



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS) Bitesize talk

Modifications

Presented by Noémie Manent and Pieter Vankeerberghen on 31 May 2022
European Medicines Agency



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CTIS Bitesize talk: Modifications

- 16:30 - 16:35 **Introduction**
- 16:35 - 17:55 **CTIS Demonstration Sessions followed by live Q&A Sessions**
- 17:55 - 18:00 **Closing remarks**

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#may31*

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- ❖ 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*
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Main Session: CTIS Demo with Q&A

Modifications

- Introduction
- Allowed submissions whilst ongoing evaluation of an application
- Substantial Modifications (SM)
- Non Substantial Modifications (NSM)
- Timer overview
- Substantial modification scope
- Live demo with Q&A



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Modifications

Presentation



Introduction

A sponsor can submit a substantial modification (SM) or a non-substantial modification to a MSC that does not have an assessment on-going in relation to this clinical trial.

NOTE: *Sponsor should ensure that the SM documentation dossier meets quality standards*



Allowed submissions whilst ongoing evaluation of an application

		Submission of a substantial modification to Part I and Part II	Submission of a substantial modification to Part I	Submission of a substantial modification to Part II	Submission of a non substantial modification	Submission of application for an additional member state
	Initial application	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC
Ongoing activity	Evaluating Part I & Part II substantial mod application	No	No	No	No	No
	Evaluating Part I only substantial mod application	No	No	No	No	No
	Evaluating Part II only substantial mod application	No	No	Only to MS who did not receive the Part II SM	No	yes
	Evaluating add additional member state	No	No	Only to MS who are not evaluating the application to add an additional MSC	No	Only to MS that is not an MSC or evaluating an assessment to become an MSC



Substantial modifications

any change to any aspect of a CT, which is made after the notification of a decision on a previously submitted application and which is likely to either have a substantial impact on subjects' safety/ rights or on the reliability and robustness of the data generated in the CT.

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		3 rd party entity	
SM scope		Entity contact details	
Proof of payment of fee		Description of changes	
Deferrals			

= Structured data field

= Document uploaded

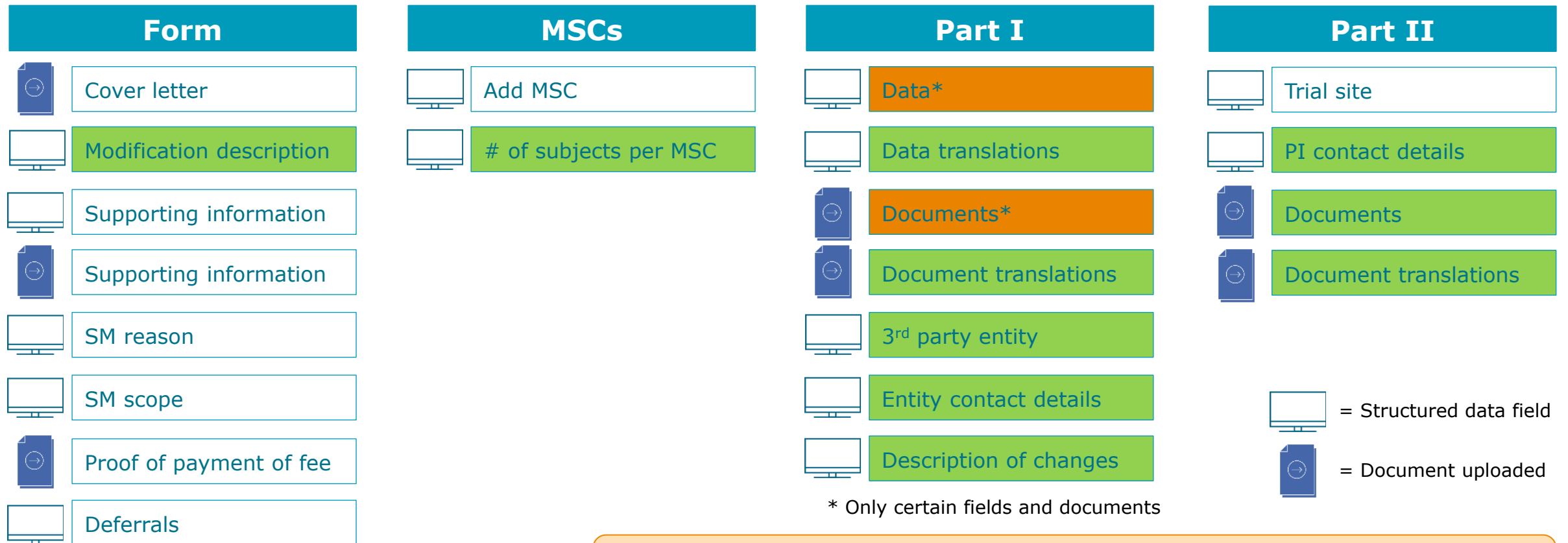
* If changes to the dossier

*Highlighted in **green**:
The possible field and document options that may be populated with an SM application type.*



Non substantial modifications

any change to the CT dossier that is not likely to have a substantial impact on the safety or rights of the subjects or the reliability and robustness of the data generated in the CT, but is relevant for the supervision



* Only certain fields and documents

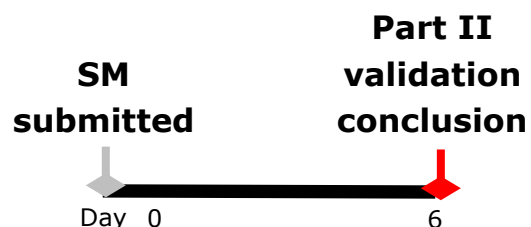
Highlighted in **green**: The fields and documents that may be populated with NSM
 Highlighted in **orange**: The fields and documents that can be modified with limitations.



Timer overview

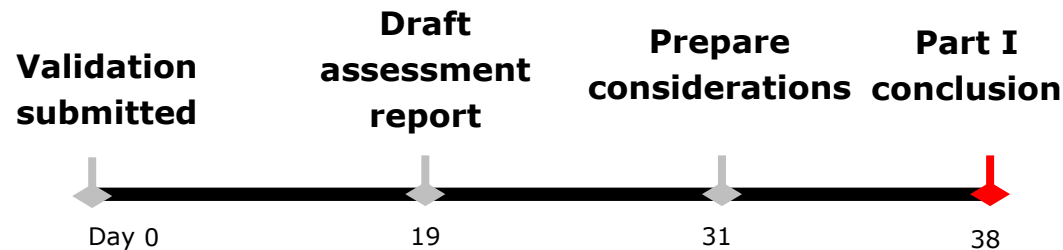
Validate (Part I /II or Part I only)

Extension 15 days

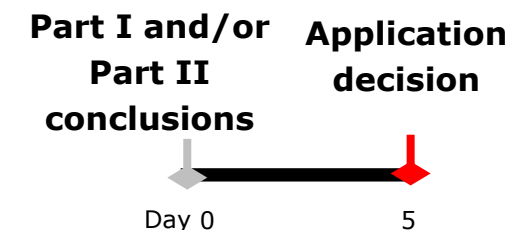


Part I assessment

Extension 31 days



Submit decision (Part I /II or Part I only)



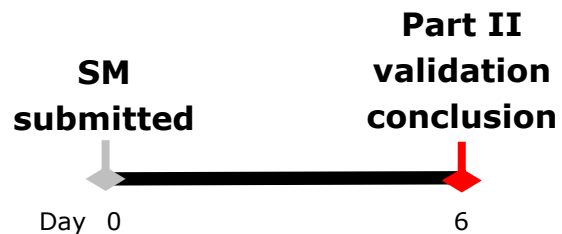
Part II assessment

Extension 31 days



Validate (Part II Only)

Extension 15 days

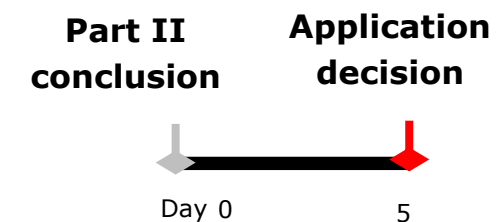


Part II assessment

Extension 31 days



Submit decision (Part II only)





Substantial modification scope

SM Part I and II
Validation
Assessment of Part I
Assessment of Part II
Decision

SM Part I Only
Validation
Assessment of Part I
Decision

SM Part II Only
Validation
Assessment of Part II
Decision



Modifications

Live system demonstration



Questions & Answers



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Thank you for attending today's event

*Next CTIS bitesize talk
on 23 June*

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