EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

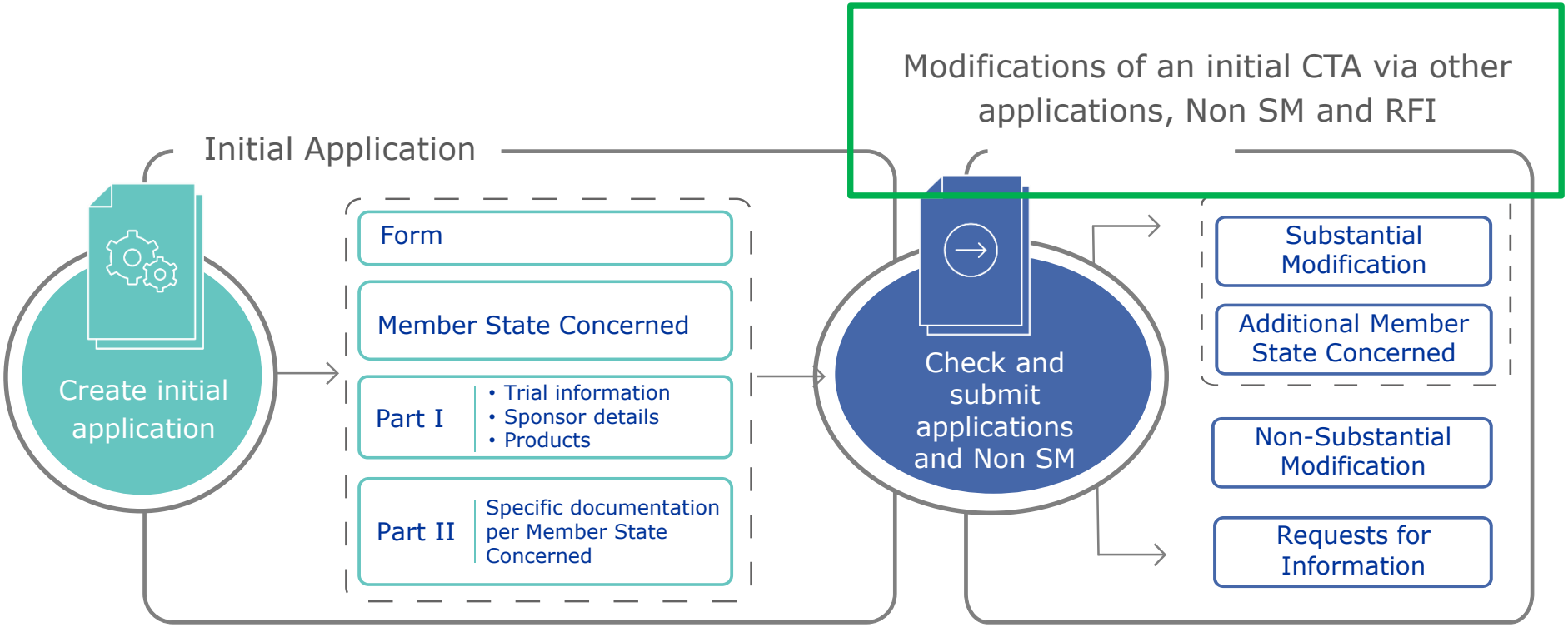
Update of an initial application

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

Presented by Laura Pioppo on 04 March 2021

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.

Sponsor – Submission of a Clinical Trial Application



Different types of applications (1/2)

1. Substantial modifications applications :

- **Part I only:** *Article 17, 18, 19*
- **Part II only:** *Article 20*
- **Part I and II:** *Article 21, 22 and 23*

Once that the initial application has been authorised, it will be possible for the sponsor to submit a modification to the application dossier which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial;

Different types of applications (2/2)

2. Addition of a Member State Concerned *(Article 14)*

Once that the initial application has been authorised, it will be possible for the sponsor to submit an application to add a new MSC and provide translations of documents according to the requirements of the MSC that is being added

- It will be possible to **submit one or more applications** to add MSC at the time
- **The newly added MSC** will consider the assessment already done – at the time of the initial application- on the part I and will be in the position document considerations on the part I
- **Part II documents provided** for the newly added MSC will be assessed by that MSC independently

Video clips – submitting substantial modifications and addition of a new MSC

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

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