DMID INFORMATION SHEET

Clinical Site Monitoring

As the Sponsor of clinical research involving new drugs, biological products for human use, and medical devices the Division of Microbiology and Infectious Diseases (DMID) is responsible for clinical site monitoring of clinical studies at domestic and international sites under Title 21 CFR Parts 312 and 812, Human Subjects Protection Title 45 CFR Part 46, and E6 International Conference on Harmonisation Good Clinical Practices (ICH/GCP).

This information sheet will provide an overview of clinical site monitoring activities that occur before, during and after a clinical study or trial.

Before Study

At all site locations a *Site Assessment Visit* is completed as requested by DMID. The purpose of the assessment visit is to verify adequacy of the performance facilities, equipment, personnel, personnel training, clinical operations, ability to enroll and conduct protocol-specific functions. In addition, the Monitor verifies compliance with ICH/GCP, overriding Federal regulations, DMID-specific guidelines, and protocol-specific requirements, as applicable.

The visit agenda includes a protocol discussion (if applicable), as well as a walking tour of each clinical site location to include all areas where clinical study activities are conducted. At the end of the visit, a summary discussion of visit findings occurs. After the visit DMID is provided with findings in written form for follow up on any issues as warranted.

Study Start

A *Study Initiation Visit (SIV)* is held before a site is authorized by DMID to begin any study-related activities at the site. The purpose of the SIV is to confirm site readiness to begin the study by review of:

- Site monitoring expectations, to include process for visit scheduling, confirmation, frequency and duration of interim visits
- Investigator and staff qualifications
- Site personnel responsibilities
- Study population and accrual goals
- Informed consent process
- Protocol and study design
- Remote monitoring procedures
- Site facilities and required equipment
- Dispensing, transport, accountability and administration of Study Product or Investigational Device, as well as any blinding considerations
- Site essential documents and logs including process for Specimen Retention records
- Case Report Form (eCRF/CRF) and Data Management responsibilities
- Serious Adverse Event (SAE) and Adverse Event (AE) reporting requirements
- Site management procedures, including but not limited to: Regulatory, Communications, Supervision, and Quality Management
- IRB/IEC guidelines and overriding Regulatory requirements
- GCP, DMID policies, procedures, and standards for conduct of clinical trials
- Training of site personnel (Protocol Specific and Non-Protocol Specific)
- Site Safety Plan, Emergency support
- DMID Site Activation process

During Study

The *Interim Monitoring Visits (IMV)* are conducted at a point and at an interval determined by DMID to assess the conduct of the clinical study or trial at a clinical study performance site. Interim monitoring visit activities will include but are not limited to:

- Verification of data entered on the study specific Case Reports Forms (CRF) or into electronic Case Report Forms (eCRF) or remote data capture system
- Proper handling, storage and/or transport of Study Product or Investigational Device
- Proper handling, storage and/or transport of study Laboratory samples/specimens
- Adherence to study eligibility inclusion/exclusion criteria
- Review of the site essential documents and logs to confirm proper site file maintenance
- Reporting of protocol deviations
- Reporting of Safety Events (Serious and Non-Serious Adverse Events)
- Adherence to all other protocol-specific requirements

Site Close-Out

A *Close-Out Visit (COV)* is conducted after the completion of a clinical study or trial to confirm that all required actions have been completed in accordance with established policies and procedures, including retrieval of Sponsor copies of essential regulatory documents, plans for appropriate retention of study records and disposition of any remaining supplies or study products. The monitoring close out visit also serves to terminate the clinical site monitoring activities at the site.

Additional Information

Once DMID has requested Clinical Monitoring Services, a member of the monitoring team will notify the site and provide contact information. Prior to that point, DMID may be contacted for further information.

At the end of every monitoring visit, the monitor will discuss visit activities and any pertinent findings with the site Staff.

After the SIV, IMV and COV written site visit reports will be provided to DMID and the site outlining the information covered during the respective visit and listing any issues or outstanding items, as warranted. If circumstances warrant an Ad Hoc/For Cause Monitoring Visit may be conducted.

Questions

Contact your DMID protocol-specific Point of Contact or email the DMID Office of Clinical Research Affairs, OCRA Help.