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
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