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European Medicines Agency

Helpdesk for non-commercial sponsors: 15-month report

1. Executive summary

This 15-month report (October 2024 – December 2025) provides an overview of the support delivered through the helpdesk for Non-Commercial Sponsors (NCSs), established to facilitate the use of the Clinical Trial Information System (CTIS) and strengthen compliance with the Clinical Trials Regulation (EU) No 536/2014 (CTR). The helpdesk acts as a centralised and expedited support mechanism, enabling EMA to address technical, procedural, and regulatory challenges faced by NCSs in collaboration with the National Competent Authorities (NCAs).

Over the reporting period, 2,532 requests were submitted by NCSs: 1,376 incidents (technical issues) and 1,156 questions (requests for service and request for information). All tickets raised during the period were closed. Performance against established Service Level Agreements (SLAs) remained consistently strong, with 87% of incidents and 89% of questions resolved within the expected timelines, demonstrating efficient case management and timely follow up.

Analysis of the enquiries raised when contacting the helpdesk, shows that most **incidents** fall under the categories “*known issues*” and “*training*.”

‘Known issues’ are predominantly related to notices and alerts or notification date submissions, while ‘training’ related incidents frequently involved support for the RFI (Request for Information) process and general CTIS functionality. Additional recurrent challenges were linked to user roles, access permissions, and the integration of CTIS with Organisation Management Service (OMS) and Extended EudraVigilance Medicinal Product Dictionary (XEVMPD).

For **questions**, the most frequent topics were training, CTR interpretation, and users’ roles. Queries on CTR interpretation were addressed in line with existing published guidance, Q&A with complex or new regulatory questions escalated to the Clinical Trials Coordination Group (CTCG).

Out of the tickets raised to the helpdesk 39 incidents and 90 questions involved NCAs for resolution. To provide more effective and targeted support for complex requests, a new tag (“NCS_TC”) was introduced in mid-2025, marking cases handled through dedicated teleconferences (TC). Between June and December 2025, 15 incidents and 9 questions were resolved using this direct approach.

Overall, the data reveals a strong reliance on the helpdesk for both operational and regulatory matters, reflecting the complexity of the importance to understand the CTIS functionalities and the main challenges faced by NCSs. The findings highlight the need for continued investment in



training, system documentation, and clarity of regulatory guidance, while also emphasising the value of strengthened collaboration between EMA technical team and NCAs.

Altogether, the findings shed light on the main areas where CTIS and the related training for non-commercial sponsors can be enhanced, and the number and nature of tickets raised provide a useful indicator of how well the available training material and guidance is understood and if and how sponsors' proficiency is improving over time.

2. Background

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

An important part of this activity has been the establishment of a dedicated helpdesk 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 centralised 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.

3. Participants

A dedicated team within EMA manages enquiries and follow a defined process flow (see Annex 1); NCAs play an active role in the helpdesk by collaborating on 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.

4. Analysis of 15 months of helpdesk activity

This document covers the activity of the helpdesk for a period of 15 months, spanning from October 2024 to December 2025.

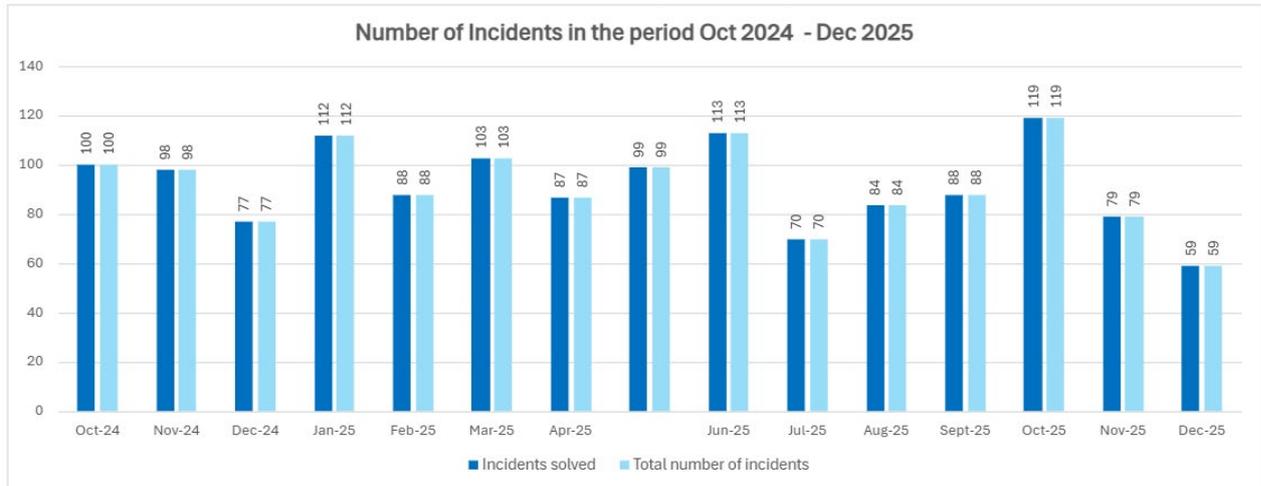
4.1. *Issues reported / Incidents in the period October 2024 – December 2025 and time for resolution*

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

The graph below (**Fig. 1**) shows the total number of incidents reported by NCSs and the number of resolved incidents for the period Oct 2024-Dec 2025 divided per month.

All incidents raised (tot = 1,376) were consistently closed throughout the period.

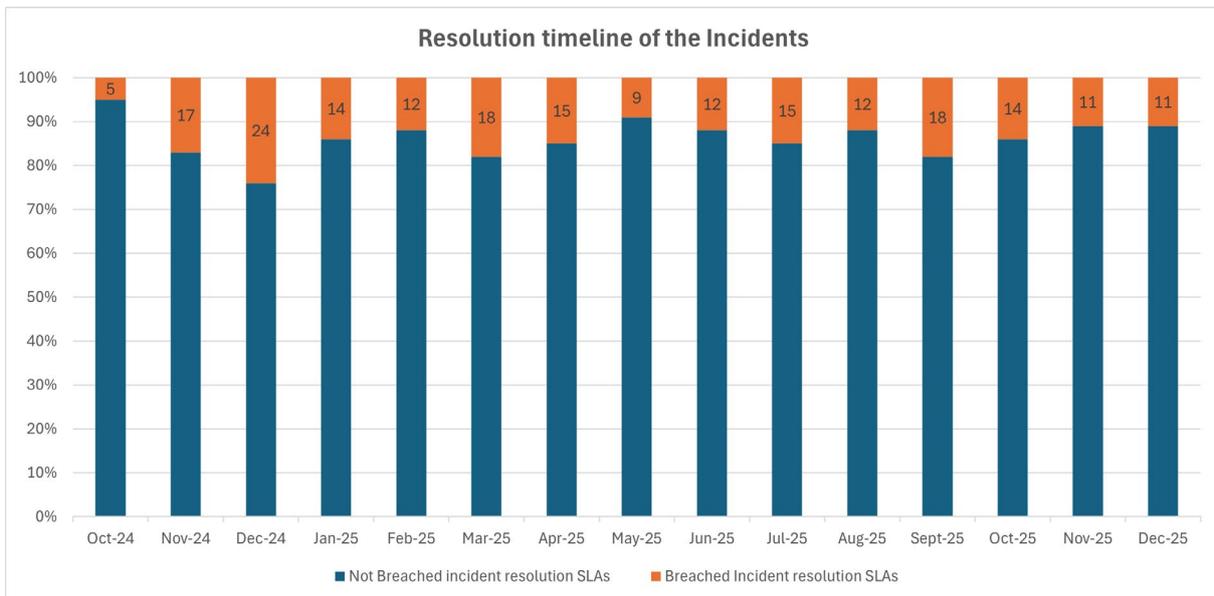
Fig. 1: Number of tickets raised on incidents in the timeframe considered Oct 2024 - Dec 2025



The graph below (**Fig. 2**) 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–Dec 2025.

Fig. 2: Resolution timeline related to the incidents raised by NCSs in ServiceNow in the timeframe considered Oct 2024-Dec 2025.

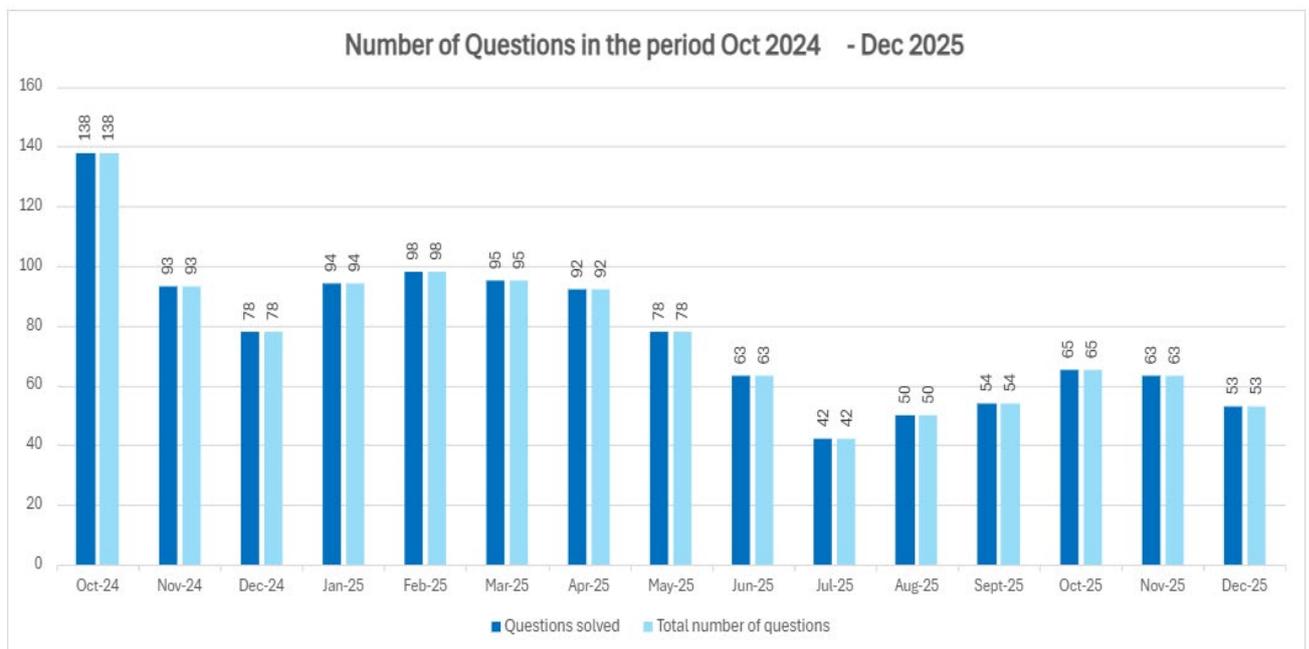


4.2. Request for service and for information / Questions in the period October 2024 – December 2025 and time for resolution

Requests for service and requests for information have been grouped together under the term “questions”. The graph below (**Fig. 3**) shows the total number of questions submitted by NCSs and the number of resolved questions for the period Oct 2024 - Dec 2025 divided per month.

All tickets raised under this category (**tot= 1,156**) in the timeframe are considered closed,

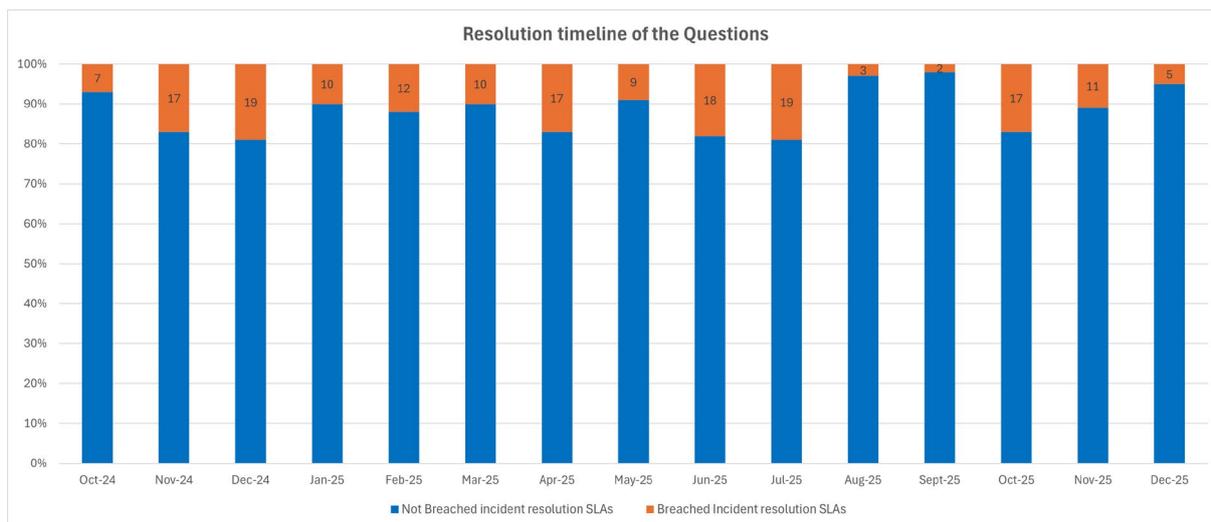
Fig. 3: Number of tickets raised on questions in the timeframe considered Oct 2024-Dec 2025.



The graph below (**Fig. 4**) 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 89% of questions has been resolved within the expected timelines based on the period Oct 2024–Dec 2025.

Fig.4: Resolution timeline related to the questions raised by NCS in ServiceNow in the timeframe considered Oct 2024- Dec 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 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 enables targeted support and clarification, as well as help gaining 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 (reproducible issue)
CTIS_publication process	For tickets related to transparency and publication aspects
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 the issue is not reproducible (e.g. temporary glitch of the system)
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 End of Trial)
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 should have not 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 Multi Factor Authentication (MFA), login issues
CTIS_ASR	For tickets related to Annual Safety Reports
NCS_TC	For tickets where a teleconference/call has been arranged with the Sponsor to clarify the reported issue
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 – Dec 2025

The graph below (**Fig. 5**) shows the most frequent categories of incidents raised by NCSs in the reporting period, considering a total number of **1,373** incidents.

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

The “known issues” category (385 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 (151 tickets) and problems with submitting notification dates (64 tickets).

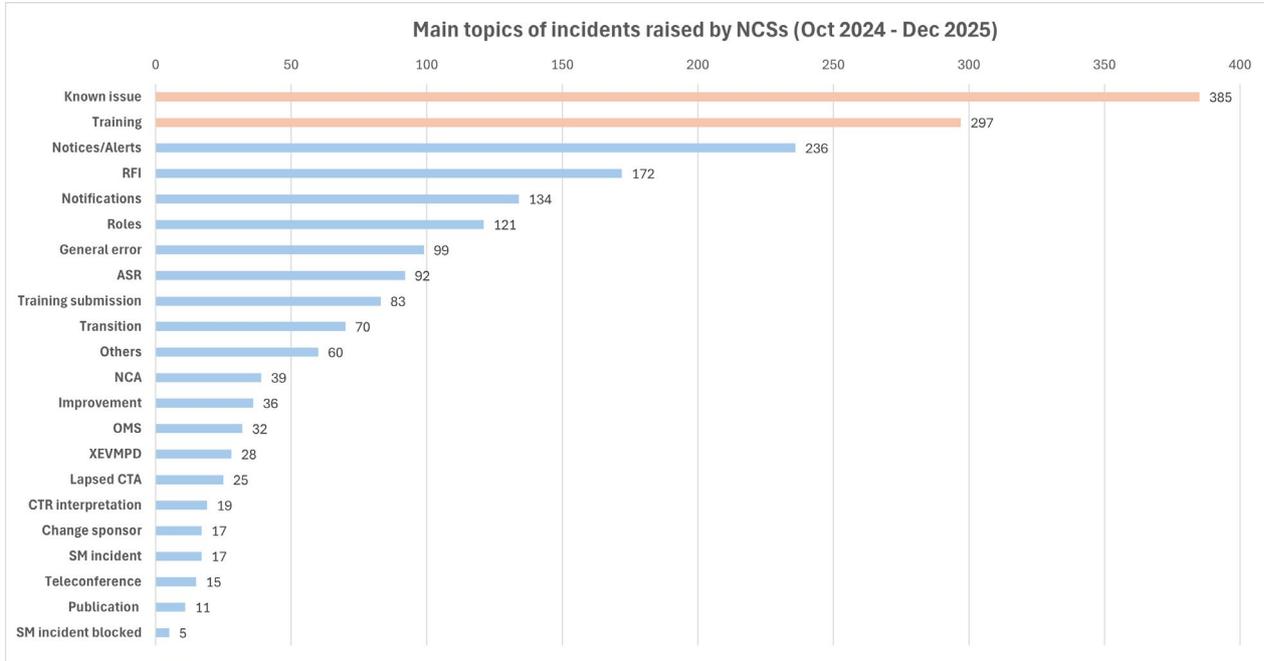
The “training” category covers tickets from users seeking guidance on CTIS functionalities. While the information shared by the helpdesk is generally available in the official user manuals and training materials, the assistance serves to help users who might have problems in navigating the system functionalities. Notably, 62 tickets under this category relate specifically to RFI (Request for Information), highlighting that sponsors often face difficulties managing the RFI response process.

Additionally, a considerable number of tickets addressed issues related to trial access permissions and general training on user roles.

A significant number of incidents also concern other systems essential for CTIS use, such as OMS and XEVMPD.

Furthermore, since the end of June, the new “NCS_TC” category has been introduced to classify tickets where a teleconference was arranged with the sponsor to resolve the issue. From June 2025 to December 2025, 15 incidents required a real-time discussion between the NCS and the helpdesk team, typically because they involved a complex inquiry or could not be resolved through written guidance alone, requiring more detailed and tailored support (**Fig. 5**).

Fig. 5: 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, 39 required interventions at the level of the NCAs involved in the assessment of clinical trial applications. The figures below illustrate the primary topics associated with these incidents and identify the NCAs involved (**Fig. 6** and **Fig. 7**).

Fig. 6 Topics where NCAs has been involved.

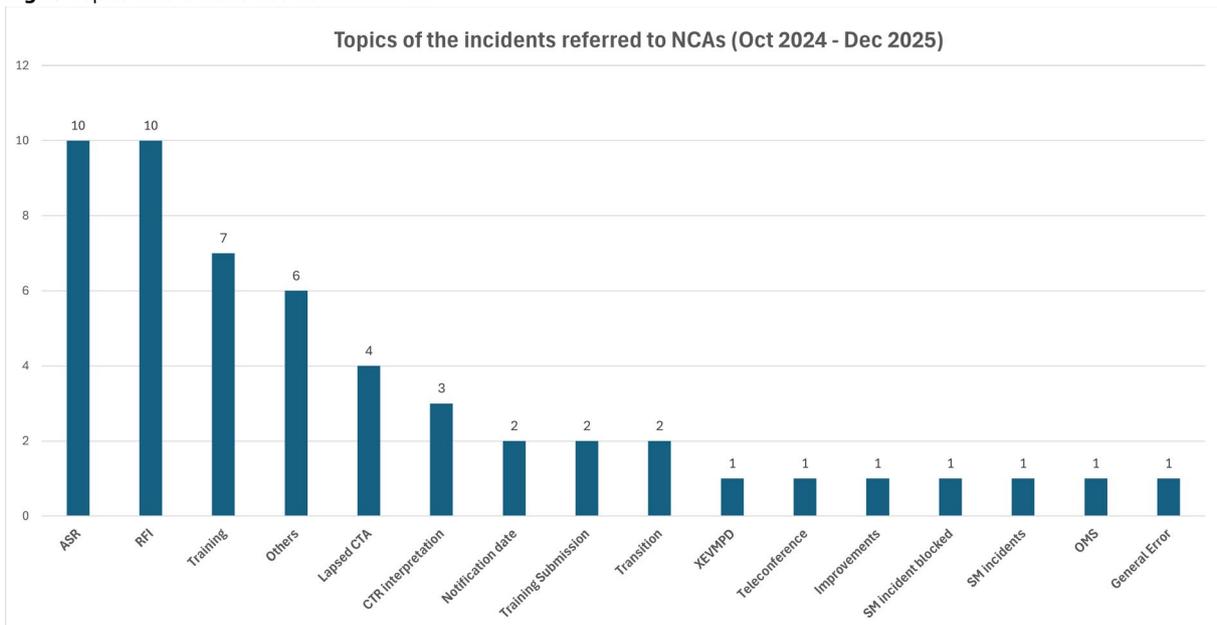
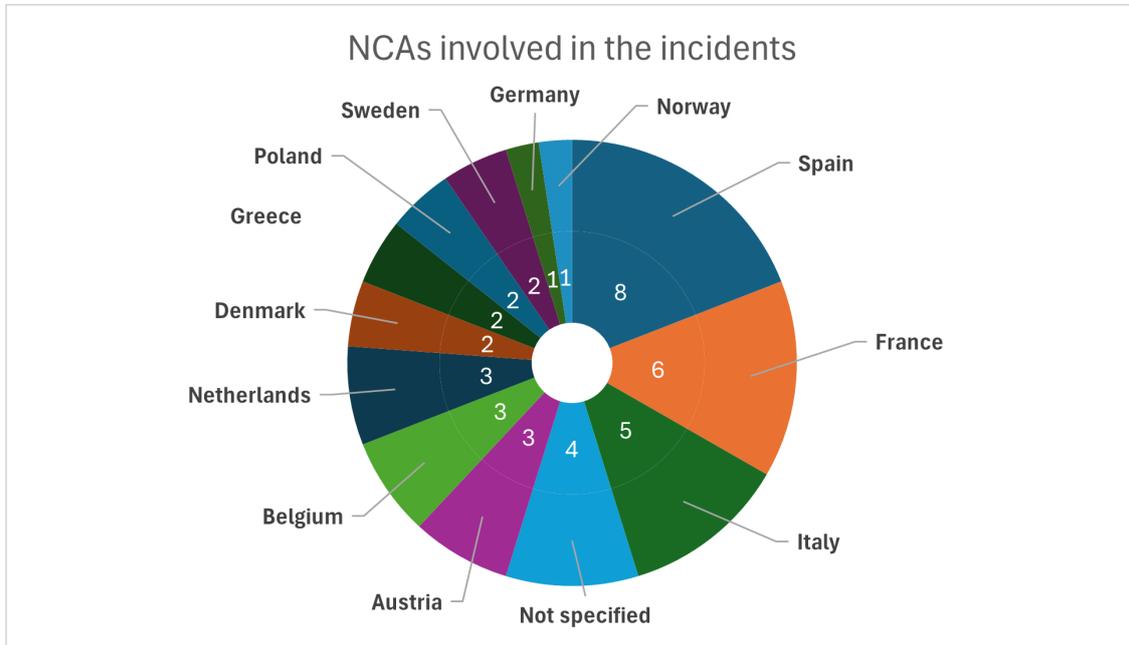


Fig. 7: NCAs involved in the incidents.



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

The graph below (**Fig. 8**) shows the most frequent categories of questions raised by NCSs in the reporting period considering a total number of questions of **1,153**.

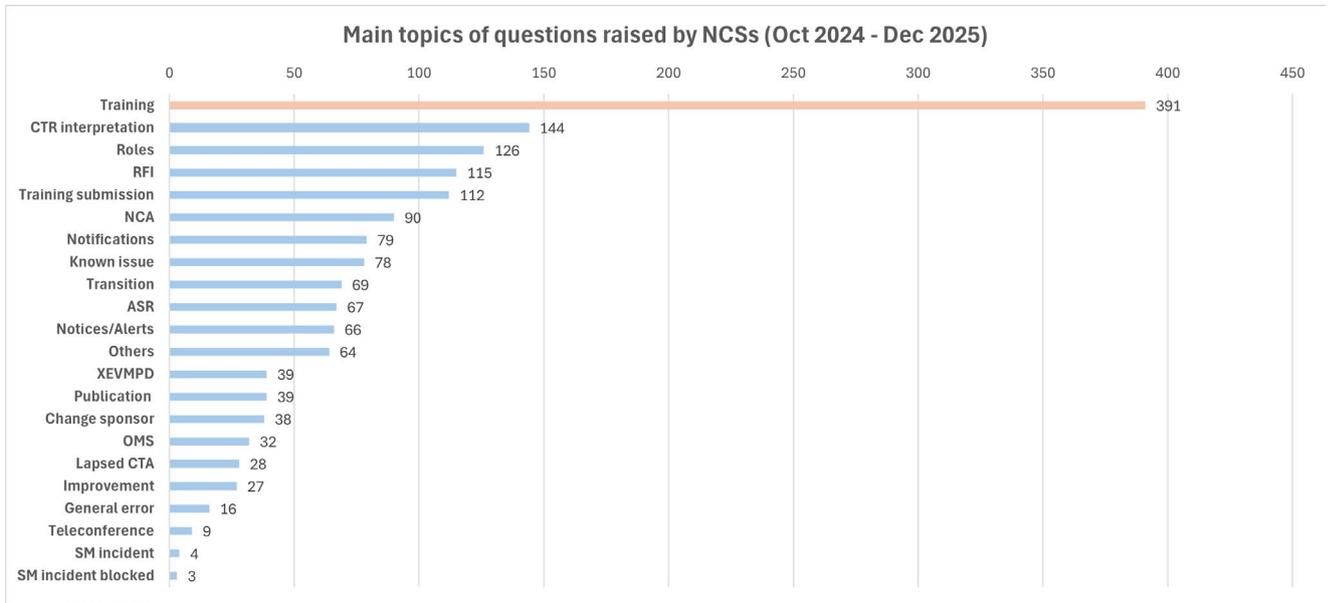
The most frequent category is "*training*". As this is used to identify tickets related to users needing advice on functionality of CTIS not surprisingly it is the most selected; the second most selected category is "CTR interpretation" to be understood as the helpdesk providing answers based on the existing materials, including the Commission's published guidance and Q&A. When sponsors raise issues that are not covered by the available documentation or that may require additional clarifications to be provided, the queries are escalated to the CTCG).

The third most selected category is "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 (115) and to submission of notification dates (79).

A total of 90 questions (out of 1,153) were discussed with the NCAs to facilitate their resolution (**Fig. 9** and **Fig. 10**).

Additionally, regarding the latest added tag "NCS_TC", 9 questions raised from June 2025 to December 2025 were addressed through teleconference with the sponsor (**Fig. 8**). These cases typically involved queries that required additional clarification to ensure alignment between the helpdesk team and the NCSs. The direct discussion allowed the team to provide precise explanations, avoiding unnecessary back-and-forth communication.

Fig. 8: 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, 90 required interventions at the level of the NCAs involved in the assessment of the clinical trial applications. The figures below illustrate the primary topics associated with these questions and identify the NCAs involved (**Fig. 9** and **Fig. 10**).

Fig. 9: Main topics of the questions referred to NCAs.

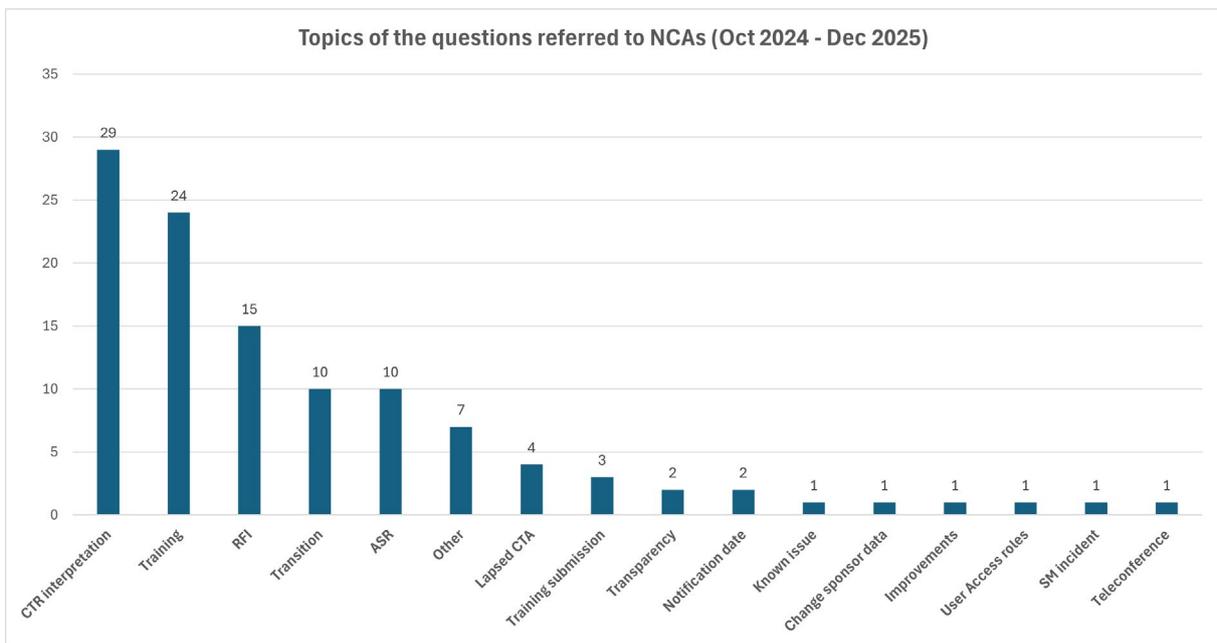
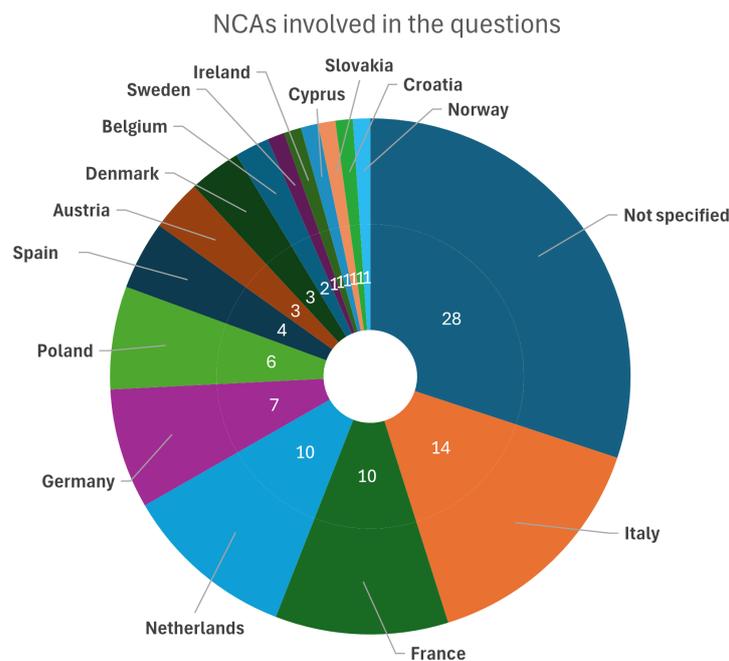


Fig. 10: NCAs to whom the questions were referred to.





6. Conclusion

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

A total of 1,376 incidents and 1,156 questions were reported during this 15-month period. All tickets raised in this timeframe have been closed.

Most tickets were resolved in a timely manner, with **86% of incidents** and **88% of questions** addressed 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 “*known issues*” and “*training*”. These broad categories reflect recurring challenges in both system usability and user experience. In particular, the number of “*training*” tags indicates a continued need for user guidance in navigating CTIS functionalities and underscores the importance of providing clear and accessible support for effective system use. The prevalence of “*known issues*” points to system-related limitations or defects that have already been identified and are actively monitored. This suggests that users are encountering mostly familiar, previously logged issues rather than new or unexpected problems, allowing teams to focus efforts on resolving these known areas and steadily improving overall system stability. Beyond these categories, a significant number of incidents were related to **Notices and Alerts, RFI, Notification date, User roles, Annual Safety Reports (ASRs)**, and (CTD to CTR) **transition** activities, as well as integration issues with external systems such as OMS and XEVMPD. Notably, 39 incidents required further actions or involvement of the NCA for resolution, while 15 incidents were addressed through teleconferences with the sponsors.

Similarly, the analysis of **questions** showed that “*training*” was the most common category, followed by “*CTR interpretation*”, highlighting the need for regulatory clarification. Other frequently raised topics included user roles, RFI, and notification date. Among the questions raised by NCS, 90 required NCA input, and 9 were resolved through teleconferences between the helpdesk team and the NCS.

Overall, the data indicates that while a large proportion of requests relate to user support and known system issues, a substantial number also involve regulatory interpretation and cross-system dependencies.

These findings will inform future improvements in user training, system documentation, and inter-agency coordination.



Annex 1. Process for CTR/CTIS helpdesk

The process of the Helpdesk is detailed in Section 3 of the previous report covering the first six month of activity and it is available at this link: [ACT EU Helpdesk for NCS report](#).