DMID INFORMATION SHEET – Protocol Deviation Reporting

Definition

A **Protocol Deviation** is any noncompliance with the clinical trial protocol, Good Clinical Practice (GCP), or protocol-specific Manual of Procedures requirements. The noncompliance may be either on the part of the subject, the investigator, or the study site staff.

DMID Reporting Requirements

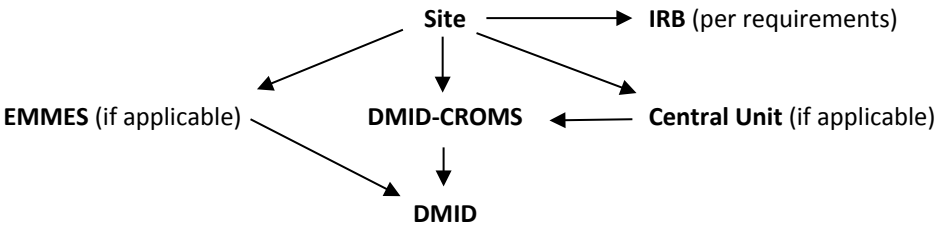
- All protocol deviations must be reported **within 5 working days of identification of the protocol deviation**, or within 5 working days of the scheduled protocol-required activity.
- If study data is captured via the **Emmes** Internet Data Entry System (IDES – known also as AdvantageEDC™), protocol deviations will be submitted via IDES. No other reporting is required. IDES will automatically notify DMID of the reported protocol deviation.
- If a clinical trial is being coordinated by a **Central Unit or Coordinating Center**, protocol deviations will be reported as specified in the respective study protocol and/or the Manual of Procedures (MOP). The Central Unit will be responsible for reporting of the protocol deviation information to DMID-CROMS.
- For those studies **not utilizing Emmes IDES (AdvantageEDC™) and not coordinated by a Central Unit**, protocol deviations must be reported to the **DMID Clinical Research Operations and Management Services (CROMS)** contractor.

How to report Protocol Deviations to DMID-CROMS

There are three different ways you may submit protocol deviation reports:

1. Via the DMID-CROMS website web-based report form. To request access to the website, please submit a request using the Systems Access Request Form.
2. Via email to protocoldeviations@dmidcroms.com. Attach both the Protocol Deviation form and Transmittal cover sheet.
3. Via Fax to 215-789-9587. Print and Fax the Protocol Deviation form and Transmittal cover sheet.

Protocol Deviation Report Flow



Questions:

Contact the Protocol Deviation Team members via email at protocoldeviations@dmidcroms.com.