**DMID CLINICAL QUALITY MANAGEMENT PLAN (CQMP)**

**EVALUATION TEMPLATE**

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| --- | --- |
| Name(s) of Evaluator(s): |  |
| Site Name(s): |  |
| DMID Protocol Number / Protocol Title: (Note: applicable for protocol-specific CQMP evaluation) |  |
| Date of Evaluation: | (Format: DD/MMM/YYYY) |

This sample CQMP evaluation template is offered for discretionary use by sites implementing a CQMP during the conduct of the research. This template may be modified to reflect the associated parameters and processes described in the CQMP.

The template is designed to guide an evaluation of a site and protocol-specific CQMP;

1. ensuring the CQMP review process is revised to capture process improvements resulting from periodic summaries of quality review activities, and issue management,
2. ensuring the CQMP process improvements are implemented in a timely manner.

When evaluating the CQMP, consider revisions resulting from routine quality review findings;

1. integrating process improvements
2. ensuring continued protections of human subject participants,
3. continued compliance with the protocol and applicable federal regulations, Good Clinical Practice standards, and integrity and reliability of study data.

The following CQMP sections are suggested areas for evaluation:

**1. CQMP Scope**: Evaluate and describe/determine

* 1. accuracy of protocol and/or site identification.
  2. added sites (i.e., multi-site protocol) where subjects are seen, and protocol-directed procedures are conducted.

1. **Roles and Responsibilities**: Evaluate and describe/ensure
   1. changes to delegated study staff roles and responsibilities.
   2. delegated study staff are listed on the Site Signature Log / Delegation of Responsibility or equivalent Delegation of Authority log.
2. **Description of Internal Quality Management Activities:** Evaluate and describe/evaluate
   1. the adequacy and accuracy of CQMP quality control and quality assurance activities currently implemented, including tools used to document quality review processes, and related internal SOPs.
   2. the adequacy of record review sample size and review frequencies and
   3. whether these parameters are effective towards ensuring human subject protections, best practices, protocol compliance, and reliability and integrity of the study data.
3. **Accuracy and Adequacy of Key Quality Indicators (KQI):** Evaluate and describe
   1. the CQMP KQI section ensures all protocol-directed processes are included.
   2. the associated quality measurements to be implemented, recorded and reported.
4. **CQMP Tools:** Evaluate and describe
   1. the effectiveness of quality tools used to document quality review activities. Consider the completeness and applicability of study procedures listed, and related documentation checks, detectability of adverse trends and resolution of corrective and preventive actions.
   2. the accuracy of quality review tools referenced in the CQMP with related activities and KQIs.
5. **Frequency of Regulatory File / Site Essential Regulatory Documents Reviews:** Evaluate and describe effectiveness of regulatory file document reviews to
   1. ensure current/valid essential regulatory are filed,
   2. ensure essential regulatory documents are available to delegated study personnel and associated departments where protocol procedures are performed (i.e., clinics, pharmacy, laboratory).
   3. site/Investigator compliance with regulatory recordkeeping requirements for human drugs and biological products and/or medical devices.
6. **Qualified study personnel / Training:** Evaluate and describe
   1. quality procedures for determining current licensing/credentials are in place for study staff interacting with and assessing human subject participants.
   2. adequacy of quality reviews for assuring study staff are qualified by education, training, and meet NIH, Institution, and DMID requirements.
7. **Communicating quality review findings:** Evaluate and determine provisions for
   1. timely communications addressing adverse findings, and implementation and evaluation of corrective actions.
   2. required communications to the sponsor/DMID, where stipulated in contractual deliverables (i.e., progress reports).
8. **CQMP modification:** Evaluate and describe effectiveness of
   1. frequency of CQMP revisions integrating process improvements.
   2. communicating CQMP revisions to site staff.

**Resources**:

Please refer to DMID CQMP Guidance and Tools, <https://www.dmidcroms.com/CRS/QM/SitePages/Qualitymanagement.aspx>