EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS) Bitesize talk

Notifications (session II)

Presented by Noemie Manent and Charalampos Drosos on 23 November 2022
European Medicines Agency

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

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**

Or scan
slido
QR code:

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)

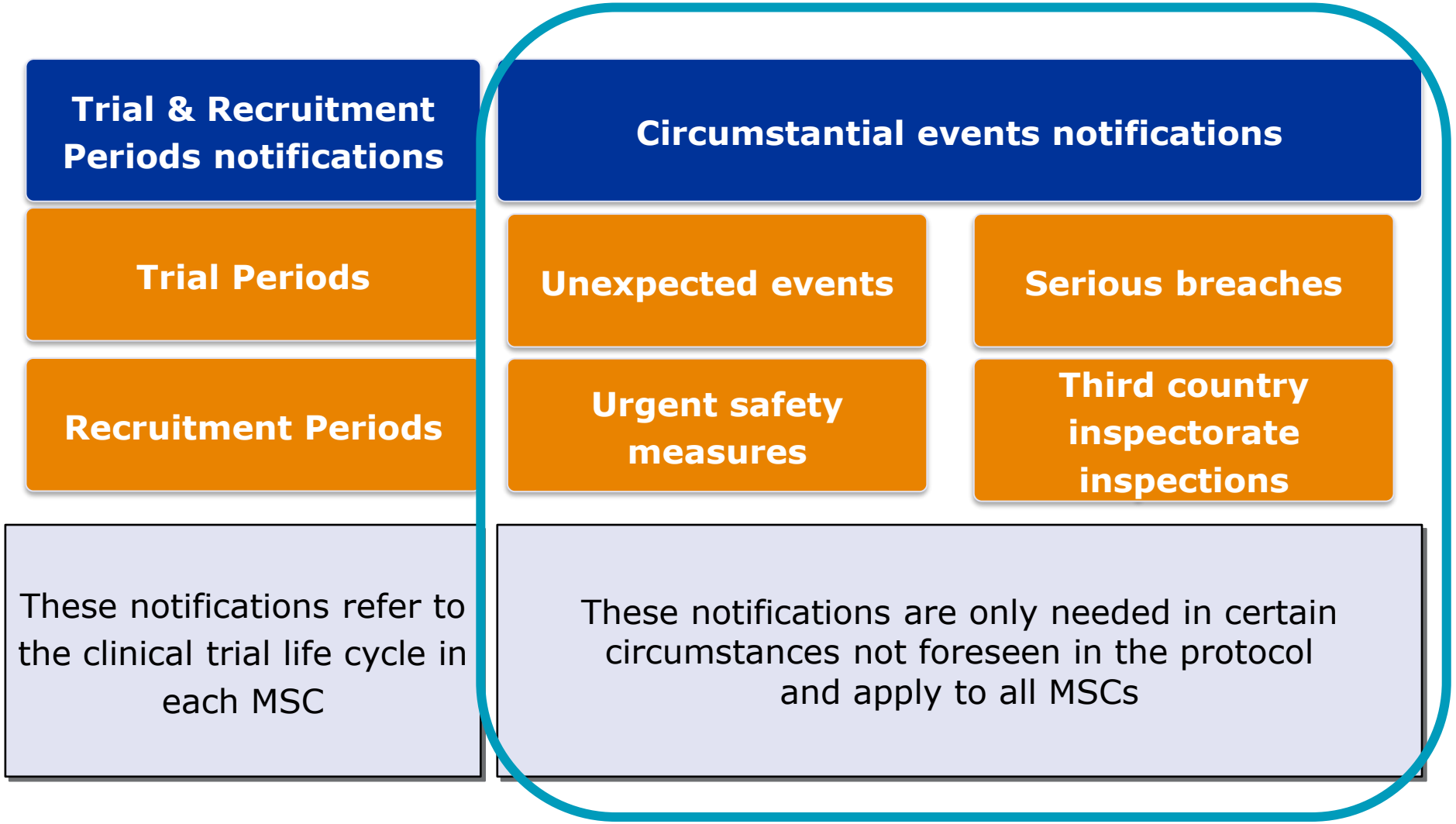
- Live demo with Q&A

Noémie Manent
CTIS Operations Workstream Lead

Charalampos Drosos
CTIS Change Management Officer

Notifications (session II)

Notifications



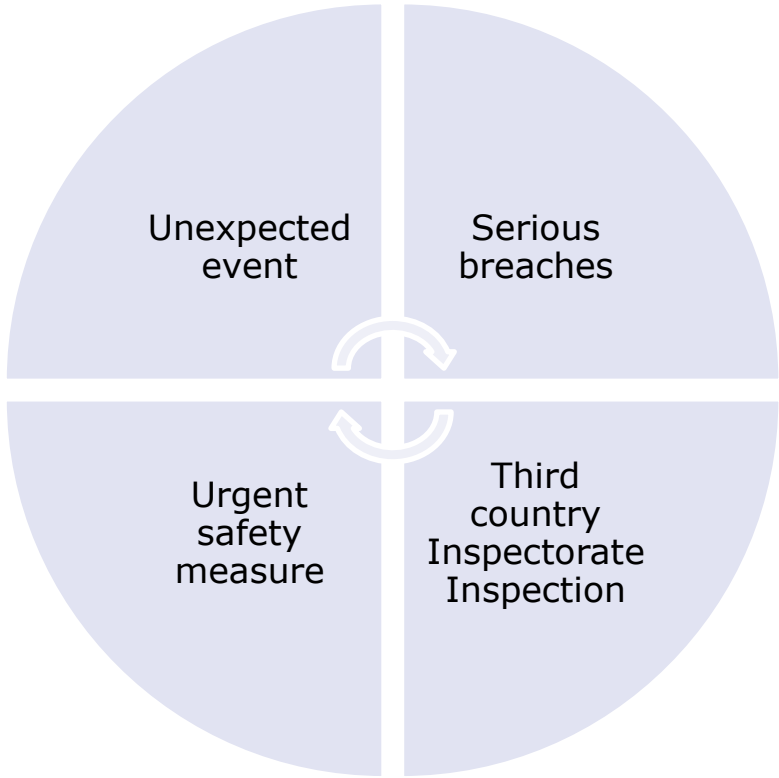
Events notifications

- *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

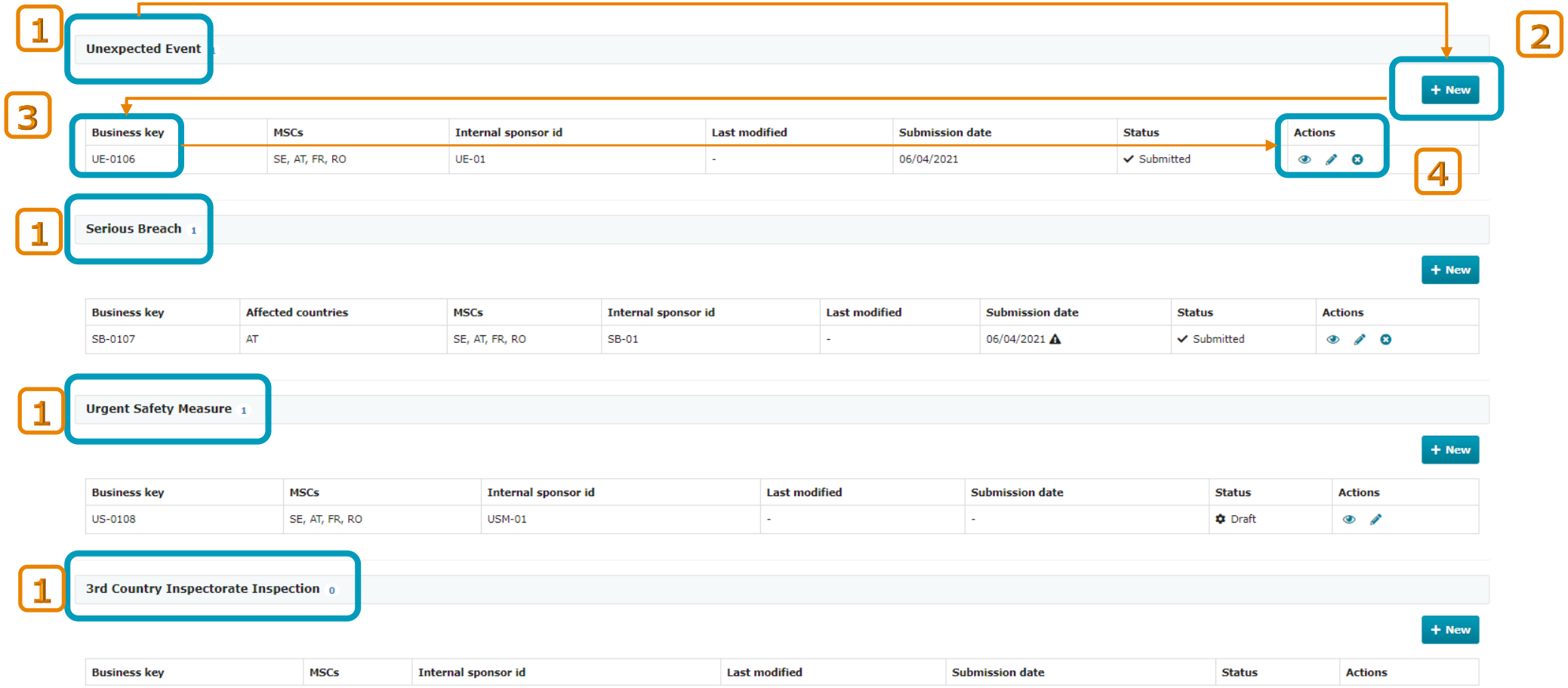
Notifications no later than **7 days** from the date of sponsor awareness.
Art. 52 of the CT Regulation

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***
& use event code ***#bt23nov***
or scan Slido ***QR code:***

Final CTIS events for 2022 – Save the date

Submit your questions in advance!

Date	CTIS event
24 November	OMS TroubleShooting Session for CTIS users
12 December	CTIS Walk-in clinic
15 December	CTIS bitesize talk: Annual Safety Report

Clinical Trials Information System: training and support | European Medicines Agency

For satisfaction feedback, Please go to ***www.sli.do*** *& use event code* ***#bt23nov***

CTIS training environment Survey 4.0

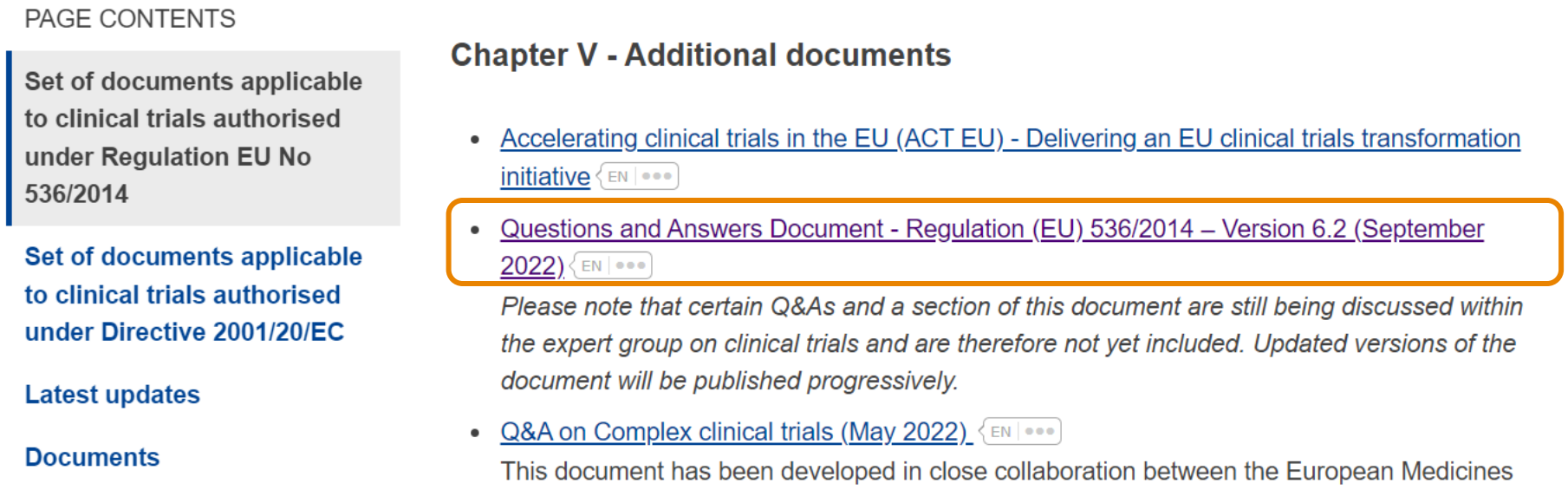
Survey 4.0 has been opened where new potential users of CTIS can express interest to access the CTIS training environment (CTIS Sandbox).

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 lists of questions and answers on the Clinical Trials Regulation under Chapter V of Eudralex 10:



PAGE CONTENTS

Set of documents applicable to clinical trials authorised under Regulation EU No 536/2014

Set of documents applicable to clinical trials authorised under Directive 2001/20/EC

Latest updates

Documents

Chapter V - Additional documents

- Accelerating clinical trials in the EU (ACT EU) - Delivering an EU clinical trials transformation initiative EN
- Questions and Answers Document - Regulation (EU) 536/2014 – Version 6.2 (September 2022) EN

  Please note that certain Q&As and a section of this document are still being discussed within the expert group on clinical trials and are therefore not yet included. Updated versions of the document will be published progressively.
- Q&A on Complex clinical trials (May 2022) EN

  This document has been developed in close collaboration between the European Medicines

[EudraLex - Volume 10 - Clinical trials guidelines - Questions and Answers Document - Regulation (EU) 536/2014 – Version 6.2 (September 2022)]

Thank you for attending today's event

Next CTIS bitesize talk on 15 December

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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