Monitoring Audit sub-Project

The *Monitoring Audit sub-Project (CT MON)* is part of *QA activities* and is undertaken by the *Monitoring Organization* appointed by the *Sponsor* and independent of the *Clinical Trial team/Sponsor/CRO*.

The *Monitoring Organization* acts as the main line of communication between the *Sponsor* and the *Investigator*.

The *Monitoring Audit* is the act of overseeing the progress of a *Clinical Trial* and ensuring that it is conducted, recorded, and reported in accordance with the *protocol, SOPs, GCP*, and *regulatory requirements*. One *Monitoring Audit* covers only one *Investigational Site* and the *Investigational Site* is one of the main characteristics of the *sub-Project*.

The *Monitoring Audit sub-Project* is triggered by:

- *Pre-Trial Monitoring Audit Notification*
- *Initiation Monitoring Audit Notification*
- *Regular/Planned Monitoring Audit Notification*
- *Triggered Monitoring Audit Notification*
- *Close-out Monitoring Audit Notification*

After registration of the Notification, the *Monitoring Audit sub-Project* becomes an active topic in the *Enriched Email Client*.

Below are presented all *significant events* that can be selected by a designated *regulatory project person,* nominated *Assistant,* or *Agent* when sending or receiving *enriched email messages* during the realization of this type of *Corporate Project*. The designated *regulatory project person*, as the *designated follower* of the *enriched emails* for the specific project, also receives copies of all *enriched email messages* sent by the *Assistant* or *Agent* and is forwarded to all *enriched email messages* received by the nominated *Assistant* or *Agent.*

Automatically generated *enriched email notifications*, sent or received, cannot be selected and are presented here for illustrative purposes only.

Also, not all *significant events* need to be selected, in fact, only the selection of *significant events* whose selection leads to a new *project activity* is mandatory, as this enables the progress of the *Corporate sub-Project*.

The procedure model can be easily modified by adding, deleting, or changing *milestones, activities,* and *significant events* to suit particular needs/requests.

Milestones, activities, and significant events

Initiated

Monitoring Audit preparation
- (ext-in) Request to schedule an Audit
- (ext-in) Response to Audit Request
- (ext-out) Request for the latest recruitment rate
- (ext-in) Latest study recruitment rate
- (ext-in) Request for the specified documentation
- (ext-in) Auditor arrival confirmation
- (ext-in/out) Related correspondence

Monitoring Audit Started

Monitoring Audit ongoing
- (ext-in) Request to schedule a Visit
- (ext-in) Response to Visit Request
- (ext-in) Monitoring Visit - minutes of meeting
- (ext-in) Monitoring Visit - Visit Report
- (ext-in) Monitoring Visit - Response
- (ext-in) Information on unwarranted deviation
- (ext-out) Issue escalation
- (ext-in) Latest study recruitment rate
- (ext-in) Draft Site Audit Report
- (ext-in) End of Monitoring Audit Declaration
- (ext-in/out) Related correspondence

Monitoring Audit Completed

Monitoring Audit Report Preparation
- (ext-in) Monitoring Audit Report
- (ext-in) Monitoring Audit Report Response
- (ext-in) Audit Report Response Reminder
- (ext-out) Request for Audit Certificate
- (ext-in) Audit Certificate
- (ext-out) Audit Certificate to IRB/NCA
- (ext-out) Risk Management Conclusion
- (ext-in/out) Related correspondence

Closed