EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Answers to Knowledge Check in the post-event survey

SME and academia Clinical Trials Information System (CTIS) two-part training webinar – day 2

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Answers to questions from the post-event survey

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Answers are shown in **bold** below.

1. What does part I of an initial CTA include?

- Cover letter and proof of payment
- Information related to the trial sites in each Member State Concerned
- **Trial-specific scientific information**

2. When can Add MSC applications be created?

- **Additional MSC CTAs can only be created if the CT has a status of authorised or authorised with conditions**
- Additional MSC CTAs can be created if the CT has a status of not authorised
- Additional MSC CTAs can be created at any time, regardless of the status of a CT

Answers to questions from the post-event survey

Answers are shown in **bold** below.

3. When should users submit a substantial modification?

- **When the sponsor needs to make a change in the CT that is likely to have a substantial impact on its subjects' safety and rights or on the robustness and reliability of its data**
- When the sponsor wants to extend the trial to another MSC
- When the sponsor wants to modify the trial to correct typographical errors or update contact details

4. What types of substantial modifications can be created?

- **Single trial modifications**
- **Multi-trial modifications**

Answers are shown in **bold** below.

5. Requests for Information can be viewed through:

- **The RFIs tab**
- **The Notices and Alerts tab**
- Clinical trials overview tab

6. What are the consequences of not answering a Clinical Trial Application (CTA) RFI?

- The CTA process will continue
- **The initial CTA will lapse**
- The CTA validation phase will be extended

7. The fields published on the CTIS public website, even in the case of deferral, include:

- **EU Clinical Trial Number**
- **Sponsor name and address**
- Identification of the investigational medicinal products (IMPs)