Clinical Trial Information System (CTIS)
Bitesize talk
Notifications (session II)

Presented by Noemie Manent and Charalampos Drosos on 23 November 2022
European Medicines Agency
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CTIS Bitesize talk:
Notifications (session II)

14:30 - 14:35 Introduction

14:35 – 15:55 CTIS Demonstration Sessions followed by live Q&A Sessions

15:55 – 16:00 Closing remarks

For questions, go to www.sli.do & use event code #bt23nov
A few housekeeping rules

For your questions, go to www.sli.do & use event code #bt23nov

Tips for optimal screen viewing

❖ Make use of the instructions under the embedded video in the event page and connect directly to the IBM channel for the full-screen experience
❖ Increase the video quality from the HD button on the right bottom of the screen setting it to 720p (or 1080p).
❖ Have a stable internet connection
Main Session: Notifications (session II)

Notifications (session II)

• Live demo with Q&A

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CTIS Change Management Officer
Notifications (session II)
Notifications

These notifications refer to the clinical trial life cycle in each MSC.

These notifications are only needed in certain circumstances not foreseen in the protocol and apply to all MSCs.
Events notifications

- Primarily independent of each other
- Can only be submitted after a clinical trial has been decided

**UE (unexpected event)**
- might influence the benefit-risk assessment of the medicinal product
- or that would lead to changes in the administration of a medicinal product or in overall conduct of a CT
Notifications no later than **15 days** from the date of sponsor awareness

*Art. 53 (1) of the CT Regulation*

**USMs (urgent safety measures)** taken to protect the subjects when an UE is likely to seriously affect the benefit-risk balance
Notifications no later than **7 days** from the date USMs were taken

*Art. 54 of the CT Regulation*

**SB (serious breach)** is likely to affect
- safety and rights of subject, or
- reliability and robustness of the data generated in the CT
Notifications no later than **7 days** from the date of sponsor awareness.

*Art. 52 of the CT Regulation*

Sponsor submits all inspection reports of third countries’ authorities concerning a CT

*Art. 53 (2) of the CT Regulation*
For notifications on events (not related to the trial and recruitment period), the sponsor user navigates to the respective notification type [1] and creates a new notification draft [2]. The system assigns a new business key [3] and adds this new notification to the list of notifications for that type. Actions buttons [4] allow the sponsor user to apply further actions for that notification.
Publication aspects

• The publication of these event notifications may require an assessment before they are published:
  ✓ 3rd Country Inspectorate Inspection notifications are published as soon as sponsors submits them

• For the other three types, their publication can be triggered by authority users and only after they perform an ad hoc assessment related to the event notification.

• Once authority users perform the ad hoc assessment they can trigger the publication of the notification details by attaching the outcome of the assessment to the notification.

• Details of the notification as well as a summary of the assessment outcome performed by authority users are published.
Demo and Q&A session

For questions, go to www.sli.do & use event code #bt23nov
We ask for *your feedback* on this event

A brief **poll is now open** in Slido

Go to [www.sli.do](http://www.sli.do) & use event code #bt23nov or scan Slido QR code:
## Final CTIS events for 2022 – Save the date

Submit your questions in advance!

<table>
<thead>
<tr>
<th>Date</th>
<th>CTIS event</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 November</td>
<td>OMS TroubleShooting Session for CTIS users</td>
</tr>
<tr>
<td>12 December</td>
<td>CTIS Walk-in clinic</td>
</tr>
<tr>
<td>15 December</td>
<td>CTIS bitesize talk: Annual Safety Report</td>
</tr>
</tbody>
</table>

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For satisfaction feedback, Please go to [www.sli.do](http://www.sli.do) & use event code #bt23nov

Submit your questions in advance!
CTIS training environment Survey 4.0

Survey 4.0 has been opened where new potential users of CTIS can express interest to access the CTIS training environment (CTIS Sandbox).

CTIS Sandbox Survey 4.0

For satisfaction feedback, Please go to www.sli.do & use event code #bt23nov
Q&As on CTR by the European Commission

The European Commission has published a detailed list of questions and answers on the Clinical Trials Regulation under Chapter V of Eudralex 10:

Thank you for attending today’s event

Further information

For the Clinical Trials Newsletter sign up at CT.NewsletterSubscriptions@ema.europa.eu.

For upcoming CTIS events, visit the EMA event page.

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Next CTIS bitesize talk on 15 December