DMID-CROMS Clinical Site Monitoring Visit Flowchart

Site Assessment Visit

Description:
To verify site suitability. Applicable ICH Guidelines for Good Clinical Practice:
4.1 Investigator's qualifications and agreements,
4.2 Adequate resources
5.6 Investigator selection
8.2.19 Pretrial monitoring report

Prospective clinical site is identified for participation in a DMID sponsored clinical trial

DMID Clinical Project Manager submits a request for site assessment visit via the NIAID DMID CRMS Clinical Site Monitoring Module

Study Initiation Visit

Description:
- A meeting prior to the official start of the study to discuss all aspects of the clinical trial and the allocation of responsibility.
- An opportunity to lay the groundwork for a successful clinical trial.
- Applicable ICH Guidelines for Good Clinical Practice:
8.2.20 Trial Initiation Monitoring Report – To document that trial procedures were reviewed with the investigator and investigator's trial staff

All applicable regulatory and contractual approvals are final at designated site(s)

DMID Clinical Project Manager submits a request for site study initiation visit via the NIAID DMID CRMS Clinical Site Monitoring Module

Interim Monitoring Visit

Description:
– Applicable ICH Guidelines for Good Clinical Practice:
1.38 Monitoring: The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirements(s).
– Applicable FDA regulation:
CFR 312.56 Review of ongoing investigations

Clinical Monitoring Plan specifies requirements for monitoring activities by milestones (if applicable) and at pre-defined intervals

Site Close-out

Description:
- Intended to bring closure to the conduct of a study at a particular site.
- Confirmation that all study procedures have been completed, data collected, and test article and supplies have been removed from the site.
- Confirmation that all of an investigator's study obligations have been met and that all of the post-study obligations, such as records retention are understood.

All applicable obligations have been met at designated site(s) (e.g., test article and/or specimen accountability, safety event follow-up, IRB notification)

Site ready for close-out?

Yes

Before, during and after the monitoring close-out visit the CROMS Essential Regulatory Documents Group or applicable document collection group is responsible for tracking of all required site close-out documentation

Site ready for close-out?

Yes

No

DMID Clinical Project Manager confirms the site is ready for monitoring close-out visit

CROMS Clinical Site Monitoring Contractor will acknowledge receipt of request for monitoring services (RFS)

CROMS Monitor will contact site to schedule visit, draft agenda, coordinate with DMID as needed and send Pre-Visit Confirmation letter to the site

Visit completed within one calendar month unless otherwise specified

No

Yes

Visit Monitoring Report drafted and routed for review

For information regarding visit parameters refer to *Guidelines for Initial DMID-CROMS Monitoring Resource Allocation*