EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Submission of an initial Clinical Trial Application in CTIS – structure, data and documents of an initial application dossier

SME and academia Clinical Trials Information System (CTIS) two-part training webinar

Presented by Laura Pioppo on 04 March 2021

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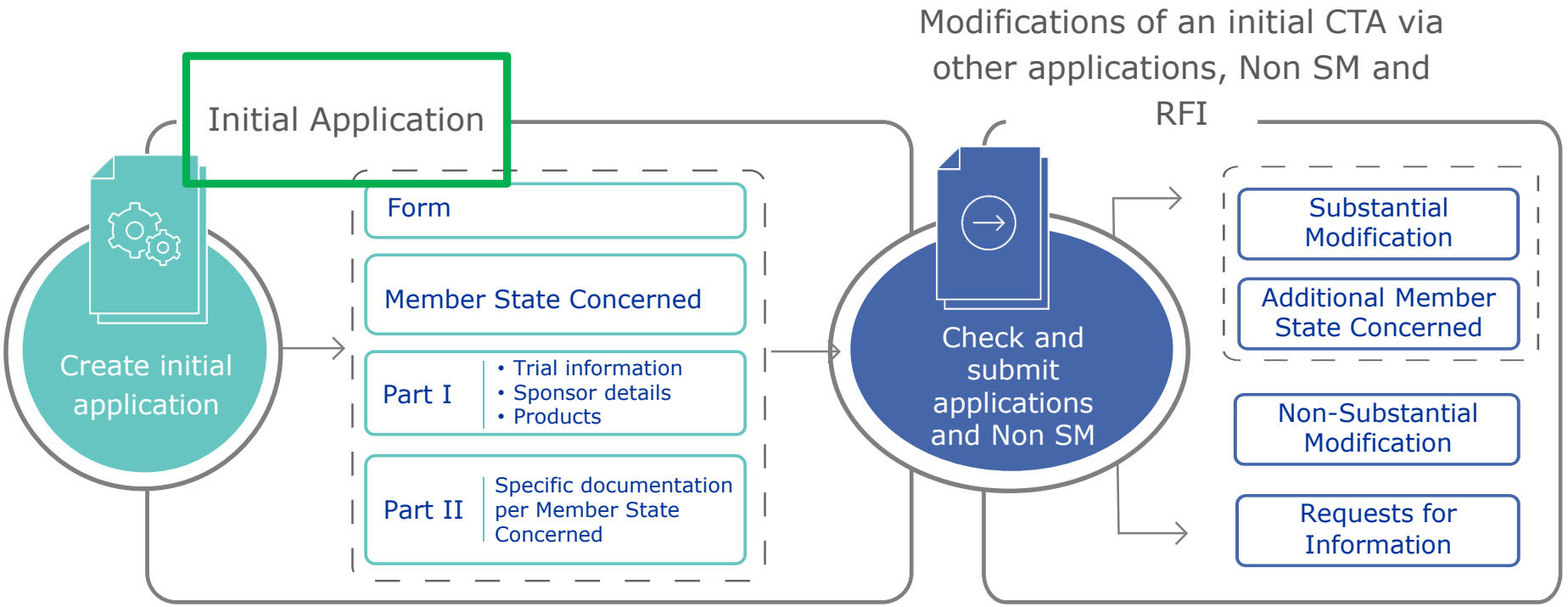
Sponsor – Submission of an initial Clinical Trial Application



Content and structure of an initial clinical trial application (CTA)

Form section: 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 chose the Member States Concerned (MSC) where the trial is intended to be conducted

Part I of the dossier: contains data/documents that are subject to common assessment led by the Reporting Member State (RMS) in collaboration with the MSC

Part II of the dossier: contains data/documents 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

Content and structure of the CTA dossier is in line with *Annex I* of the CT Regulation.

The initial application can be of two types:

- **Full initial**: all the MSC receive part and part II (*Article 5*)
- **Partial initial:** all MSC receive part I and some, or none, of the MSC receive part II (*Article 11*)

Article 26 ‘***Language requirements’:*** “ The language of the application dossier, or parts thereof, shall be determined by the Member State concerned.”

Sponsor has **the possibility to update the information** contained in the dossier after submission to the Member States concerned when replying to an RFI as applicable or, when submitting a substantial or non substantial modification. Also translation of part I documents can be provided when adding a new MSC.

Video clips – submitting an initial clinical trial application

EMA CTIS training programme Module 10 – Create, submit and withdraw a clinical trial

Click here for online training materials related to this module.

Any questions?

Further information

CT.Sponsortraining@ema.europa.eu

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