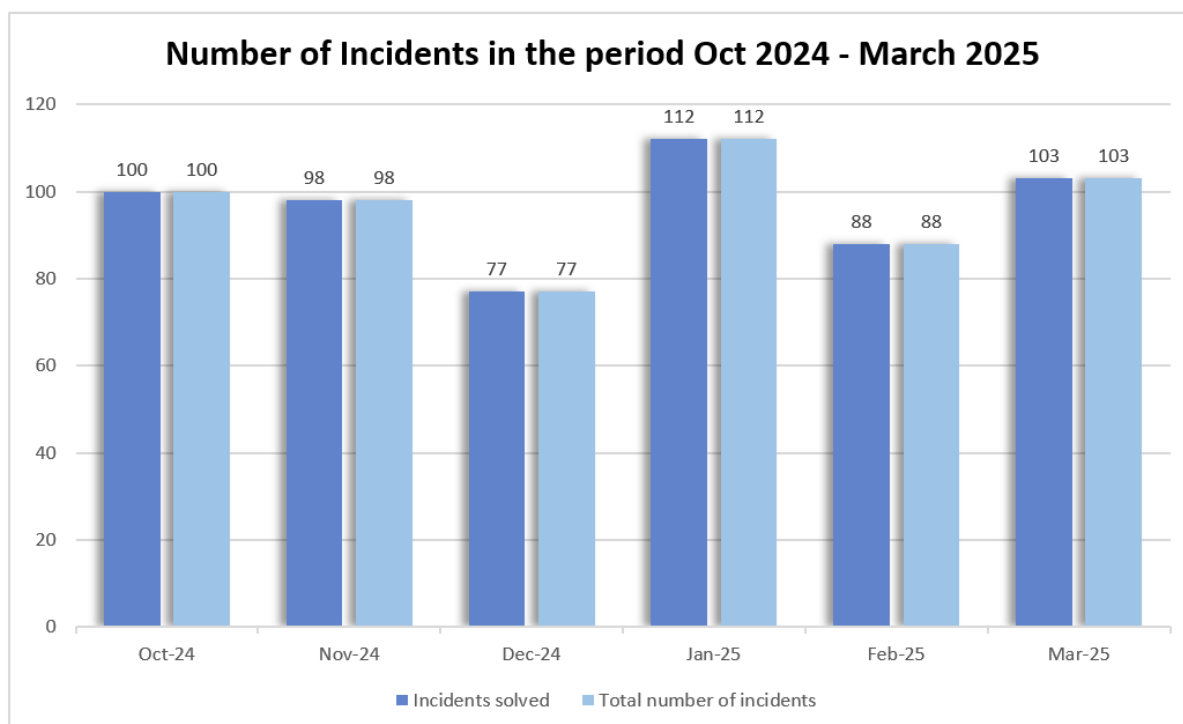
4.1. Issues reported / Incidents in the period October 2024 – March 2025 and time for resolution

The issues reported in ServiceNow related to technical problem with CTIS are also called “incidents”.

The graph below (**Fig. 2**) shows the total number of incidents reported by NCSs and the number of resolved incidents for the 6-month period Oct 2024-March 2025 divided per month.

All tickets raised under this category (**tot=578**) in the timeframe are considered closed.

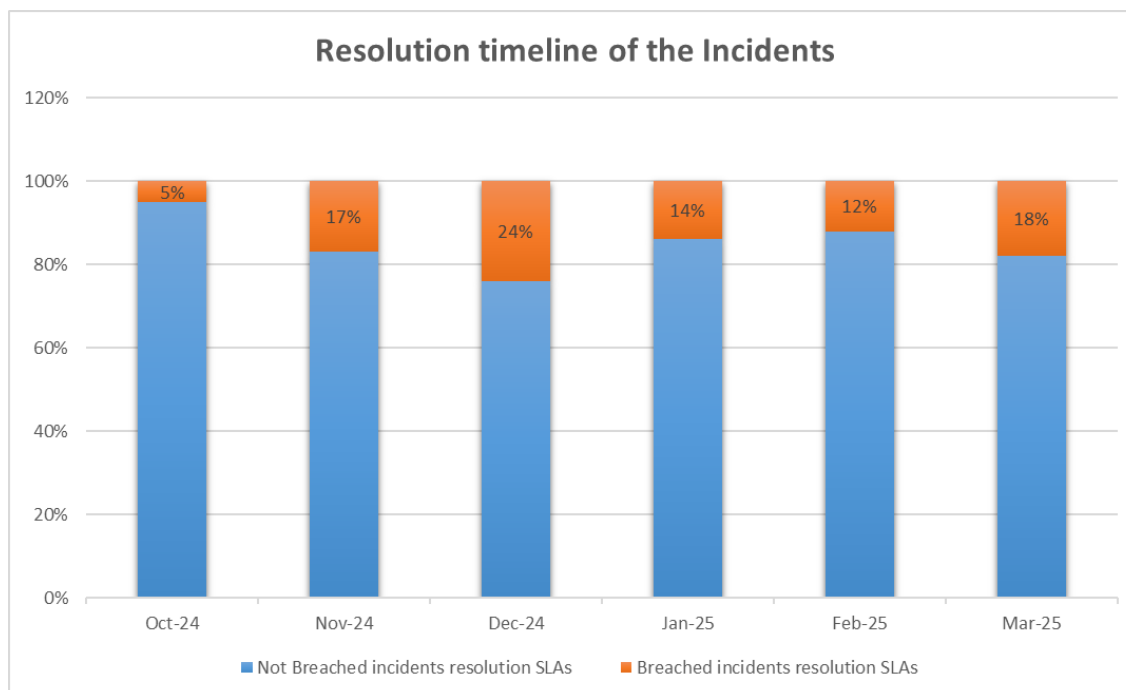
Fig. 2: Number of tickets raised on incidents in the timeframe considered Oct 2024- March 2025.



The graph below (**Fig. 3**) shows the percentage of incidents resolution based on SLAs timelines above mentioned, including percentage of tickets closed within and above the expected timeline.

An average of 87% of incidents has been resolved within the expected timelines based on the period Oct 2024–March 2025.

Fig. 3 Resolution timeline related to the incidents raised by NCSs in ServiceNow in the timeframe considered Oct 2024- March 2025.

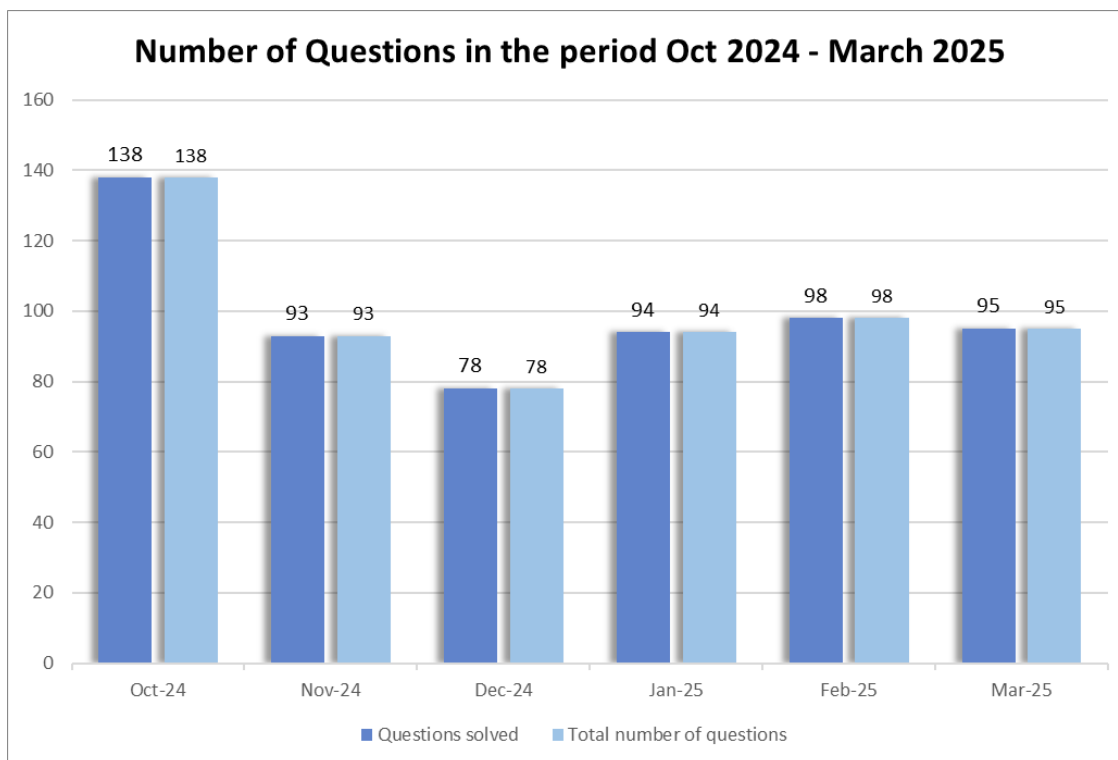


4.2. Request for service and for information / Questions in the period October 2024 – March 2025 and time for resolution

For the purpose of this report, requests for service and requests for information have been grouped together under the term “questions”. The graph below (**Fig. 4**) shows the total number of questions submitted by NCSs and the number of resolved questions for the 6-month period Oct 2024-Mar 2025 divided per month.

All tickets raised under this category (**tot=596**) in the timeframe are considered closed.

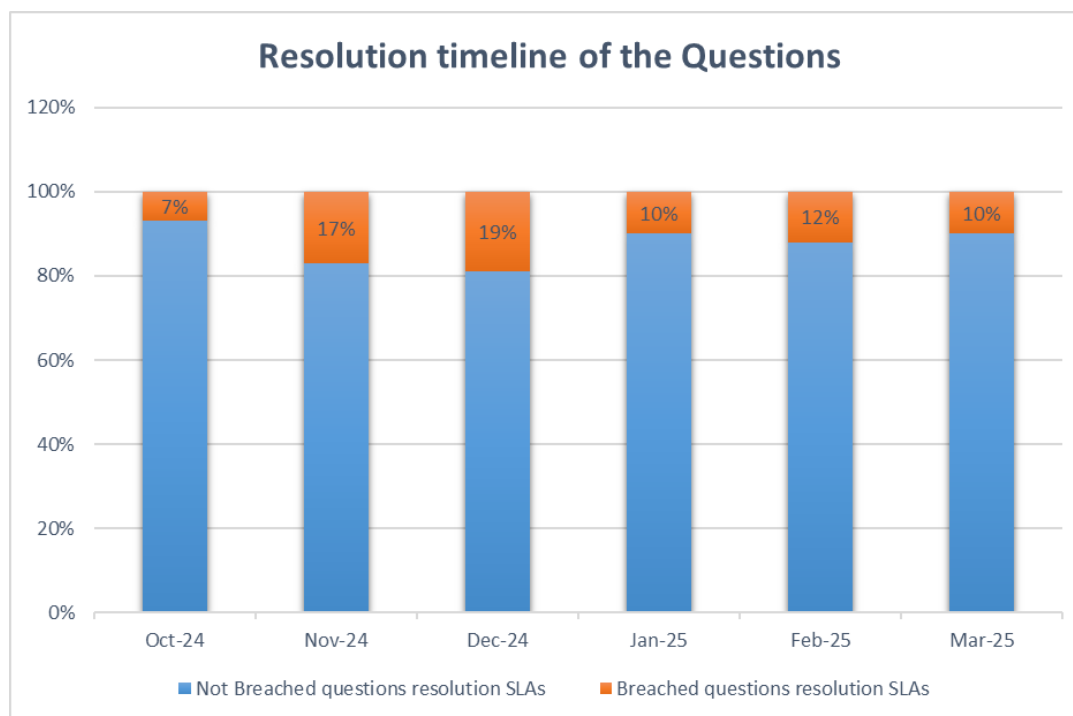
Fig. 4 Number of tickets raised on questions in the timeframe considered Oct 2024- March 2025.



The graph below (**Fig. 5**) shows the percentage of questions resolution based on the SLAs timeline, including percentage of tickets closed within and above the expected timeline.

An average of 90% of questions has been resolved within the expected timelines based on the period Oct 2024–March 2025.

Fig. 5 Resolution timeline related to the questions raised by NCS in ServiceNow in the timeframe considered Oct 2024- March 2025.



5. Main topics of the enquiries raised by NCSs

The following table (**Table 1**) shows a list of tags used to categorise the enquiries raised by NCSs. For each incoming enquiry one or more tags were assigned to accurately capture and categorise the nature of the request, enabling a structured and systematic classification of all requests. This categorisation will enable targeted support and clarification, as well as help gain a better understanding of the challenges faced by NCSs.

After tagging all requests, data was compiled and displayed in two sub-sections: one for incidents and one for questions. These sub-sections show the most common types of requests, offering insights into recurring issues and key areas of interest for NCSs.

Table 1. Tags used to categorise the enquiries (both incidents and questions) raised by NCSs.

Tag	When to be used
Change_sponsor_data	When a request is submitted for support to update sponsor data or the issue is related to a Sponsor (ORG ID) change
CTIS_improvement	For suggestions to improve CTIS functionality
CTIS_SM incident	For tickets related to incidents of SMs for trials (not blocking)
CTIS_SM incident blocked	For tickets related to SMs of trials whereby submission or response to RFI is blocked
CTIS_training	For tickets related to users needing advice on functionality of CTIS
CTIS_training_submission	For tickets related to user needing advice on how to proceed with the submission of the applications
CTIS_known issue	For tickets related to known issues and when tickets are associated to created Problems (issue reproducible)
CTIS_publication process	For tickets related to transparency
CTIS_RFI	For tickets related to RFI issues
CTIS_CTR interpretation	For tickets requesting general advice of interpretation of EU CTR and related to regulatory topics
CTIS_General error	For tickets related to general errors in CTIS functionality not associated to a Problem because not reproducible (e.g. temporary glitch)
CTIS_Transition	For tickets related to transition applications
CTIS_Lapsed CTA	For tickets related to lapsed trials
CTIS_Notification date	For tickets related to issues with notification dates (e.g. start of recruitment, temporary halt, global/local EOT)

CTIS_User access_roles	For tickets related to users not being able to access a trial or user is able to access part of a trial that they do not have access to or related to training about roles in general
CTIS_XEVMPD	For tickets related to integration between CTIS and XEVMPD
CTIS_OMS	For tickets related to integration between CTIS and OMS
CTIS_Notices_alerts	For tickets related to notices and alerts
CTIS_other	For tickets that cannot be classified otherwise (e.g related to MFA, login issues)
CTIS_ASR	For tickets related to ASRs
NCS_NCA	For tickets submitted by Non-commercial Sponsors in which NCA will be involved or where advice to refer to NCA is provided

5.1. Main topics of the incidents raised by NCSs in the period Oct 2024 – Mar 2025

The graph below (**Fig. 6**) shows the most frequent categories of incidents raised by NCSs in the reporting period, considering a total number of **578** incidents.

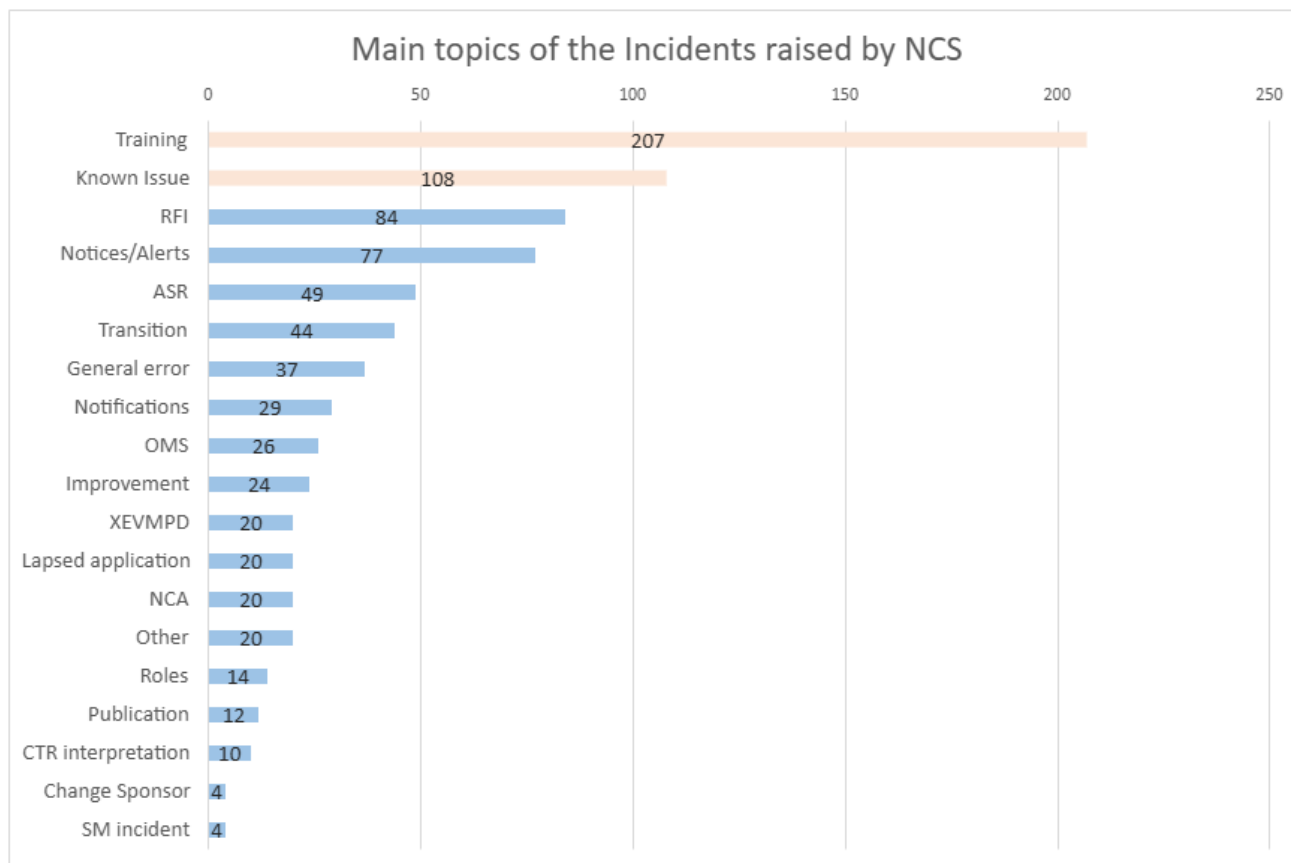
The two most frequent categories identified are “training” and “known issues” which are broader categories that include additional subcategories categories.

The “training” category covers tickets from users seeking guidance on CTIS functionalities. While the information shared by the helpdesk is generally available in the official user manuals and training materials, the assistance serves to help navigating these materials to the users who demonstrate a lack of familiarity with the system. Notably, 45 tickets under this category relate specifically to RFI (Request for Information), highlighting that sponsors often face difficulties managing the RFI response process.

The “known issues” category (108 tickets) includes cases associated with previously identified technical problems, which are recurrent under specific conditions and reproducible by the technical team. The most common issues reported in this category concern incorrect notices and alerts being triggered (44 tickets) and problems with submitting notification dates (12 tickets).

A significant number of incidents also concern other systems essential for correct sponsor registration in CTIS, such as OMS and XEVMPD.

Fig. 6 Main topics of the incidents in the timeframe considered.



5.1.1. Incidents raised by NCSs with implication of NCAs

Among the incidents reported by the NCSs, 20 required interventions at the level of the NCAs involved in the Clinical Trial Assessment. The figures below illustrate the primary topics associated with these incidents and identify the NCAs involved (**Fig.7** and **Fig. 8**).

Fig. 7 Topics where NCAs has been involved.

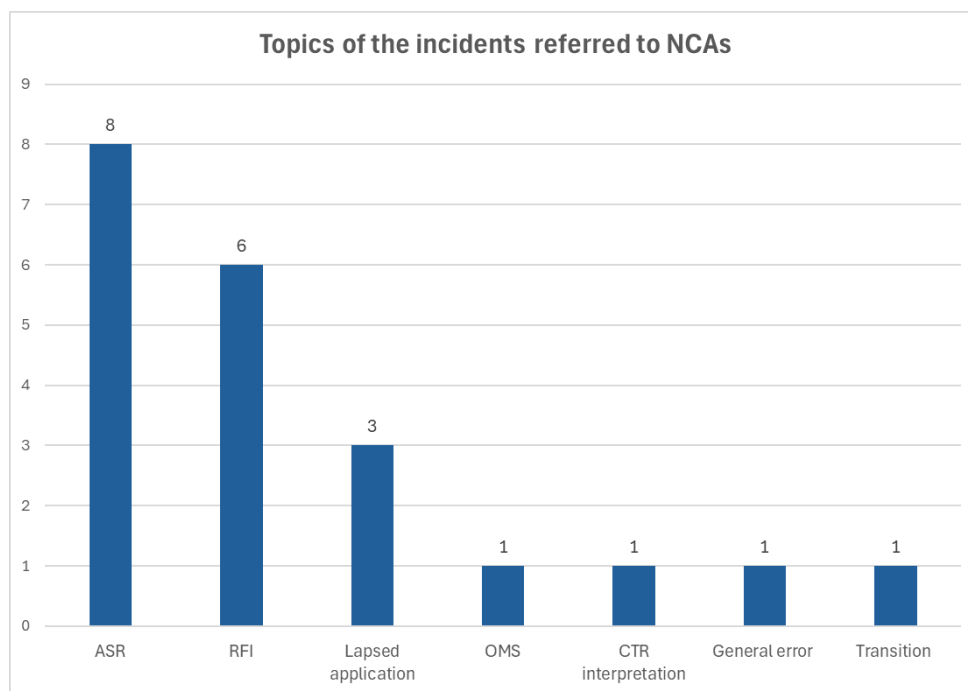
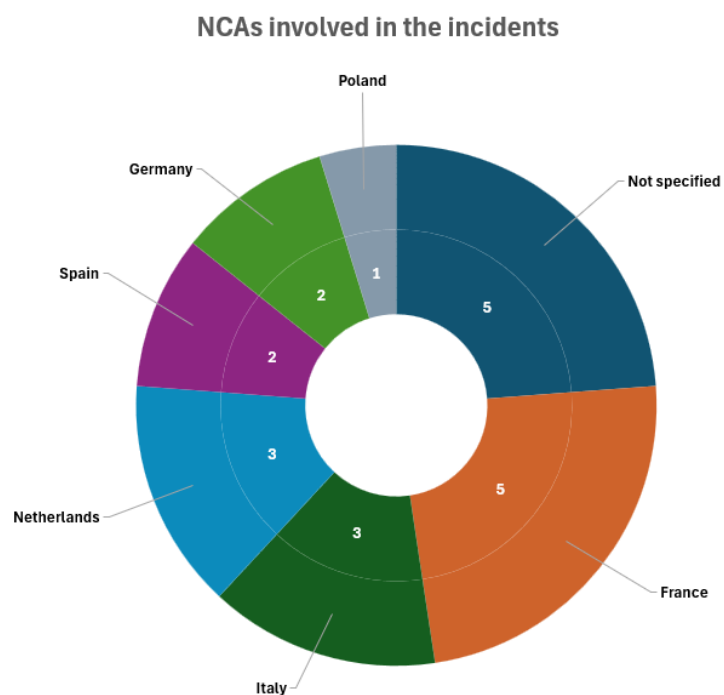


Fig. 8 NCAs involved in the incidents.



5.2. Main topics of the questions raised by NCSs in the period Oct 2024 - Dec 2025

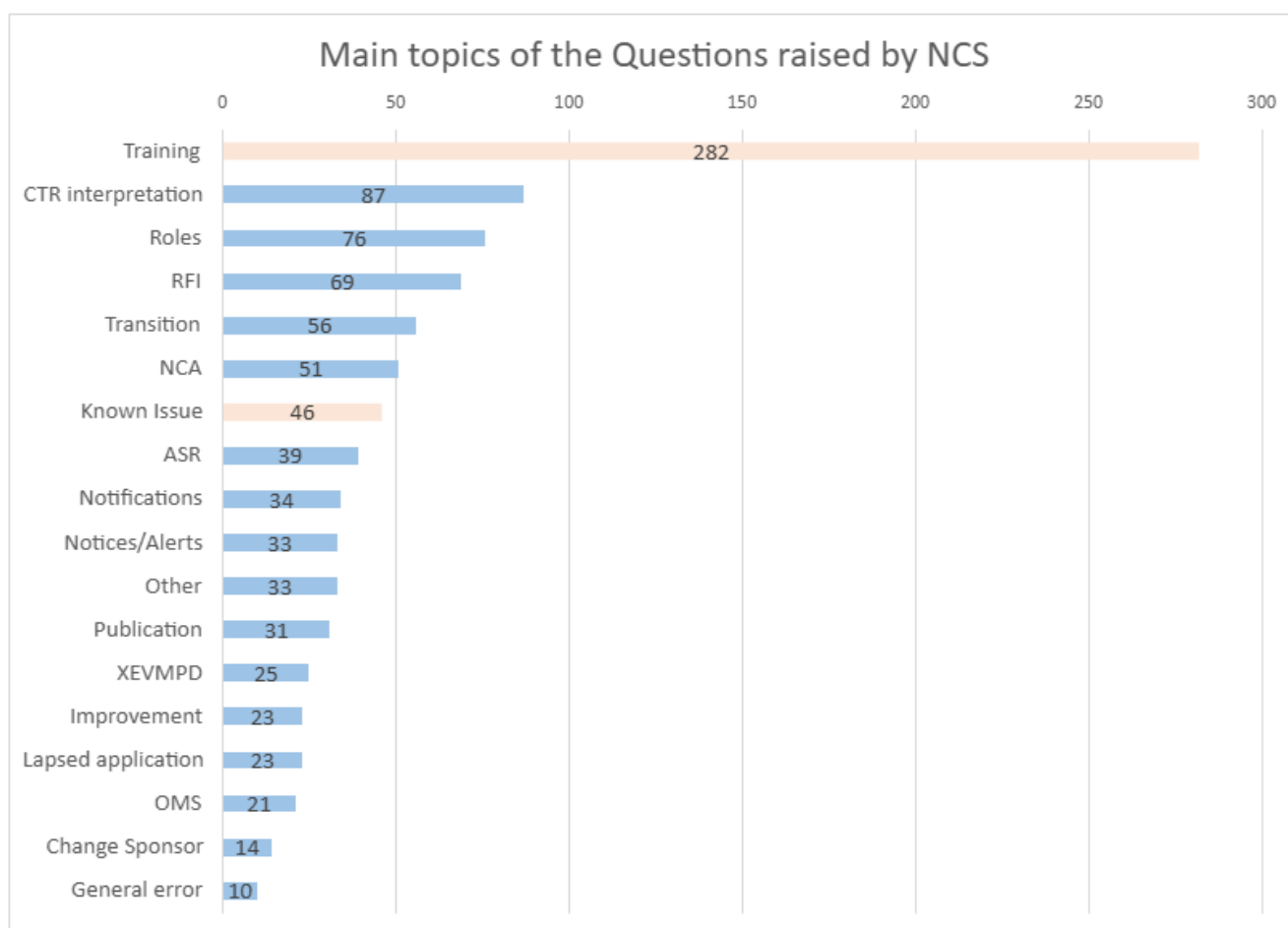
The graph below (**Fig. 9**) shows the most frequent categories of questions raised by NCSs in the reporting period considering a total number of questions of **596**.

The most frequent category is "*training*". As this is used to identify tickets related to users needing advice on functionality of CTIS not surprisingly it is the most selected; the second most selected category is "CTR interpretation" that is clearly related to the interpretation of the Regulation and other regulatory questions.

This is followed by "roles" related to users not being able to access a trial, or simply not able to proceed with the assignment of roles to perform certain actions. Many enquiries are again related to RFI and to transition of clinical trial applications from the Clinical Trials Directive to the Clinical Trials Regulation during the transition period that ended in January 2025.

51 questions (out of 596) required the intervention or are referred somehow to one NCA to facilitate the resolution (**Fig. 10** and **Fig.11**).

Fig. 9 Main topics of the questions in the timeframe considered.



5.2.1. Questions raised by NCSs requiring involvement of NCAs

Among the questions raised by NCSs, 51 required interventions at the level of the NCAs involved in the Clinical Trial Assessment. The figures below illustrate the primary topics associated with these questions and identify the NCAs involved (**Fig.10** and **Fig. 11**).

Fig. 10 Main topics of the questions referred to NCAs.

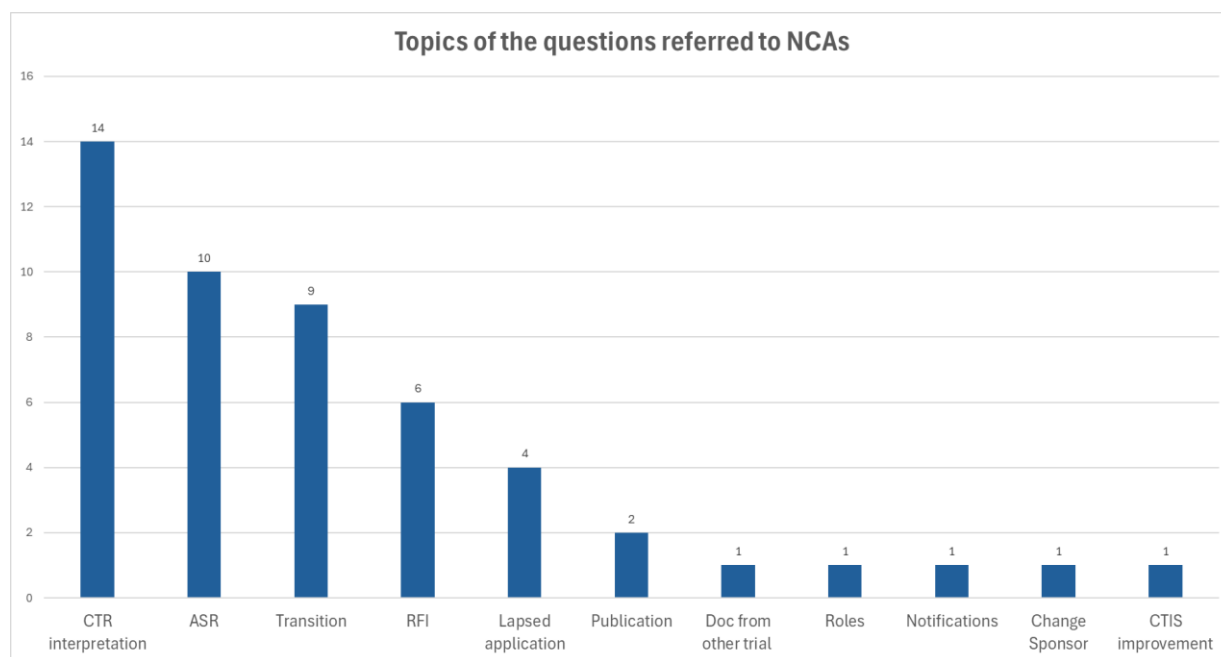
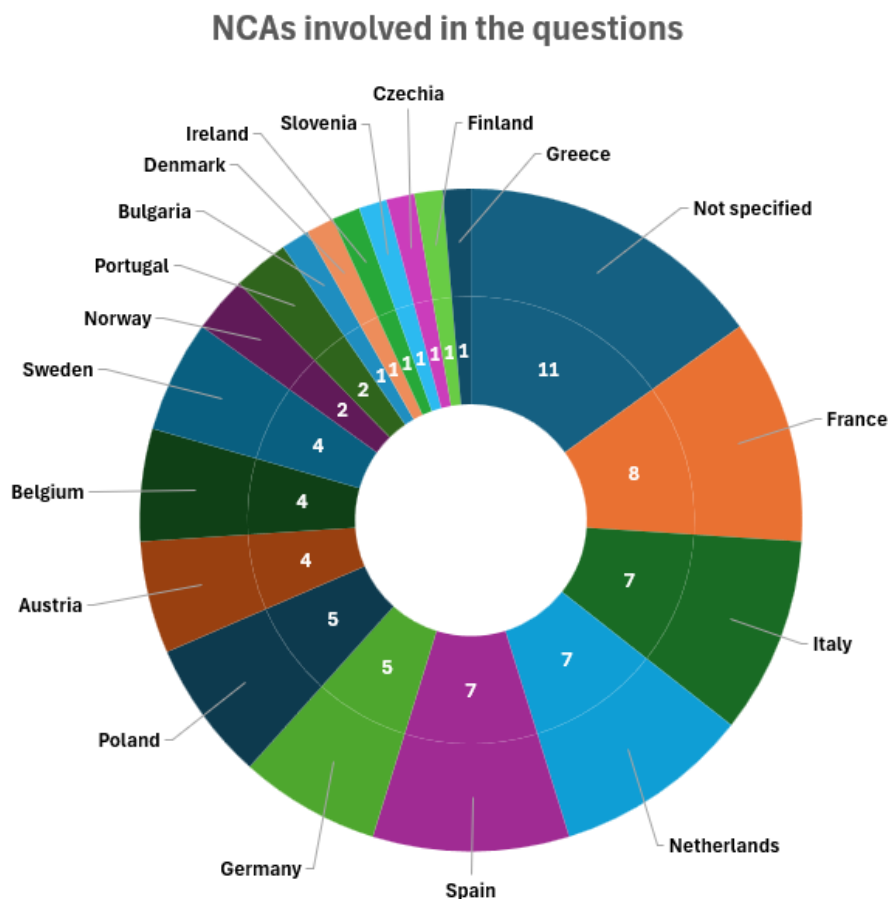


Fig. 11 NCAs to whom the questions were referred to.



6. Conclusion

The analysis of the tickets submitted by NCSs to the helpdesk between October 2024 and March 2025 provides valuable insights into the nature and frequency of the issues encountered with CTIS.

A total of 578 incidents and 596 questions were reported during this six-month period. All tickets raised in this timeframe have been resolved. Most tickets were resolved in a timely manner, as matter of fact **87% of incidents** and **90% of questions** were addresses within the expected timeline demonstrating effective handling and closure by the support team.

The categorisation of incidents revealed that the most frequently selected tags were “*training*” and “*known issues*”. These broad categories reflect a recurring need for user guidance on CTIS functionalities, and the presence of system-related problems already identified and tracked. Beyond these, a significant number of incidents were related to **RFI, Notices and Alerts, Annual Safety Reports (ASRs)**, and (CTD to CTR) **transition** activities, as well as integration issues with external systems such as OMS and XEVMPD. Notably, 20 incidents required further actions or involvement of the NCA for resolution.

Similarly, the analysis of questions showed that “*training*” was again the most common category, followed by “*CTR interpretation*”, which highlights the need for regulatory clarification. Other frequent



topics included user roles, RFI, and transition. Among the questions raised by NCS, 51 required NCA input.

Overall, the data indicates that while many requests are related to user support and known system issues, a substantial portion also involves regulatory interpretation and cross-system dependencies.

These findings will be useful to support future improvements in user training, system documentation, and inter-agency coordination.