Data Quality Control (QC) Check Plan

<<Study Name/Acronym>>

**Database URL:**

**Effective Date:**

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| **Authorship History** | | |
| **Author Name and Designation** | **Version No** | **Date** |
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| **Review Schedule**  **Only applicable to Standard QC Check Plans. Delete this section from Additional QC Check Plan** |
| This document will be subject to formal review **<<insert appropriate time period>>** from **<<insert effective date>>**. This document is also subject to interim reviews as and when appropriate. All revision history must be documented in the tables below. |

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| **Document Review History** | | |
| **Version No** | **Date** | **Summary of Revisions** |
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| **Approval** | | | |
| **Name and Designation** | **Version Approved** | **Date Approved** | **Signature** |
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*All text in italic green is for guidance purposes only and should be deleted from the final version. This template is for guidance only and should be altered as appropriate.*

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| **Type of QC Check Plan and Purpose of Document (delete as appropriate)** |
| **Standard QC Check Plan:**  This document outlines the criteria on which quality checks on study data will be carried out for the duration of the study and the proposed schedule of completion. |
| **Additional QC Check Plan**  *Specify reason for additional check (e.g. data extract requested for interim analysis, repeat QC check required due to high-error rate etc.)* |

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| **Study Details** | |
| **Data Entry Method (tick all that apply)** | eCRF at Site  pCRF at Site  pCRF at ECTU |
| **If mixed-method, please give details** | *Where data entry is more than one of the above option, specify details (e.g. All visit data entered via pCRF at site. All Follow-up Questionnaires received by post entered from pCRF at ECTU)* |
| **TSC and/or DMC (Standard QC Check Plan only)** | TSC  DMC  Not applicable |
| **If TSC and/or DMC in operation, please specify proposed schedule** | *Specify if meetings are annually, six-monthly (from Charter) and date of last meeting (if available)* |
| **Monitoring and SDV Plan (Standard QC Check Plan only)** | Monitoring Plan  SDV Plan  Not applicable |
| **If applicable, specify details of plan** | *Specify version no and effective dates of plans and specify any information relevant to QC checks (e.g. Primary Outcome data will be checked by Monitor, Plans have no impact on ECTU QC Checks)* |

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| **QC Check Details** |
| **Type and Details of Check**  *Specify details of check for each category or specify ‘Not applicable’ and specify reason* |
| **Data Entry Check:** |
| **Primary Outcome Check:** |
| **Other Critical Data Check:** |

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| **Proposed QC Check Schedule**  **Applicable to Standard QC Check Plan only. Dates subject to alteration as necessary.** | |
| QC Check Period: MMMYYYY-MMMYYYY  *Specify the period of time where QC Checks will be completed. This is usually from start of recruitment phase until projected last patient, last visit date/end of follow-up date (e.g. Recruitment for 36 months beginning April 2019 with 24-Month follow-up period – QC Check Period is Apr 2019- Apr 2024)* | |
| Scheduling  *Specify how proposed schedule has been devised (e.g. to coincide with TSC/DMC schedule). Specify dates below (MMM/YYYY only). Add rows as required to cover the duration of the study* | |
| 1st Check | MMMYYYY |
| 2nd Check | MMMYYYY |
| 3rd Check | MMMYYYY |
| 4th Check | MMMYYYY |
| 5th Check | MMMYYYY |
| 6th Check | MMMYYYY |
| Final Check | MMMYYYY |

<<<<<<<<<<<<For Template use only. Remove this page from study specific version>>>>>>>>>>>>>>

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|  | | | **Template Revision History** | |
| **Version No** | **Effective Date** | **Revised By (Name and Designation)** | | **Summary of Revisions** |
| 1.0 | 27th March 2018 | Lynsey Milne (Assistant Data Manager) | | * Initial Creation * Template version set at 1.0 |
| 2.0 | 21st August 2020 | Lynsey Milne (Assistant Data Manager) | | * Updated at scheduled review * New Review Schedule section added * Minor formatting changes |
| 3.0 | 15th June 2023 | Lynsey Milne (Data Manager), Christopher Flitcroft-White (Assistant Data Manager) | | * Updated at scheduled review * Minor formatting/wording changes |