EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 January 2022
EMA/28670/2022
European Medicines Agency

Demonstration for CTIS stakeholders on the Functionalities of the Clinical Trials Information System

20 January 2022, 09:00-17:00 CET

Virtual Meeting

Background and objectives

The way clinical trials are conducted in the European Union (EU) and European Economic Area (EEA) will undergo a major change when the Clinical Trials Regulation (Regulation (EU) No 536/2014) comes into application on 31 January 2022. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU/EEA, via the Clinical Trials Information System (CTIS). CTIS will contain the centralised EU portal and database for clinical trials foreseen by the Regulation.

The EMA is organising this extensive CTIS demonstration in preparation for the Go-Live of CTIS on 31 January 2022.

The aim of the event is to showcase the status of the system and elaborate on how to perform real-life business cases by walking the audience through a typical Clinical Trial workflow in CTIS. The event is aimed at stakeholders that have been involved in the CTIS project in any capacity, e.g. through testing, training or review of materials.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Demonstration for CTIS stakeholders on the Functionalities of the Clinical Trials Information System

Introduction

08:30 – 09:00	**Joining and technicalities**	**30'**
09:00 – 09:15	**Welcome address and opening remarks** *Xavier de Cuyper (Chief Executive Officer, FAMHP – Federal agency for medicines and health products, Belgium)* *Kristof Bonnarens (DG SANTE, European Commission)* *Fergus Sweeney (EMA)*	**15'**

User Administration

09:15 – 09:30	**Access and user management, roles and permissions** *Laura Pioppo (EMA)* *Olga Alvarez and Melis Koyuncuogullari (EMA Service Provider)*	**15'**

Initial Clinical Trial Application *Completion and evaluation*

09:30 – 11:15	• **Submission of an initial application** • **Evaluation of an initial application by the Member States Concerned:** – Selection of the reporting Member State – Validation – Assessment of part I and part II, including request for information – Decision by each Member States Concerned *Laura Pioppo (EMA)* *Olga Alvarez and Melis Koyuncuogullari (EMA Service Provider)*	**105'**
11:15 – 11:25	**Q&A**	**10'**
11:25 – 11:40	**Coffee break**	**15'**

Modifications

11:40 – 12:50	• **Description of changes that can be applied via a substantial and non-substantial modification** • **Addition of a new MSC and translations of data and documents** *Laura Pioppo (EMA)* *Olga Alvarez and Melis Koyuncuogullari (EMA Service Provider)*	70′
12:50 – 13:00	**Q&A**	10′
13:00 – 13:45	***Lunch break***	45′

Notifications and supervision activities

13:45 – 15:05	• **Trial and recruitment periods notifications** • **Circumstantial event notifications** • **Supervision activities – Corrective measures** *Laura Pioppo (EMA)* *Olga Alvarez and Melis Koyuncuogullari (EMA Service Provider)*	80′
15:05 – 15:15	**Q&A**	10′

CTIS Public domain

15:15 – 15:45	**Access to clinical trials information to the members of the public** *Laura Pioppo (EMA)* *Olga Alvarez and Melis Koyuncuogullari (EMA Service Provider)*	30′
15:45 – 16:00	***Coffee break***	15′

Annual Safety Reports

16:00 – 16:30	**Submission and evaluation of the annual safety report** *Laura Pioppo (EMA)* *Olga Alvarez and Melis Koyuncuogullari (EMA Service Provider)*	30′

Q&A and Conclusion

16:30 – 17:00	**Questions and Answers**	**30'**

Kristof Bonnarens (DG SANTE, European Commission)

Marianne Lunzer (AGES, CTIS Member State Product Owner)

Ruediger Pankow (Parexel International, CTIS Sponsor Product Owner)

Fergus Sweeney (EMA)

Pieter Vankeerberghen (EMA)

Petri Paakkonen (EMA)

Fia Westerholm (EMA)

Ana Rodriguez (EMA)

Laura Pioppo (EMA)

Steven Le Meur (EMA)