**INSTRUCTIONS FOR USING**

**THE**

**DMID QUALITY MANAGEMENT SUMMARY REPORT TEMPLATE**

**Background**: This Quality Management Summary Report template is developed in Microsoft Word to guide site or project modification, as needed; to summarize quality review findings, for quality analysis, and communication to site staff.

**How to use this tool**: This report is formatted to capture quality review documentation from routine chart reviews, regulatory file reviews, and any other site/project-specific internal quality review documentation. Adverse trends identified in this report can inform site best practices, necessary revisions to existing quality management plans and continuous improvement and effectiveness. This report, and any other internal quality management documentation should be filed in a separate quality management binder.

For each Summary Report:

1. **Complete - general**: Begin modifying this tool by completing the header information (name of Institution/site, reporting period, date of report, and audit participants).
   1. For site modification, please remove references to ‘DMID’, and ‘Sample’ and replace with Institution/site name.
   2. These instructions may be retained/modified to ensure best documentation practices and user understanding.
   3. When preparing a summary report, consider applicable data collection/reporting sources (i.e. local and/or centralized databases) supporting protocol activity and the sponsor’s reporting requirements.
2. **Complete Section 2, Identification of Problem Areas**.
   1. **Complete the Tables**:To ensure the content of reporting adequately addresses key areas of protocol conduct,
      1. Provide the DMID Protocol Number in the first Column
      2. Provide the Case Report Form (CRF) Number in the second Column:
      3. Summarize Finding(s) in the third Column; reference applicable Key Quality Indicator(s) and Source Documentation: Name applicable key quality indicators, as listed in the associated Clinical Quality Management Plan (i.e. informed consent, eligibility, study product management, specimen collection, etc.), as well as broader processes (i.e. best practices, protocol conduct, quality control, quality assurance, etc.).
   2. **Describe sections a-d**: For each section in the summary report (e.g., Quality Control Review, Subject Record Review, etc.), describe sections a-d using the ‘<instructions>’ as a guide.
      1. Trend Analysis (‘a’): <describe adverse quality trends detected during review of routine QC and QA documentation.>
      2. Corrective and Preventive Actions (‘b’): <describe actions taken to eliminate the cause of an actual problem and steps taken to prevent the problem from recurring.>
      3. Evaluation/Re-Evaluation (‘c’): <describe follow-up actions taken and corresponding date(s) for evaluation of effectiveness of implemented corrective actions.>
      4. Resolution Date (‘d’): <provide completion date of resolution of adverse quality process trends findings, Corrective Action Preventive Action.>
3. **Apply Version Control**:When adopting and modifying this tool for discretionary sue, correct the footer to reflect version control. Please refer to the[DMID Information Sheet: Document Version Control Guidelines.](https://www.dmidcroms.com/Shared%20Documents/Document%20Version%20Control%20Guidelines%20Info%20Sheet.pdf#search=document%20version%20control%20guidelines)
4. **Manage Issues**: Document quality review findings and review periodically; resolve findings in a timely manner, apply continuous improvement from measurements of effectiveness; and revise the Clinical Quality Management Plan accordingly.
5. **Sign and Date**: the signature of the delegated study staff completing the summary report should correspond to the role identified in the site/protocol-specific CQMP and as listed on the Site Study Personnel Signature-Responsibility List or equivalent Delegation of Authority document.

**Resources:**

DMID Clinical Research Resources - Regulatory File Document Guidelines: <https://www.dmidcroms.com/SitePages/Guidelines.aspx>

DMID Source Document Standards for Clinical Research

<https://www.dmidcroms.com/SitePages/Guidelines.aspx>

U.S. Food and Drug Administration E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

<https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf>

ICH Guideline for Good Clinical Practice E6(R2) (Section 8, Essential Documents):

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

OHRP Code of Federal Regulations Title 45 Part 46:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

U.S. Food and Drug Administration, Title 21 Part 312, Investigational New Drug: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312)

U.S. Food and Drug Administration, Title 21 Part 812, Investigational Device Exemptions: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)

DMID SAMPLE QUALITY MANAGEMENT SUMMARY REPORT TOOL

<*Replace DMID SAMPLE with Institution/Site Name*>

Date of Report:<*enter date report was written*>

Reporting Period: From <dd-mmm-yyyy> Through <ddmmm-yyyy>

1. **Staff Participation in Audits:** <*List the name, title, and role of each staff member involved in the internal review processes>*

* <*Name*, *Title, and* *Role*>
* <*Name*, *Title, and* *Role*>

1. **Identification of Problem Areas** 
   1. Quality Control Activities – Quality Control is the real time, day-to-day, observation and documentation of the sites work processes to ensure that accepted procedures are being followed, study data is attributable, legible, contemporaneous, original, accurate and complete (A.L.C.O.A.C per ICH E6 (R2), section Records 4.9.0). For example, review of eligibility criteria information on each (100%) Case Report Form (CRF) prior to entry into a database.

**Quality Control Reviews:** <*insert the protocol number, CRF number/name and a summary of the findings>*

| Protocol Number | CRF Number/Name | Summary of Finding(s); associated Key Quality Indicator; Source Documentation |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  | <*Insert or delete rows as needed*> |

1. Trend Analysis:
2. Corrective Actions Preventive Actions:
3. Evaluation/Re-Evaluation:
4. Resolution Date:
   1. Quality Assurance Activities -Quality Assurance is the periodic, systematic, objective, and comprehensive examination of the total work effort to determine the level of compliance with accepted Good Clinical Practice Standards. For example, a monthly review of source documents compared to Case Report Form pages to determine adherence to protocol requirements, integrity and reliability of study data, and protections to human subject are in place. Consider a sample range of 10-30% depending on enrollment, and/or previous QC/QA reports indicating increasing error or improvement rates in a particular key quality indicator.

**Subject Record Review:** <*insert the DMID protocol number and a summary of adverse findings detected during quality review of subject records*>

| Protocol Number | Summary of Finding(s) and associated Key Quality Indicator |
| --- | --- |
|  |  |
|  |  |
|  | <Insert or delete rows as needed> |

1. Trend Analysis:
2. Corrective Actions Preventive Actions:
3. Evaluation/Re-Evaluation:
4. Resolution Date:

**Regulatory Files Reviewed:** <*Insert the protocol number and a summary of the findings found during regulatory file review>*

| Protocol Number | Summary of Finding(s) |
| --- | --- |
|  |  |
|  |  |
|  | <*Insert or delete rows as needed*> |

1. Trend Analysis:
2. Corrective Actions Preventive Actions:
3. Evaluation/Re-Evaluation:
4. Resolution Date:

**Study Product Review:** <i*nsert the protocol number and a summary of the findings found during study product review>*

| Protocol Number | Summary of Finding(s) |
| --- | --- |
|  |  |
|  |  |
|  | <*Insert or delete rows as needed*> |

1. Trend Analysis:
2. Corrective Actions Preventive Actions:
3. Evaluation/Re-Evaluation:
4. Resolution Date:

**Other Areas of Review:** <*insert the protocol number and a summary of the finding from other areas reviewed>*

| Protocol Number | Summary of Finding(s) and associated Key Quality Indicator |
| --- | --- |
|  |  |
|  |  |
|  | <*Insert or delete rows as needed*> |

1. Trend Analysis:
2. Corrective Actions Preventive Actions:
3. Evaluation/Re-Evaluation:
4. Resolution Date:
5. **Summary Report Conclusion/Follow-up actions:** *<Summarize report results and plans for process improvement where applicable. If findings are not resolved at the time of this summary report, describe plans for resolution and/or process improvements, including root cause analysis, training, staffing, updates to tools, etc. If the issues found within this report constitute a re-evaluation of the Clinical Quality Management Plan (CQMP), describe those plans/ timelines for review, submission to DMID>*

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Site Quality Management Designee/Coordinator Signature