Data Cleaning 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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| **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 Data Cleaning Plan and Purpose of Document (delete as appropriate)** |
| **Interim Data Cleaning Plan:**  This document outlines the data that will be cleaned specifically for the interim analysis of *<<specify the scope of the interim analysis (e.g. all Baseline data collected for the first 100 participants randomised to x arm of study)>>*.  **Final Data Cleaning Plan:**  This document outlines the data that will be cleaned in preparation for the final analysis of all study data. |
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| **Proposed Data Cleaning Schedule**  **Note – dates are as planned at Effective Date of this document. Dates are subject to change in case of alterations to the study protocol** | |
| Proposed Start Date |  |
| Proposed Data Cleaning Deadline |  |

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| **Standard Checks and Reviews**  **This section may not be applicable to any Interim Data Cleaning – to be deleted/amended as appropriate** | |
| **Dataset** | **Checks and Reviews to be completed** |
| Adverse Events (AE) and Serious Adverse Events (SAE) | * Check of all AE Dates on database as follows: * Resolved Date is not before Start Date * Start Date is not prior to study consent * Check for unusual dates and outliers (e.g. logical dates that are obviously wrong) * Reconciliation of all AE on study database with SAE on pharmacovigilance database as follows: * Each AE assessed as being an SAE has been reported as such to the Sponsor * Each SAE reported to the Sponsor has been recorded as an SAE * SAE Start Dates are logical (e.g. same as AE or later within AE period) * SAE and AE Resolved Dates are the same * Description of SAE and AE correspond |
| Deaths | * Check of all Dates related to Death Event on database as follows: * Date of Death is not prior to study consent * Date of Change of Status is not prior to Date of Death * If Death Data is recorded elsewhere apart from Change of Status, check for discrepancies in dates recorded * Check Cause of Death is recorded * If applicable, check AE and SAE have been recorded for death |
| Change of Status | * Check of all Change of Status on database as follows: * Change of Status Date is not before study consent * Check all Change of Status Dates are logical |

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| **Outcome-specific Checks and Reviews** | | |
| **Outcome** | **Related Datasets and Timepoints** | **Checks and Reviews to be completed** |
| *List all Primary and Secondary Outcomes* | *List all datasets and timepoints related to this outcome* | *Specify checks that will be completed or if none, state why* |
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| **Other Checks and Reviews** | | |
| **Dataset** | **Reason for Check** | **Checks and Reviews to be completed** |
| *List any other datasets to be included* | *Specify reason for check* | *Specify checks that will be completed* |
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<<<<<<<<<<<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 | 21-Aug-2020 | Lynsey Milne( Assistant Data Manager) | * Initial Creation * Template version set at 1.0 |
| 2.0 | 15-June-2023 | Lynsey Milne (Data Manager)  Christopher Flitcroft-White (Assistant Data Manager) | * Minor change to Proposed Data Cleaning Schedule section |