EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work-planning and management tools

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

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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.

CTIS supports sponsor users in compiling, recording, submitting clinical trials data carried out in the EU. These activities are supported with three workload management functionalities.

Sponsors

academia organisations and industry

1. **Compile, record and submit** data for CTs carried out in the EU.
2. **Respond** to RFIs sent by Member State Concerned (MSC).
3. **Submit** notifications to Member States for events occurred during the life cycle of their trials (e.g. recruitment of patients, end of the trial, subject safety issues, etc).

CTIS offers two general, and one specific workload management functionalities to support sponsor users in efficiently organising their activities regarding CTs.

Notices and alerts

Enables to monitor the messages triggered following the occurrence of events during the lifecycle of a CT (i.e. from creation and submission of an initial CTA until the final reporting of a CT).

Who can view it?

Sponsors and Marketing Authorisation Holder

RFIs

Enables users to access the requests from Member States about information that needs to be clarified in the context of validation and assessment of a CTA, ad hoc assessments, corrective measures or ASRs.

Who can view it?

Sponsors

Timetable

Enables to monitor the completed phases of a CTA and the projected dates by which the remaining phases will (latest) be completed.

Who can view it?

Sponsors

Notices and alerts

Notices

Messages that inform users of any event occurred during the life-cycle of all the CTs they are involved in. They are generally of an **informative nature**.

Examples: Examples: Application submitted, Non Substantial Modification submitted, Validation conclusion recorded, Decision submitted, etc.

Alerts

Messages that inform the users of **an action to be performed** regarding a specific CT in which they are involved.

Examples: Examples: Unexpected Event submitted, Discuss who should be RMS task open, Corrective measure has been made, etc.

RFIs

CTA RFIs

Validation and assessment

RFIs raised during the evaluation of an initial CTA, the assessment of an application for SM and/or the assessment of an application for subsequent addition of a MSC.

CT RFIs

Ad hoc assessment

RFIs raised to request additional information to the sponsor as part of an ad hoc assessment.

Corrective measures

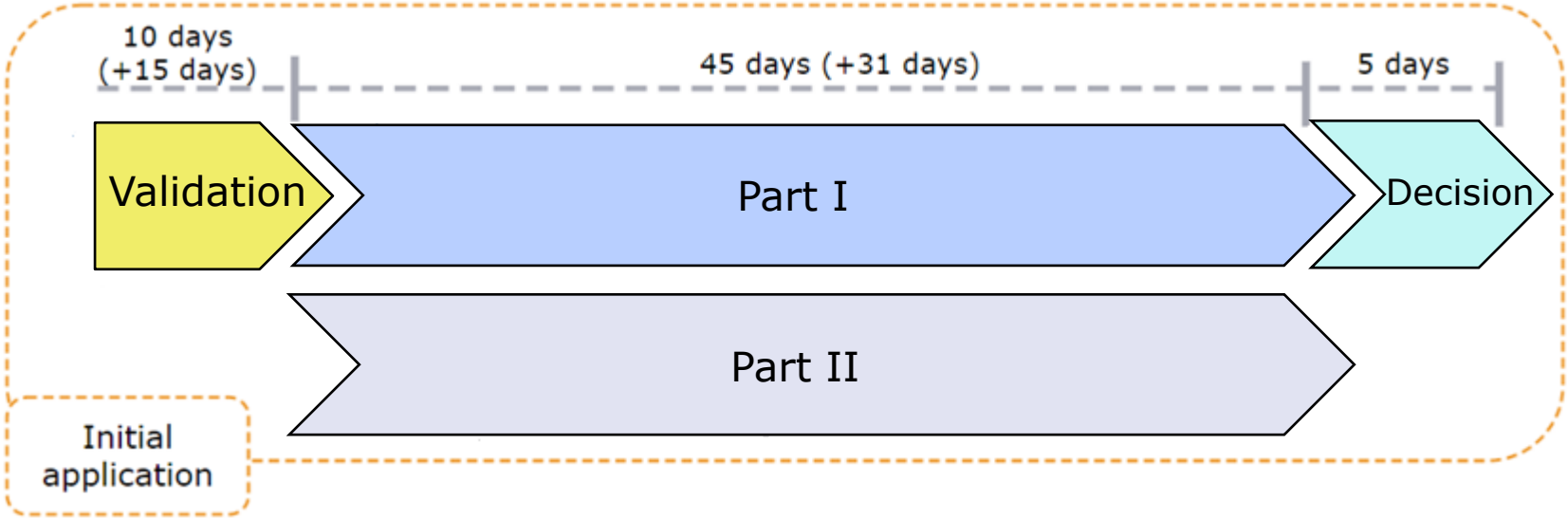
RFIs raised to request the sponsor's opinion before applying a corrective measure.

Annual Safety Reporting

RFIs raised during the assessment of an ASR prepared by a sponsor to monitor the safety status of an IMP used in a CT.

Timetable

The Timetable allows users to monitor the progress of the assessment of a particular CTA, by displaying the actual completion dates of each phase of the assessment, and the expected completion date of the remaining ones.



Validation: the validation process starts with the submission of the CTA dossier and the request of the RMS by the sponsor in the case of multinational trials. It ends with the final validation of the application by the MSC, and in case of a multinational CTA, by the RMS.

Part I: The ***assessment of Part I*** starts with the initial assessment by the RMS and the draft assessment report sent to all MSC. After the MSC submit their considerations, these are consolidated in a final report of the assessment of Part I of a CTA.

Part II: The ***assessment of Part II*** entails that the individual (national) assessment of each MSC regarding the CTA. This assessment includes: informed consent, subject recruitment, data protection, reward/compensation of investigators/subjects, suitability of investigators and of trial sites, etc.

Decision: after Part I and Part II assessment, a notice of single decision by each MSC is sent to the sponsor through the CTIS.

Video clip – RFI list functionality

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EMA CTIS training programme Module 04: Support with workload management

Click here for online training materials related to this module.

Any questions?

Further information

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