EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Clinical Trial Information System (CTIS) Bitesize talk

## Annual Safety Report (ASR)

Presented by Ornela Ademi, Cátia Gonçalves and Noemie Manent on 15 December 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:
## Annual Safety Report (ASR)

16:30 - 16:35 **Introduction**

16:35 – 17:55 **CTIS Demonstration Sessions followed by live Q&A Sessions**

17:55 – 18:00 **Closing remarks**

*For questions, go to **www.sli.do** & use event code **#bt15dec***

# A few housekeeping rules

For your questions,
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## 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: Annual Safety Report (ASR)

## Annual Safety Report

- Presentation
- Live demo with Q&A

*For questions, go to **www.sli.do** & use event code **#bt15dec***

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**Ornela Ademi**
CTIS Change Manager

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**Cátia Gonçalves**
CTIS Scientific Officer

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**Noémie Manent**
CTIS Operations Workstream Lead

# Annual Safety Report

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# What is an Annual Safety Report (ASR)

Relevant Regulation: **Article 43 of Regulation (EU) 536/2014** and **Implementing Regulation (EU) 2022/20 of Regulation (EU) 536/2014 (CTR)**

According to Article 43 of the CTR, sponsors shall submit annually a report on the safety of each investigational medical product (IMP) used in a clinical trial. This obligation:

- starts with the first authorisation of a clinical trial
- ends when the last clinical trial conducted with the IMP is finalised

This ASR is a document provided by the sponsor to the Member State Concerned to enable them to monitor and evaluate the evolving safety profile of the IMP and the mitigation of potential risks.

ASRs and DSURs are **not published**.

# Clinical trial safety reporting under CTR

- Electronic submission of SUSARs and ASRs is required
  - SUSARs to the EudraVigilance database (Art. 42 of Reg (EU) 536/2014)
  - **ASRs via CTIS (Art. 43 of Reg (EU) 536/2014)**
- Communication between MSs & sponsors via CTIS
- Safety assessing Member State (saMS) (elaborated in the **Implementing Regulation (EU) 2022/20** of Reg (EU) No 536/2014):
  - assesses safety relevant data, substance-based (an ASR can be related to more than 1 trial and more than 1 IMP)
  - Conducts coordinated safety assessment with RMS and MSCs using the same active substance(s)
  - develops general recommendations in relation to safety concerns
- RMS/MSC implement the recommendations if applicable to their trials via corrective measures

# ASRs during transition period

- If a clinical trial is ongoing under CTR while others are under the Directive 2001/20/EC, an ASR should be submitted in CTIS.

- Sponsors to name all MSs concerned for all ongoing CTs in EU/EEA.

- Sponsors are still obliged to submit ASRs to Ethics Committees (CT-3) (national legislations) and inform investigators of any new safety data or change in benefit-risk evaluation.

# Annual Safety Report in CTIS – Sponsor workspace

- Sponsor user role 'ASR submitter'
  - View, create, submit an ASR
  - View an RFI; create and submit an ASR RFI response
  - View, upload, and download ASR documents and details
  - View ASR RFI Assessment comment
  - View ASR summary conclusion

- Informative cover letter - not required by regulation, but can be provided in the CTIS in the ASR document placeholder

- Note: Document attachments in CTIS to be in **pdf** format and up to **50MB** (each)

# Annual Safety Report in CTIS – Authority workspace

MSCs

- assess ASR
- assess RFI response (if applicable)

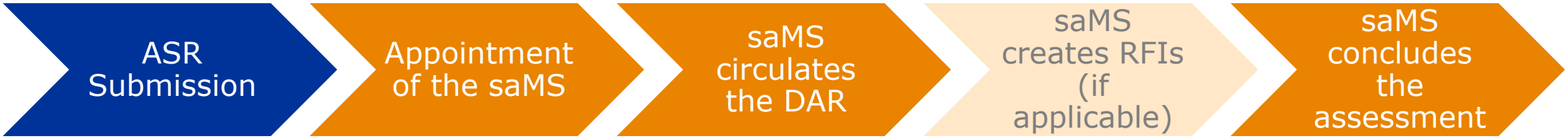
saMS (appointment (lead) by selection)

- leads safety assessments - responsible for the assessment of a specific ASR – collaborates with the other concerned saMS, RMS/MSC
- consolidates MSCs considerations regarding the draft assessment report (if applicable)
- creates RFIs

Member States may levy a fee when they carry out safety assessment activities as a safety assessing Member State (Art 14 of Implementing Reg (EU) 2022/20 of Reg (EU) No 536/2014 ).

# Assessment phases of an Annual Safety Report in CTIS

## (Implementing Regulation (EU) 2022/20 of CTR)




Within 60 days after Data Lock Point

7 - 12 days

**< 42 days after** or < **84 days from** submission of (latest) ASR (**if RFI**)

# Useful information sources (links) on ASR

**Online training MODULE 18**

Clinical Trials Information System (CTIS): online modular training programme | European Medicines Agency (europa.eu)

**Reg (EU) No 536/2014 Questions & Answers version 6.2**

**(European Commission's detailed list of Q & A on the Clinical Trials Regulation under Chapter V of Eudralex 10)**

regulation5362014_qa_en.pdf (europa.eu)

**Commission Implementing Regulation (EU) 2022/20 of Reg (EU) No 536/2014**

Publications Office (europa.eu)

**Sponsor Handbook**

CTIS Sponsor Handbook 2022 (europa.eu)

# Demo and Q&A session

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# We ask for *your feedback* on this event

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

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# CTIS training and information events for 2023

CTIS bitesize talks and CTIS Walk-in clinics will continue in 2023.

***Submit your questions in advance!***

For more information:

- Clinical Trials Information System: training and support | Training and Information events
- Clinical Trials Highlights Newsletter

*For satisfaction feedback, Please go to* ***www.sli.do*** *& use event code* ***#bt15dec***

# CTIS Sponsor Handbook version 3.00

Updates on priority topics (e.g. transition from CTD to CTR), references and links to further supporting materials.

**CTIS Handbook for clinical trial sponsors**

*For satisfaction feedback, Please go to* ***www.sli.do*** *& use event code* ***#bt15dec***

# 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* ***#bt15dec***

# Thank you for attending today's event

*Next CTIS bitesize talk dates will be announced in early 2023*

## Further information

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

For upcoming CTIS events, visit the EMA event page.

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
**Telephone** +31 (0)88 781 6000

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