OSRO Clinical Site Monitoring (CSM) - Visits, Reports, Task Flow

Site Assessment Visit SAV

- To verify site suitability.

Applicable ICH GCP:
4.1 Investigator's qualifications and agreements
4.2 Adequate resources
8.2.19 Pretrial monitoring report

Determination by OSRO that a site assessment visit is needed.

Site Initiation Visit SIV

- 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 GCP:
8.2.20 Trial Initiation Monitoring Report – To document that trial procedures were reviewed with the Investigator and Investigator's trial Staff.

- Email request for clinical site monitoring is sent to OSROMonitoring@mail.nih.gov **4 to 8 weeks before the team's target SIV date**. Includes: PI name, Protocol Title, Study Product Name, Manufacturer Name, Protocol document in WORD format, the SIV target date and a site Point of Contact.
- Before the SIV date is confirmed, the site essential regulatory documents (per OSRO 203 Clinical Trial Records Policy) are received by OSRO Monitoring for review; all queries or discrepancies resolved and the complete essential regulatory file accepted.
- SIV meeting coordination is the Site's responsibility.

Interim Monitoring Visit IMV

Applicable ICH GCP:
- 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.

Applicable FDA regulation:
- CFR 312.56 Review of ongoing investigations

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

Trigger for development of a protocol-specific CMP is CSM receipt of request for a Site Initiation Visit.

Close-out Visit COV

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

All applicable obligations have been met at designated site(s) e.g., copies of close-out essential documents collected for Sponsor file, data and monitoring queries resolved, test article/study product final disposition, specimen tracking, safety event follow-up, IRB notification.

OSRO will process request.

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

Site and OSRO agree with plan to conduct close-out visit.

Site ready for close-out?

YES

NO

Monitor works with OSRO and site to track completion of all required close-out obligations.

Visit complete within required timeframe?

NO

YES

Visit Monitoring Report generated.

Next visit will be scheduled and completed per the protocol CMP e.g., IMV or COV as appropriate.

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