EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Sponsor activities during the life-cycle of a clinical trial: submission of notifications

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

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Definition and types of notifications

Notifications allow sponsors to notify MSC about relevant events occurred when conducting a CT. They can be classified in two main groups:

Trial and recruitment periods notifications

Trial and recruitment periods

Most of these notifications are executed in all trials, as they refer to the CT life cycle.

Other notifications

Unexpected event

Serious breach

Urgent safety measure

Third Country Inspectorate Inspection

These notifications are only needed in certain circumstances that were not foreseen in the protocol.

Trial and recruitment periods

Trial and recruitment period notifications enables sponsors to inform MSC of critical moments during the conduct of a CT. Some of them are needed in certain circumstances while others are mandatory. Such notifications must be made **within 15 days** from the start of the event.

Start trial

The first act of recruitment of a potential subject for a specific CT. It could be the date of initiation of the CT in the first site, or the date when the first study specific advertisement is published.

Start recruitment

The first visit of the first subject. The recruitment shall begin within 2 years from the CT authorisation. If an extension to start the recruitment is needed beyond 2 years, the sponsor must submit a SM application

End recruitment

The act of not recruiting subjects anymore in a MSC.

End of trial

The last visit of the last subject, or a later point in time as defined in the protocol.

These notifications allow to interrupt a CT on specific grounds and to resume it afterwards, if required.

Temporary halt

An interruption not provided for in the protocol of the conduct of a CT by the sponsor with the intention to resume it. There are two types depending whether the notification is related to a matter of subject safety and/or benefit-risk balance, or not.

Restart of the trial

The act of restarting the trial after a temporary halt, or after suspension of the CT by a MSC. Depending on the circumstances a SM may need to be submitted and authorised to restart the trial.

Restart of recruitment

The act of restarting the recruitment of subjects. The trial must have been restarted in order to be able to restart the recruitment.

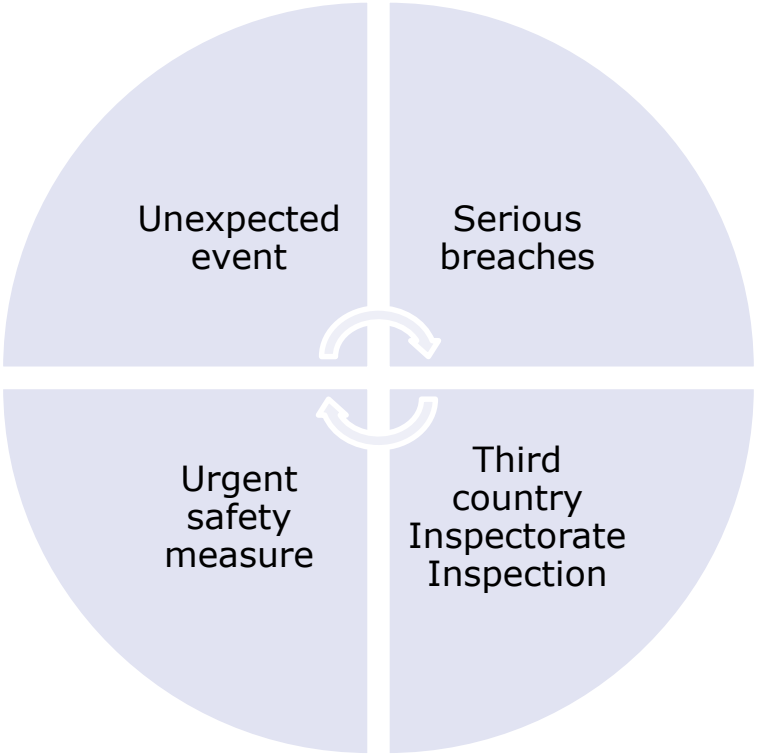
Other notifications

Allows the sponsor to inform the MSC about any UE that might materially influence the benefit-risk assessment of the medicinal product, or that would lead to changes in the administration of a medicinal product or in overall conduct of a CT *(e.g. a significant hazard to the patient population).* Such notifications must be made no later than **15 days** from the date the sponsor became aware of the event.

Art. 53 of the CT Regulation.

Allows the sponsor to inform where an unexpected event is likely to seriously affect the benefit-risk balance and the USMs which have been taken to protect the subjects. The sponsor must notify the MSC of such events **within 7 days** from the date the measures were taken.

Art. 54 of the CT Regulation.



Allows the sponsor to inform about a breach likely to affect the safety and rights of a subject or the reliability and robustness of the data generated in the CT. These notifications must be made no later than **7 days** from the date on which the sponsor became aware of the breach.

Art. 52 of the CT Regulation.

Enables the sponsor to submit all inspection reports of third countries authorities concerning a CT.

Art. 53 (2) of the CT Regulation.

Ad hoc assessments enable the MSC to assess information related to a notification, an IMP or any other information relevant to the supervision of the trial. Such type of assessments may be generated in two situations:

Assessment related to a notification

e.g. temporary halt, serious breach, unexpected event or urgent safety measures.

Assessment related to other aspects of a CT

e.g. safety made for the same CT, or another CT using the same medicinal product, etc.

During this process the MSC may request information to the sponsor through the **RFI functionality.**

Video clip – Manage a CT - Trial and recruitment periods

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EMA CTIS training programme Module 05: Manage a clinical trial through CTIS

Click here for online training materials related to this module.

Video clip – Manage a CT - Other notifications

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Any questions?

Further information

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