DMID INFORMATION SHEET

Essential Regulatory Documents and Site Activation

Clinical site essential regulatory documents serve to demonstrate compliance with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements.

The Essential Regulatory Documents Group (ERDG) provides essential document tracking and review services to the Division of Microbiology and Infectious Diseases (DMID) and their Partners for domestic and international protocols.

Services include:

- Collection, review, and maintenance of the DMID protocol and site-specific essential regulatory document files before, during and after site close-out.
- Communication with site Staff to address document requirements and resolve issues or discrepancies, as applicable.
- Transfer of site essential regulatory documents to the DMID Regulatory Services contractor for submission to an IND or IDE, as required.
- Distribution of DMID Site Activation Memo authorizing the respective site to begin study-related activities.

This information sheet will provide an overview of essential regulatory document collection, tracking and review before, during and after a clinical study or trial.

Before the Study

1. Once the final DMID approved study protocol is present in the DMID-CROMS Document Library, the DMID staff will request that the essential regulatory documents be collected from the participating site(s).
2. The ERDG will send an email notification to the site(s) specifying the required documents and will ship an Essential Regulatory Document Binder to the site(s) that may be used to organize and maintain the site essential regulatory documents file.
3. Upon receipt of the requested essential documents, ERDG will perform a quality review for completeness, accuracy and compliance to all applicable regulations and DMID requirements.
4. The respective site will be notified of the review findings within no more than 4 business days of receipt.
5. The site will receive an email with review findings. If issues are noted, the email will specify the discrepancies and will request updated documentation.
6. Reminder emails will be sent to the site and the DMID point of contact if there is no response at 14 and 30 day intervals.

DMID Site Activation

A formal DMID Site Activation notice authorized by DMID is required before study activities may begin at a site. Process leading up to release of a DMID site activation notice:

1. ERDG will **notify DMID** when all site essential documents have been reviewed and found to be complete, accurate and in compliance with applicable regulations and the DMID requirements.
2. DMID will determine when a site may begin study-related activities and request that the ERDG team inform the site.
3. Within one business day, ERDG will send an email notification of **DMID Clinical Site Activation** authorizing the respective site to begin study-related activities.

During Study

- Over the duration of the study and until the site is formally closed, ERDG tracks the expiration status of required essential regulatory documents. The DMID protocol and site-specific essential regulatory document file maintained in the DMID-CROMS Document Library must be kept current.
- As necessary, ERDG will send email **Site Reminders** to request document updates at 30 days prior to expiration, and to the site and DMID 15 days prior to expiration. The site and DMID will receive notification 1 day post expiration if the requested documents have not been received by ERDG.

Close-Out

ERDG will confirm and track disposition of site close out documents, conduct a quality review of the close out documents submitted and notify the site of any missing or discrepant documents, as appropriate.

Additional Information

The ERDG and the Clinical Site Monitoring team will coordinate efforts to confirm a current and complete Site and Sponsor essential documents file are maintained over the duration of a study and at study site close-out.

For ERDG contact information, guidelines and forms click here

Questions

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