EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS) Bitesize talk

Initial clinical trial application

Presented by Charalampos Drosos & Laura Pioppo on 23 March 2022
European Medicines Agency

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CTIS Bitesize talk: Initial clinical trial application

14:00 - 14:05 **Introduction**

14:05 – 15:25 **CTIS Demonstration Sessions followed by live Q&A Sessions**

15:25 - 15:30 **Closing remarks**

*For questions, go to **www.sli.do** & use event code **#march24***

A few housekeeping rules

For your questions,
go to **www.sli.do**
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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.

Main Session: CTIS Demo with Q&A

- Initial application: Part I & Part II
- Evaluation section and timetable

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Charalampos Drosos
CTIS Change Management Officer

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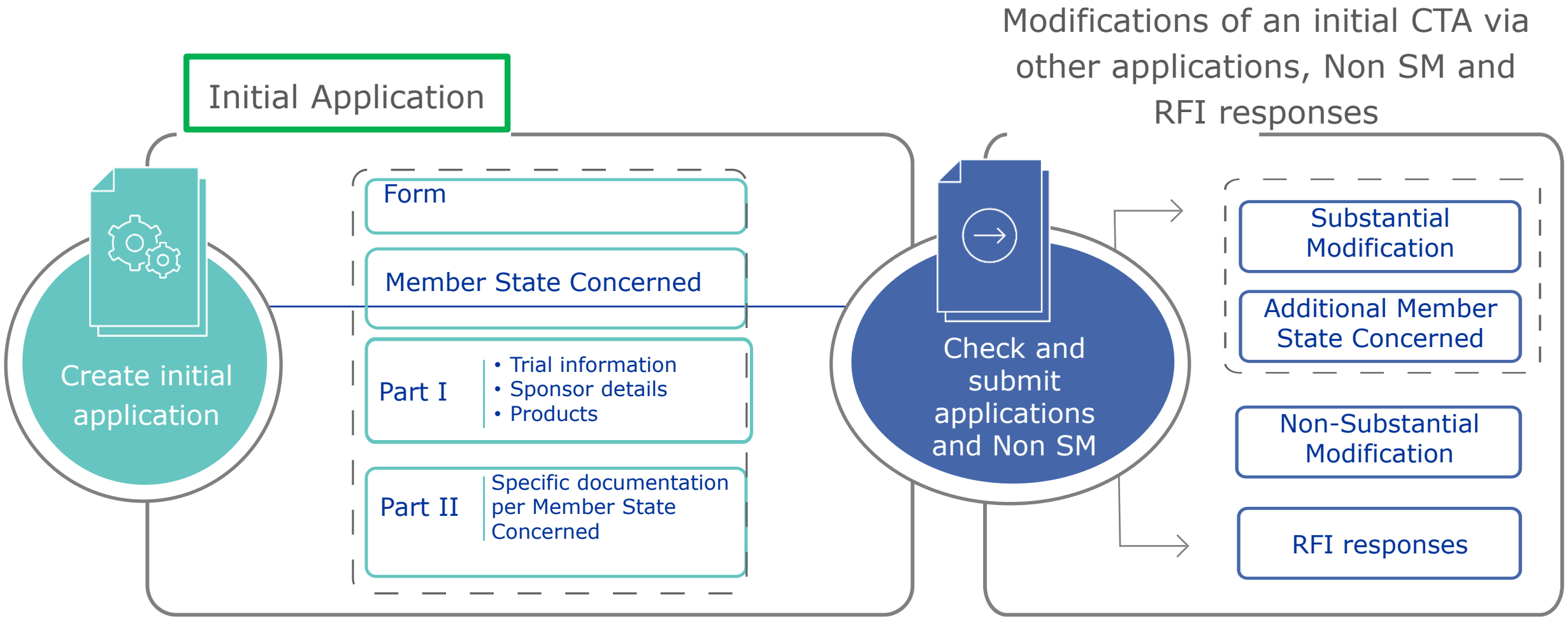
Scientific Officer in CTIS programme

Content of an initial clinical trial application



Content and structure of an initial CTA dossier

Form : will enable the sponsor to 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 data/documents, such as protocol, IMPD, investigator's brochure, that are subject to common assessment led by the Reporting Member State (RMS) in collaboration with the MSC

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

Evaluation: is the section where sponsor users can access RFI and conclusions on the assessments done by the RMS/MSC including the assessment reports for part I and part II

Timetable: gives a projection on the timelines for evaluation of the application

Content and structure of a clinical trial application

When working on a CTA, and before submission, the user can click on:

Check: This enables the user to verify that all the mandatory fields have been completed and mandatory documents have been provided. The system will flag in red the outstanding section(s).

Save: This enables the user to save the draft CTA and make it visible to him/herself and to the users within the same organisation with the same profile.

Cancel: This enables the user to cancel the draft application prior to submission. Clinical trial data and documents will no longer be accessible after cancellation.

Submit: This enables the user to proceed with the submission of the application for evaluation. After submission, the application will be visible in the authority domain to the MSC for the application.

Questions & Answers

For questions,

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Thank you for attending today's event

Next CTIS bitesize talk on 28 April

Please provide your feedback for this event in our EUsurvey
(link available on EMA event page)

Further information

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