EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Demonstration on Clinical Trial Information System (CTIS)

Demonstration for CTIS stakeholders - Virtual Event

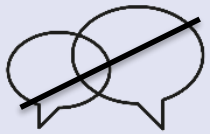
20 January 2022

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.

EUROPEAN MEDICINES AGENCY

Etiquette for
Demonstration for CTIS stakeholders starting at 9.00 am

Microphones are muted



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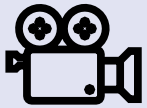

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Write your questions in Slido

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Use event code

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Xavier De Cuyper

Chief Executive Officer

FAMHP – Federal agency for medicines and health products, Belgium

Welcome to the CTIS Demo

- **CTIS** and the **Clinical Trials Regulation (CTR)** go live on January 31, 2022 at 9.00 AM
- The goal of **CTR** is to create an environment that is favourable to conducting clinical trials in the EU, with the highest standards of safety for participants and increased transparency of trial information. **CTIS** will be the single entry point for submitting clinical trial information in the EU.
- How do we handle this change?
  - Be pragmatic and creative when needed
  - Go step by step
  - Be resilient and always continue
- **Sponsors, competent authorities and ethics organisations will each have their responsibility to make the CTR and CTIS the success European patients deserve.**

Kristof Bonnarens

DG SANTE, European Commission

- The **Clinical Trials Regulation** aims to harmonise the submission, assessment and supervision processes for clinical trials throughout the EU/EEA.
- Once applicable, the Regulation will create a **framework for a robust and agile approval** process requiring close coordination between Member States. In addition, it will ensure sufficient **transparency** and adequate public scrutiny to help the research community and build trust in citizens toward clinical research.
- The CTR defines the CTIS as the **single entry point** for Clinical Trial Applications. This will allow the streamlining of the application on the basis of the CTR rules
  - After 31 January 2022: CTIS as single entry point for clinical trial application submission, authorisation and supervision in EU and EEA – sponsor can chose to submit through CTIS or according to CTD rules
  - One year later: all new clinical trials to be submitted to CTIS and authorised according to CTR
  - The transition period for trials ongoing at 31 January 2023 will be a maximum of 3 years (31.1.2025)

Sincere thanks to everyone involved in this project –

Wishing the audience success in their duties and responsibilities in CTIS!

Fergus Sweeney

Head, Clinical Studies and Manufacturing Task Force
European Medicines Agency

CTR **harmonises the submission, assessment and supervision of clinical trials** in the EU/EEA.

CTIS is the business tool of the **Clinical Trials Regulation**.

Public health

Facilitates large-scale trials to address key health issues (EU Beating Cancer plan, COVID-19…)

Research and innovation

Enables knowledge sharing and expert collaboration.

Investment in research

Ensures the EU/EEA remains an attractive clinical research hub globally.

Key Messages

- CTIS will be the **single-entry** point for clinical trials information in the European Union (EU) and in the European Economic Area (EEA).
- CTIS provides **harmonised and simplified end-to-end electronic application procedures** over the lifecycle of clinical trials across the EU/EEA.
- The Clinical Trial Regulation foresees a **3-year transition period**. **All initial applications** for clinical trials must be submitted through CTIS as of **31 January 2023**, while **all ongoing clinical** trials must be transferred to CTIS by **31 January 2025**.
- CTIS will offer **transparent and searchable clinical trial information to patients, healthcare professionals and the general public**. Clinical trial results will be available both as a technical summary and in lay language.
- CTIS is a unique **intuitive tool that facilitates submission** of clinical trial applications including those for multi-national trials.

Demonstration on Clinical Trial Information System (CTIS)

Demonstration for CTIS stakeholders - Virtual Event

20 January 2022

User Administration

Objectives of this demo

- User access to CTIS secure domain, via the use of individual credentials
- Role assignment to CTIS users performed by the administrator
- Visibility of user's profile via CTIS secure domain
- 'Request a role' functionality – available for sponsors

Initial Clinical Trial Application
Completion and evaluation

Objectives of this demo

- Description of the various component of an initial clinical trial application (CTA)
- Submission of an initial application
- Evaluation of an initial application by the MSC including:
  - ❑ Selection of the reporting Member State
  - ❑ Validation
  - ❑ Assessment of part I and part II (with RFI)
  - ❑ Decision by each MSC

Form: will enable the sponsor to provide cover letter, statement of compliance with GDPR, set the trial category and define the timelines for the publication of data/documents

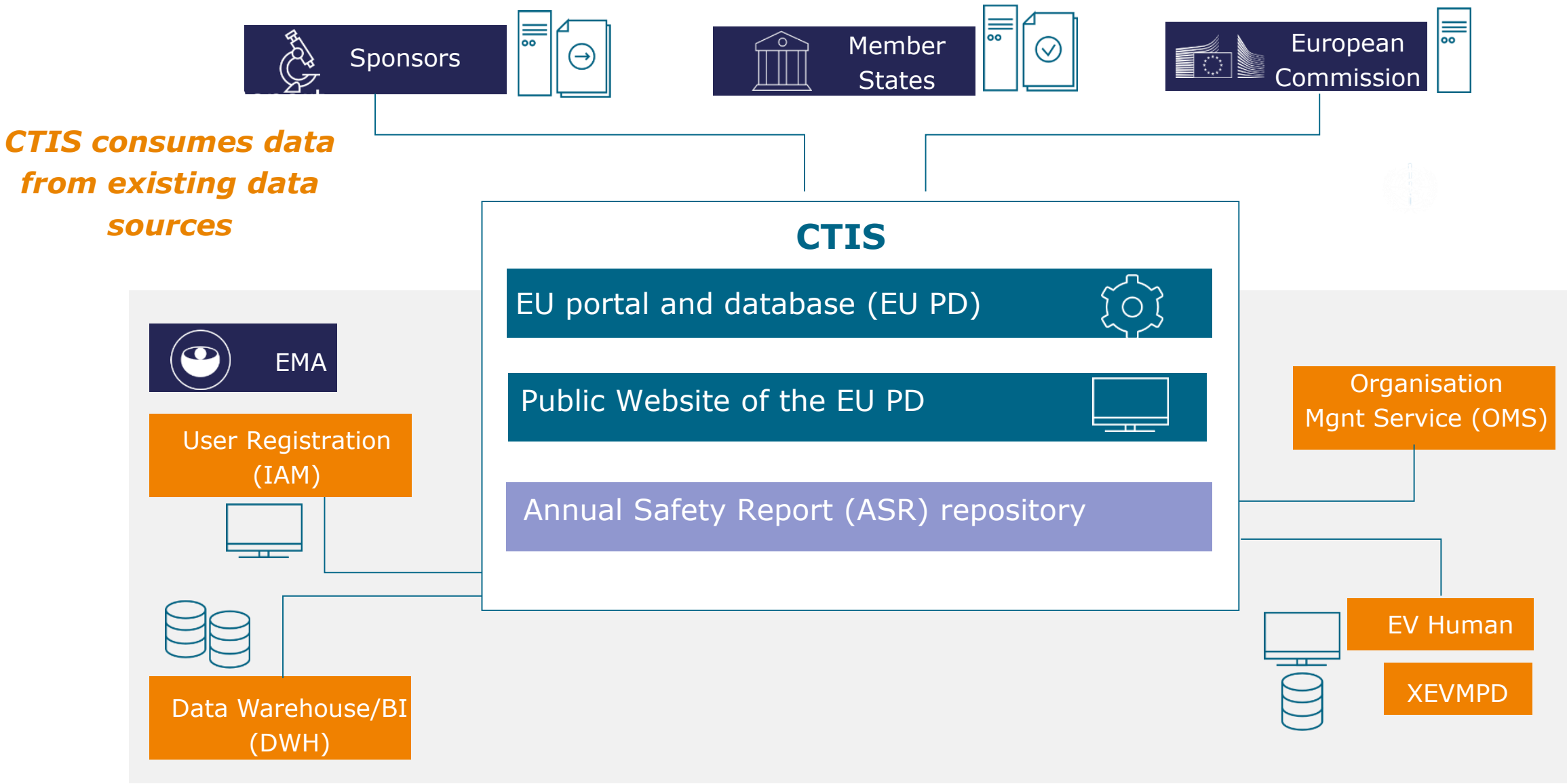
MSC: will enable the sponsors to choose the Member States Concerned (MSC) where the trial is intended to be conducted

Part I: contains clinical trials data/documents, such as protocol, details on study design, products documentation (IMPD, IB), sponsor details. These documents are subject to common assessment led by the Reporting Member State (RMS) with the MSC

Part II: contains data/documents, such as informed consent form, recruitment arrangements, PI CV, suitability of sites, documents that are of pertinence of the individual MSC assessment

Content and structure of the clinical trial application (CTA) dossier is in line with *Annex I* of the CT Regulation.

Article 26 'Language requirements': " The language of the application dossier, or parts thereof, shall be determined by the Member State concerned."



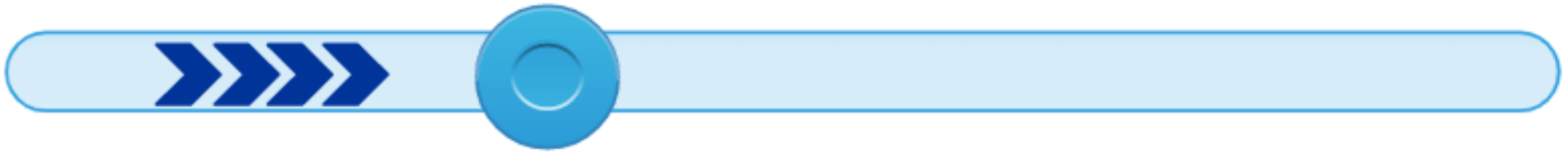
Initial application evaluation

Validation

- MSCs and RMS document considerations and RMS may raise RFIs
- Sponsor submits RFIs responses
- MSCs and RMS assess RFIs responses

The validation phase can take up to **10 days** that can be **extended by up to 15 days** if **RFIs** are raised (10 days for sponsor to respond + 5 days for the MSCs to review the response)

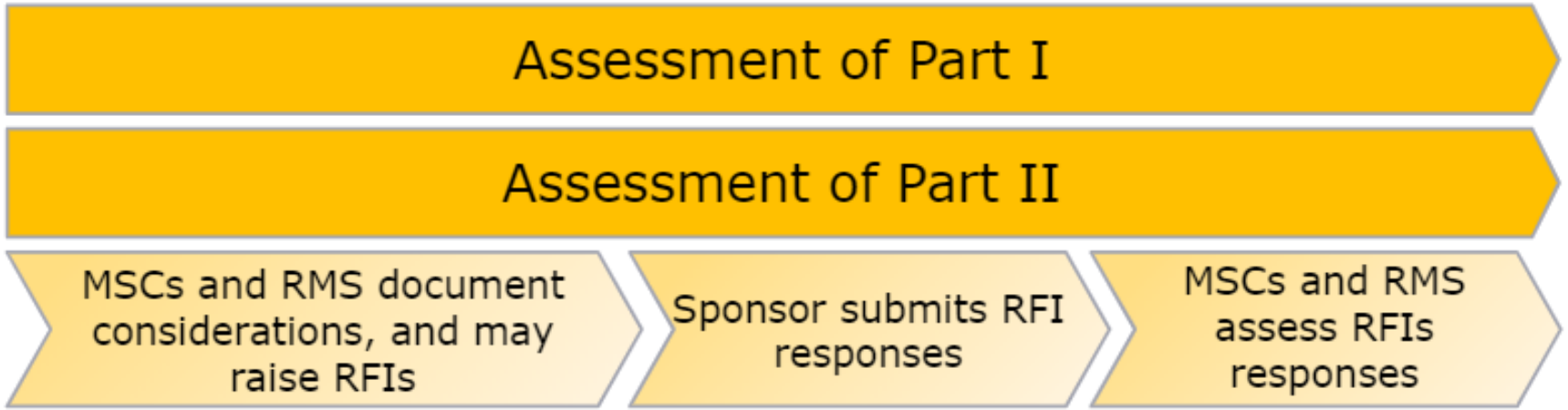
Phases and timelines for the evaluation of a CTA



Validation
10 days

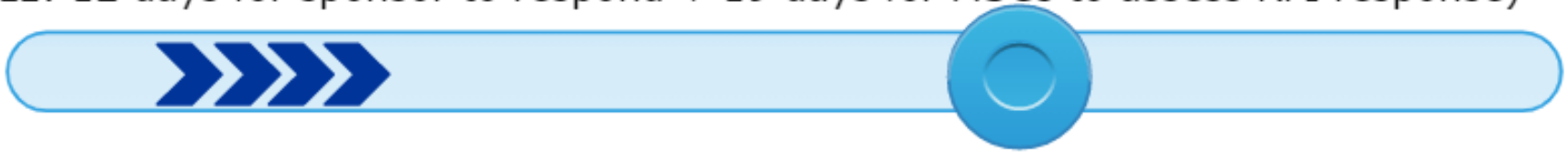
Assessment
45 days

Decision
5 day



The assessment phase can take up to **45 days** that can be **extended by up to 31 days** if **RFIs** are raised (for **Part I**: 12 days for sponsor to respond + 12 days for MSCs to review the response + 7 days for the RMS to consolidate the review. For **Part II**: 12 days for sponsor to respond + 19 days for MSCs to assess RFI response)

Phases and timelines for the evaluation of a CTA



Validation
10 days

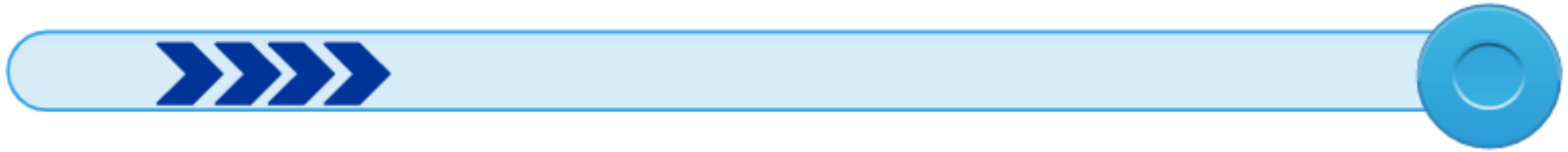
Assessment
45 days

Decision
5 days

Decision

The Decision phase can take up to **5 days.**

Phases and timelines for the evaluation of a CTA



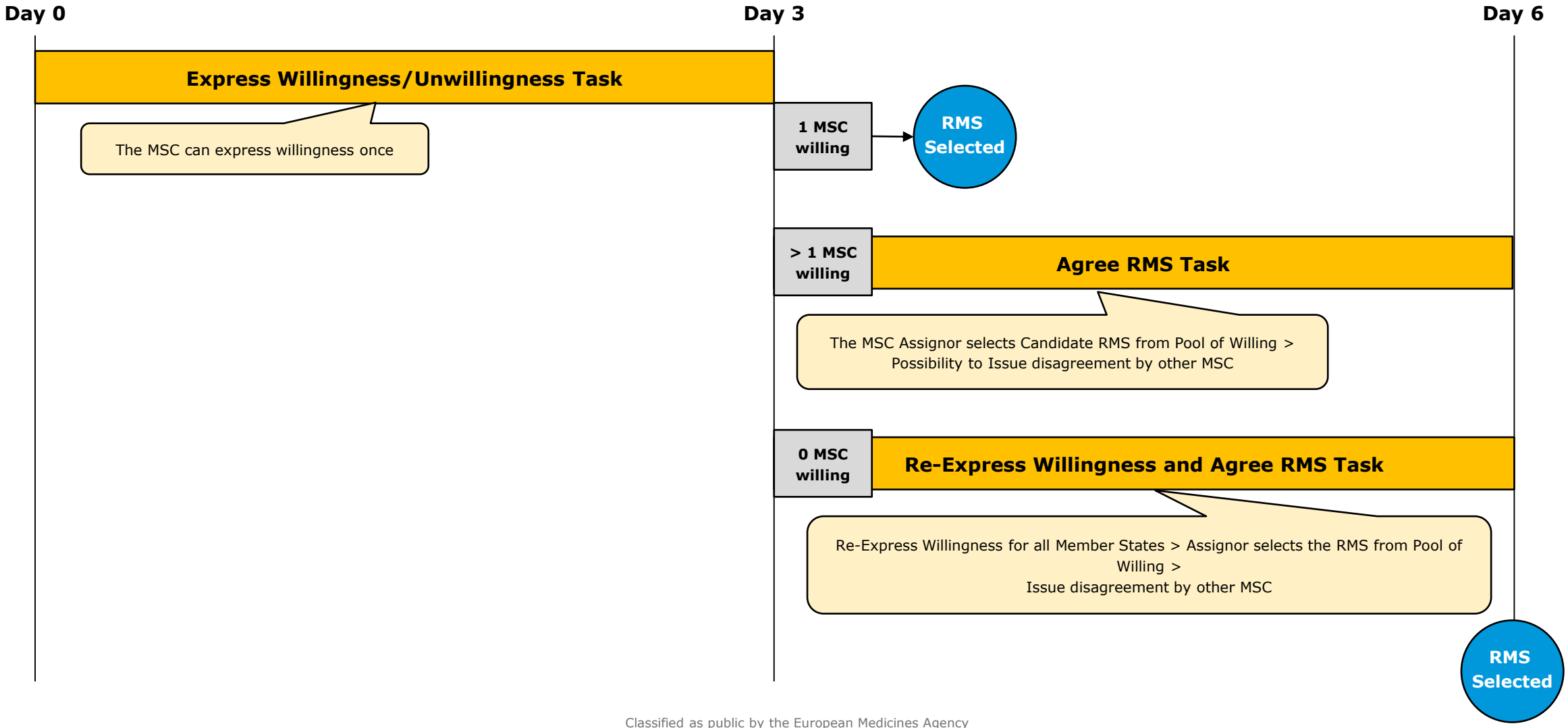
Validation
10 days

Assessment
45 days

Decision
5 days

Details on RMS selection for demo

RMS Selection Process Overview



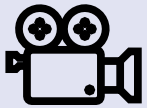
Coffee break

Next up - Modifications

- 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

Microphones are muted

Chat is disabled



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Use event code **#CTISdemo**

Or use Slido QR code

Modifications

Objectives of this demo

- Description of changes that can be applied to an application via a substantial modification
- Description of changes that can be applied to an application via non substantial modifications
- Addition of a new MSC and translations of data and documents

Substantial modifications: *The possible field and document options that may be populated with a substantial modification application type are highlighted in green.*

Form	MSCs	Part I*	Part II*
Cover letter	Add MSC	Data	Trial site
Modification description	# of subjects per MSC	Data translations	PI contact details
Supporting information		Documents	Documents
Supporting information		Document translations	Document translations
SM reason		3rd party entity	
SM scope		Entity contact details	
Proof of payment of fee		Description of changes	
Deferrals			

* If changes to the dossier

= Structured data field

= Document uploaded

***Non substantial modifications**: The fields and documents that may be populated with non substantial modification are highlighted in green, while those that can be modified with limitations are highlighted in orange.*

Form	MSCs	Part I	Part II
Cover letter	Add MSC	Data*	Trial site
Modification description	# of subjects per MSC	Data translations	PI contact details
Supporting information		Documents*	Documents
Supporting information		Document translations	Document translations
SM reason		3rd party entity	
SM scope		Entity contact details	
Proof of payment of fee		Description of changes	
Deferrals			

* Only certain fields and documents

= Structured data field

= Document uploaded

Addition of a new MSC: *The fields and documents that may be populated for this application type are highlighted in green.*

Form	MSCs	Part I	Part II
Cover letter	Add MSC	Data	Trial site
Modification description	# of subjects per MSC	Data translations	PI contact details
Supporting information		Documents	Documents
Supporting information		Document translations	Document translations
SM reason		3rd party entity	
SM scope		Entity contact details	
Proof of payment of fee		Description of changes	
Deferrals			

= Structured data field

= Document uploaded

Modifications – Assessment Phases

SM Part I and II	SM Part I Only	SM Part II Only	Additional MSC
Validation	Validation	Validation	Assessment of Part I *
Assessment of Part I	Assessment of Part I	Assessment of Part II	Assessment of Part II
Assessment of Part II	Decision	Decision	Decision
Decision			

**Additional MSC can create considerations on Part I and RMS can create RFIs, but no hard task is generated*

NOTE: *Non substantial modifications do not have an assessment process*

Lunch break until 13:45h

Next up - Notifications and supervision activities

- Trial and recruitment periods notifications
- Circumstantial event notifications
- Supervision activities – Corrective measures

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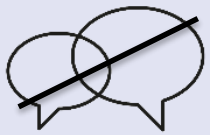

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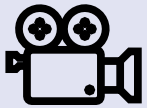

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Notifications and supervision activities

Objectives of this demo

- Trial and recruitment periods notifications
- Circumstantial event notifications
- Supervision activities - Corrective measures

Trial & Recruitment Periods notifications	Circumstantial events notifications	
Trial Periods	Unexpected events	Serious breaches
Recruitment Periods	Urgent safety measures	Third country inspectorate inspections

These notifications refer to the clinical trial life cycle in each MSC	These notifications are only needed in certain circumstances that were not foreseen in the protocol, may apply to one or multiple MSC(s)

Supervision Measures
Corrective Measures

Request a modification

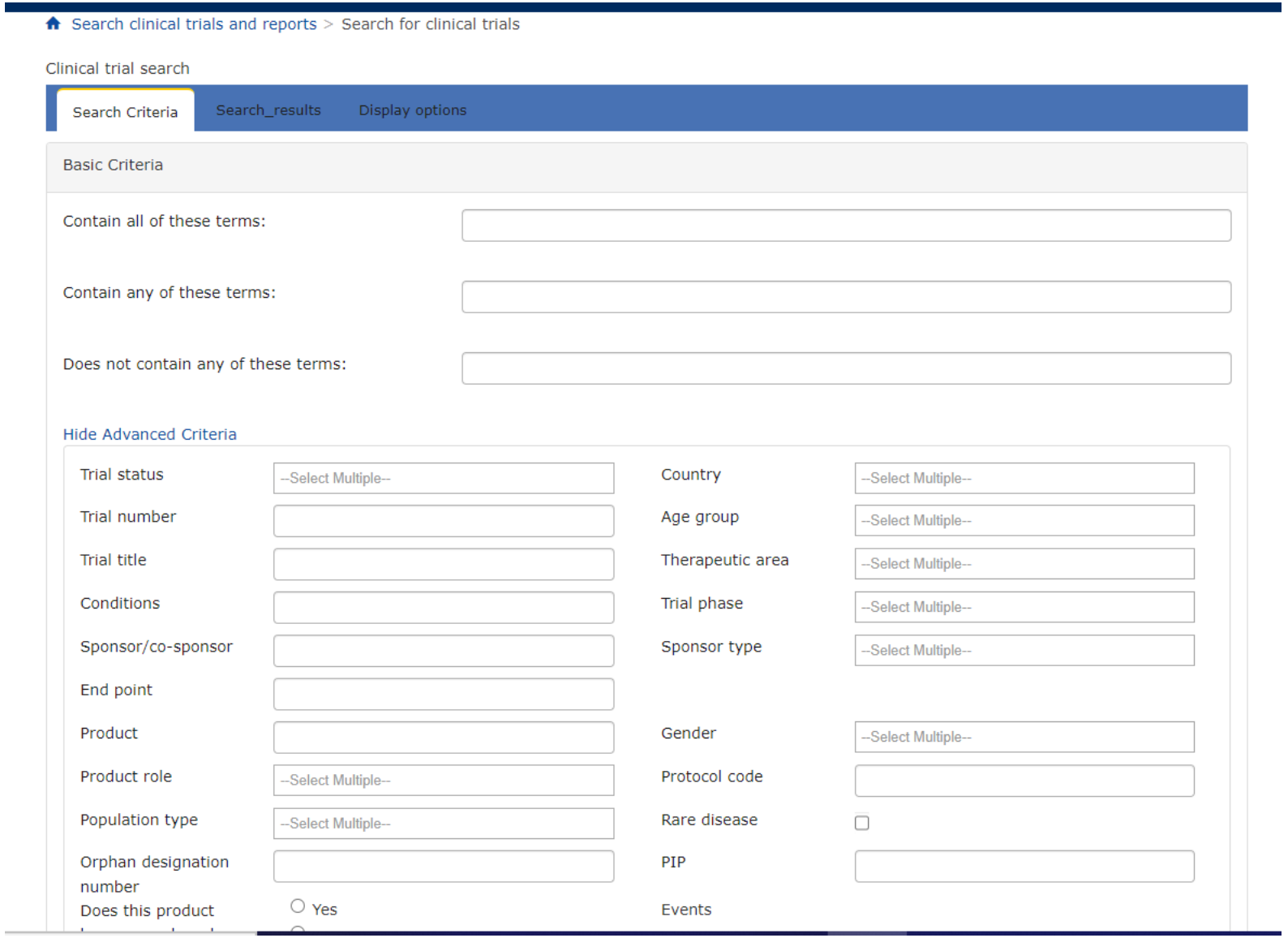
Suspend clinical trial authorisation

Revoke clinical trial authorisation

These measures are taken by the MSC individually and can lead to a change in the trial status

CTIS Public domain

Public domain of CTIS will allow access to clinical trials information to the members of the public. Clinical trials data transparency is one of the pillars of the CT Regulation



LR09 Copy Trial - ASR - Authorise

EUCT number: 2022-510562-35-00

Download CT

Summary | Full trial information | Events | Trial Results | Corrective measures | Inspection records

Trial information

Conditions(s)	LR Medical condition	Member states concerned	AT
Sponsor		Low intervention study	No
Trial Phase	Human Pharmacology (Phase I)- First administration to humans	Population type	Healthy Volunteers
Therapeutic area	Diseases [C] - Bacterial Infections and Mycoses [C01]	Transition Trial	No
First submitted	14/01/2022		
Last update	14/01/2022		
FIH	Yes		
Medical device	No		

Overall Trial status

Start of trial

Global end of trial

	Trial								Recruitment		
Member state	Current status	**Decision date**	**Last update**	**Start date**	**Temporary Halt**	**Restart**	**End (or early termination)**	**Reason for early termination**	Start	End	**Restart**
Austria	Authorised	14/01/2022									

Coffee break

Next up - Annual Safety Reports

- Submission and evaluation of the annual safety report

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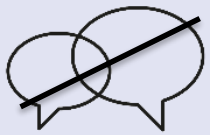

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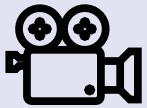

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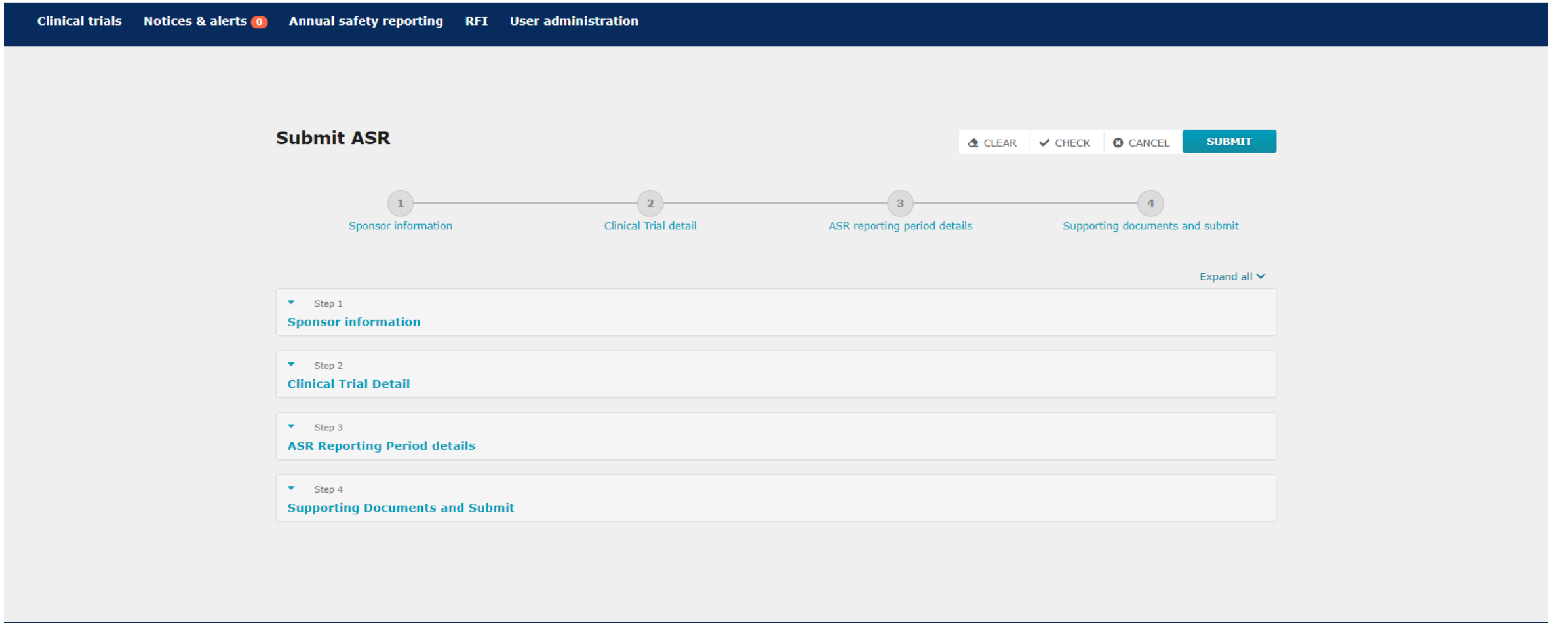
Annual Safety Reports

Objectives of this demo

- Present the steps for submission and evaluation of the annual safety report

Clinical trials



Questions & Answers

Q&As - Panellists

Any Questions? Go to **www.sli.do**

Use event code: **#CTISdemo**

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Kristof Bonnarens

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CTIS Member State Product Owner

Ruediger Pankow

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Fia Westerholm

European Medicines Agency

Ana Rodriguez

European Medicines Agency

Laura Pioppo

European Medicines Agency

Steven Le Meur

European Medicines Agency

Conclusion

Key Messages

- CTIS will be the **single-entry** point for clinical trials information in the European Union (EU) and in the European Economic Area (EEA).
- CTIS provides **harmonised and simplified end-to-end electronic application procedures** over the lifecycle of clinical trials across the EU/EEA.
- The Clinical Trial Regulation foresees a **3-year transition period**. **All initial applications** for clinical trials must be submitted through CTIS as of **31 January 2023**, while **all ongoing clinical** trials must be transferred to CTIS by **31 January 2025**.
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- CTIS is a unique **intuitive tool that facilitates submission** of clinical trial applications including those for multi-national trials.

Accelerating Clinical Trials in the EU (ACT EU)

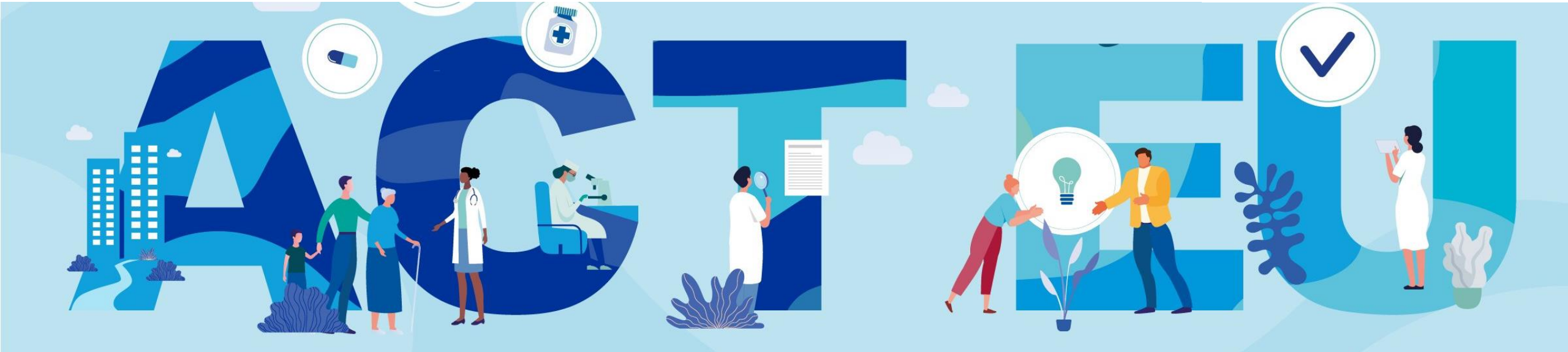
Launched on 13 January 2022

ACT EU will promote the development of high quality, safe and effective medicines by:

- strengthening the environment for clinical trials;
- integrating clinical research in the European health system; and
- engaging all stakeholders by establishing a multistakeholder platform.

More information to follow soon!

Co-led by the EC, HMA and EMA



Thank you for attending today's Demonstration event on the Clinical Trial information System (CTIS)

Further information

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