DMID CLINICAL QUALITY MANAGEMENT PLAN FACT SHEET

Scope and Policy

The DMID Clinical Quality Management policy applies to sites conducting DMID-funded Human Subjects research. A Clinical Quality Management Plan (CQMP) serves as an on-site management tool, describing quality control (QC) and quality assurance (QA) processes to be implemented by the clinical site for internal evaluation and documentation of site performance of protocol procedures; identifying and resolving problems at the earliest stages. The CQMP prompts site staff to:

- Verify compliance with the protocol,
- Ensure data accuracy and completeness of data capture in a timely manner,
- Protect human subjects' rights and welfare, and
- Ensure Good Clinical Practice (GCP) standards and regulatory requirements are met.

Definitions

Quality Management (QM): The overall system that includes all activities involved in quality assurance and quality control, including the assignment of roles and responsibilities, the reporting of results, and the resolution of issues identified during the review.

Quality Control (QC): The real time ("day-to-day") observation and documentation of the sites work processes to ensure that accepted procedures are followed.

Quality Assurance (QA): The periodic, systematic, objective, and comprehensive examination of the total work effort to determine the level of compliance with Good Clinical Practice (GCP) standards.

Clinical Quality Management Plan (CQMP): A written document specific to a clinical research setting, encompassing both Quality Control and Quality Assurance procedures, and detailing the scope, responsibility, quality indicators, sample size, and frequency of these activities.

DMID Clinical Quality Management Training Module

The DMID Clinical Quality Management training module is available through the DMID-CROMS web site, Learning Management System, https://www.dmidcroms.com; provide user credential, then select the Training icon to enter the Learning Management System.

DMID Clinical Quality Management Guidance and Tools

DMID Clinical Quality Management Plan guidance, sample templates and tools are located on the DMID-CROMS web page, https://www.dmidcroms.com/CRS/QM/SitePages/Qualitymanagement.aspx, and available for discretionary use by contractor/clinical sites developing a CQMP.

Clinical Quality Management Plan – Submission, Review, and Acceptance

- The DMID-CROMS CQMP review service is requested at the discretion of DMID. This request applies to initial and revised CQMPs. Documentation of the review process is communicated to the contractor/site, and DMID.
- Where the CQMP is a deliverable stipulated in a DMID funding agreement (i.e., contract, Statement of Work), it is subject to approval by DMID.

Additional Information

- During DMID Clinical Site Monitoring visits, a member of the monitoring team will verify the current CQMP implemented at the site, and request the signatory and date of the most recent documentation of quality management activities. Should the monitoring team have questions, DMID may be contacted for further information.
- For questions, contact the DMID protocol-specific Point of Contact; the DMID Clinical Project Manager (CPM), Project Officer (for clinical research conducted under grant), or the DMID Contracting Officer's Representative (COR) (for clinical research conducted under contract). For questions about CQMP guidance and tools, contact the DMID-CROMS CQMP Team, CQMP@dmidcroms.com