Data Management Plan Template – Instructions on how to use:

Explanatory text appears in *purple italics* under each section heading, and states what should be contained in that section. The purple explanatory text should be deleted upon finalisation of your Data Management Plan (DMP)

Examples are provided in green text. All require complete customization for your study.

Text appearing in <red> should be replaced as applicable to your study.

Sections “13 Software Development Lifecycle procedures”, “14 Instrumentation, Calibration and Maintenance” and “15a Data Protection Impact Assessment” should only be completed if relevant to the trial.

Delete this page once the DMP is finalized.

Data Management Plan - <Short Trial Name>

<Full Trial Name>

Document Approval

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Role | Signature | Date |
|  | Sponsor-Investigator |  |  |

Contributors

|  |  |  |
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|  | Name | Role |
| Author |  |  |
| Reviewer |  |  |

Revision Chronology

|  |  |  |
| --- | --- | --- |
| Version No. | Date | Summary of Changes |
| 1.0 |  | Initial Version |

Acronyms

|  |  |
| --- | --- |
| AE  | Adverse Event  |
| CAPA  | Corrective and Preventative Action  |
| CDISC | Clinical Data Interchange Standards Consortium |
| CEBU  | Clinical Epidemiology and Biostatistics Unit  |
| CMP  | Clinical Monitoring Plan  |
| CRDO  | Clinical Research & Development Office   |
| CRF  | Case Report Form  |
| DAG   | Data Access Group  |
| DCC  | Data Coordinating Centre  |
| DPIA  | Data Protection Impact Assessment  |
| DM  | Data Manager  |
| DMP  | Data Management Plan  |
| DMS  | Data Management System  |
| DPO  | Data Protection Officer  |
| DSMC  | Data Safety Monitoring Committee  |
| DSP   | Data Sharing Plan  |
| DVP  | Data Validation Plan  |
| EDC  | Electronic Data Capture  |
| EMR | Electronic Medical Record |
| GCP  | Good Clinical Practice  |
| GDPR   | General Data Protection Regulation  |
| HREC  | Human Research Ethics Committee  |
| ICH-GCP  | International Conference on Harmonisation-Good Clinical Practice  |
| IP  | Intellectual Property  |
| IRB   | Institutional Review Board  |
| ISF   | Investigator Site File  |
| MCRI   | Murdoch Children’s Research Institute  |
| MCTC  | Melbourne Children’s Trial Centre  |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MOP  | Manual of Procedures  |
| PICF   | Participant Information and Consent Form  |
| PRO | Patient Reported Outcomes |
| RGO  | Research Governance Office  |
| RCT  | Randomised Control Trial  |
| SAP  | Statistical Analysis Plan  |
| SAE  | Serious Adverse Event  |
| SDTM | Study Data Tabulation Model |
| SDV  | Source Data Verification  |
| SIF  | Site Information File  |
| SOP   | Standard Operating Procedure  |
| TMF   | Trial Master File  |

# Protocol Summary

*A brief description of the protocol should be included in the DMP along with reference to where the current version of the protocol can be accessed. The description might cover information relevant to data such as target number of participants, sites (and their locations), relevant study epochs and lengths, and expected recruitment window. Including the protocol version is essential to create a link between differing versions of the DMP over the life of the trial with revisions to the protocol.*

*It is recommended that this is presented as a table that can form the basis of eventual trial metadata e.g.*

|  |  |
| --- | --- |
| Current protocol version number | V2.1 |
| Current protocol version date | DD/MM/YYYY |
| Trial Phase | Phase II  |
| Consent Method | Paper Consent, uploaded to Florence eBinders™ |
| Mode of Consent | Prospective, Retrospective, Opt-Out, Waiver, etc |
| Blinding Scheme | Double blind |
| Planned Number of Participants | 300 |
| Population | Children aged between 4 and <18 years of age |
| Trial Disease/Condition Indication | Tonic-Clonic Epilepsy |
| Arms | 2 |
| Interventions | Phenytoin, Placebo |
| Study Epochs | Screening/Consent: 14 daysTreatment: 3 monthsFollow-up: 9 months |
| Sites | Victoria, Australia: 3 hospitalsNew South Wales, Australia: 2 hospitalsUnited Kingdom: 1 hospital |
| Start Date of Recruitment | 1/10/2023 |
| Expected End Date of Recruitment | 31/12/2024 |
| End Date of Follow-Up (if applicable) | 31/12/2025 |
| Expected Date of Archiving | 31/12/2026 |

*A list of common Trial Summary Elements is maintained by CDISC and can be found at* <https://evs.nci.nih.gov/ftp1/CDISC/SDTM/SDTM%20Terminology.html#CL.C67152.TSPARM> . *Those included in the DMP should be tailored to the specifics of the trial protocol.*

# Scope of data management operations covered by the DMP

*The statement here should cover the Society for Clinical Data Management (SCDM) definition of a DMP as “A compilation of, or index to, comprehensive documentation of data definition, collection and processing, archival, and disposal, sufficient to support reconstruction of the data handling portion of a clinical study.”*

*e.g.*

This plan covers all data-related sponsor activities and processes throughout the lifecycle of the trial from collection, processing and transformation to sharing, archiving and eventual disposal.

# Data sources

*The DMP should address all data sources for a study* *. Data sources can be illustrated diagrammatically or in tabular form. For example, data sources may include:*

Participants

Central

Sites

Trial Database

Site study team

EDC

Local Labs

Electronic Medical Record

PRO – questionnaires etc

Wearables, apps etc

Flow of data from sources to trial database

Document storage (e.g. Florence E-binders™)

Data storage (e.g. REDCap)

Safety Reviewers

Safety database

eCRF

Source docs

Safety Review

EMR extract

eCRF

PROMS

App data

|  |  |  |
| --- | --- | --- |
| Data Type | Data Provider | Data Storage |
| CRFs | Sites enrolling and managing participants | CRFs entered into REDCap |
| Weekly Extracts of EMR data | Sites enrolling and managing participants | Uploaded to REDCap data repository |
| Source documents | Sites enrolling and managing participants | Uploaded to ISF in Florence eBinders™ |
| Patient Reported Outcome Instruments | Participants | Completed surveys stored in REDCap |
| Quarterly serology results | Central Labs | Bulk Uploaded to REDCap data repository |
| Safety review | Central AE/SAE reviewers | Uploaded to REDCap data repository |

# Personnel

*The personnel section of the DMP should list, or reference a list of, project personnel, duration of their association with the project, their roles, responsibilities, training and qualifications as required in ICH E6 R2, sections 4.1.5, 5.5.1, and 5.5.3*

*e.g.*

Data Management for <short trial name> has been led by <data manager’s name> since 01-01-2023. Their qualifications are kept in the TMF along with the delegation log listing all other personnel performing data management functions for the trial.

# Risk Identification and Management

*Whether a risk-based approach is used or not, the DMP should include the identification of processes and data that are critical to ensure human subject protection and the reliability of trial results (ICH E6 R2 section 5.0.1). Evaluation of risks should take into account the likelihood of hazards, their potential impact, and their detectability (ICH E6 R2 5.0.3). An example of common risks and their management:*

|  |  |  |
| --- | --- | --- |
| Risk Type | Risk Identification | Risk Management |
| Data Security and Privacy Risks | Unauthorized access, data breaches, or privacy violations | Implement strict access controls and encryption to protect sensitive patient data.Conduct regular security audits and penetration testing.Train staff on data security protocols and best practices.Comply with all Australian data protection regulations and global legislation such as HIPAA or GDPR if relevant. |
| Data Quality Risks | Inaccurate, incomplete, or inconsistent data | On-entry and post-entry data validation checks and quality control procedures (as outlined in Data Quality Control section below).Data surveillance for completeness and coherence (e.g. data surveillance tools, regular data metrics reporting).Conduct routine data monitoring and source data verification both at site and remotely.Provide training to clinical staff involved in data entry.Published Manual of Procedures and CRF Completion Guidelines. |
| Loss of Data Risks | Data loss due to hardware or software failures, system downtime | Develop a disaster recovery plan.Regular updates and patches of software to prevent vulnerabilities.Store data in secure locations with scheduled backups and offsite storage.Regularly test data recovery processes. |
| Patient Recruitment and Retention Risks | Difficulty in recruiting and retaining study participants | Develop strategies for effective patient recruitment and retention, including minimising trial burden for participants and promoting benefits of participation.Monitor and assess patient engagement and satisfaction.Collect and report on reasons for withdrawal from Trial and review procedures if necessary. |
| External Data Risks | Issues with external data sources or data transfer | Establish data transfer protocols and ensure data source reliability.Validate and document data received from external sources.Plan for contingencies if external data sources fail or change. |
| Ethical and Regulatory Compliance Risks | Ethical violations or regulatory non-compliance | Ensure adherence to ethical guidelines and regulatory requirements through mandatory staff training at sponsor and site level, particularly around informed consent.Establish a governance framework to review and address ethical issues.Stay informed about changing regulations and ensure ongoing compliance.Regular surveillance of compliance issues. |

*For trials with novel sources of data, such as those drawing data from EMR extracts, a description of any preliminary scoping and verifying of suitability, quality and expected completeness of the proposed data should be documented here.*

# Project management

*The project management section of the DMP should enumerate data-related deliverables, milestones, timelines, tasks required to meet the timelines, and related SOPs where relevant. e.g.*

|  |  |  |  |
| --- | --- | --- | --- |
| Milestone | Action | Timeline | SOP |
| Fortnightly from commencement of recruitment | Metrics report circulated | 1 day |  |
| 100 participants randomised | Data for DSMC | 2 weeks | XXXX\_DSMB-data-extract |
| 200 participants randomised | Data for DSMC | 2 weeks | XXXX\_DSMB-data-extract |
| All participants complete 6-month assessment | Dataset for Interim Analysis  | 4 weeks | XXXX\_analysis-data-extract |
| All participants complete follow-up, site close out | Database lock | 6 weeks | XXXX\_completion-of-data-cleaning, XXXX\_database-lock |
| Close out complete | Dataset for Final Analysis  | 3 weeks | XXXX\_analysis-data-extract |
| Close out complete | Dataset prepared for sharing | 8 weeks | XXXX\_dataset-anonymisation, XXXX\_data-transfer |
| Date trial archived | All trial documents and data handed over for long-term archival storage in accordance with institutional policy | 4 weeks |  |

# CRF

*This section should describe the CRF and other instrument development process, including development of the CRF Completion Guidelines.* *Reference to all study forms and CRF completion guidelines should be included in this section; including:*

* *Use of template forms (e.g. CDASH-compliant standard CRFs such as Adverse Events and Concomitant Medications) and any trial-specific adaptations made to the templates.*
* *Development and user-acceptance testing of study-specific CRFs and forms. User-acceptance testing is particularly important to document thoroughly as it is a vital component in the documenting of the fitness-for-purpose of trial data collection instruments.*
* *Reference to CRF Completion Guidelines and any EDC user training materials and how there are made readily available to site staff.*

# Data mapping

*The mapping of each data element to the database or other structure in which the data are stored or made available for use should be provided. This has often been accomplished using annotated CRFs. An annotated CRF is a copy of the data collection form overlaid with data element names, some components of data definition such as data type and valid values on entry, and metadata such as visit labels. A good guide to best practices can be found at* [*https://www.pinnacle21.com/blog/best-practices-annotated-crf*](https://www.pinnacle21.com/blog/best-practices-annotated-crf)

*For data collected through interfaces other than EDC systems, annotated mock-ups/screenshots of App Screens/EMR/Patient Diaries etc can be provided to show the path of data from initial entry to study database.*

*Alternately annotations can be provided in a spreadsheet which will be less time consuming and may be more appropriate for studies with significant bulk imports of data, such as pragmatic trials where the majority of data will be sourced from EMR extracts rather than CRFs.*

*The DMP should either reference where the data mappings are stored or provide them as an appendix.*

# Data definition

*The DMP should document or reference complete data definitions for all elements in the final dataset. These definition tables are often referred to as a data dictionary or metadata tables. These will include:*

* *All variables originating from CRFs, whether entered by site staff or autogenerated (such as hidden timestamps).*
* *Data supplied in bulk such as central lab results or EMR extract tables*
* *Predefined and derived elements*

*It is usual to either provide this as an appendix to the DMP or record where it is stored in the TMF. A sample table covering adverse events is provided in Appendix A.*

# Data transformation

*Data will commonly be transformed throughout the study for processing, storage and analysis e.g. from CRFs and raw ePRO data to CDISC Submission Data Tabulation Model (SDTM) for storage. Such transformations should be documented in the DMP or their external documentation referenced.*

*Particularly for studies involving collection of data elements not directly specified by the sponsor such as extracts from the EMR, it is important to document, in human readable form, the steps taken to transform the data from its raw state to stored and analysis-ready forms with clear mapping of the source and destination data elements.*

*An example of data transformation would be the standardisation of pathology result units entered into CRFs, along with the creation of derived columns for null flavour data such as “unknown” or “not recorded” values.*

# System Access and Privileges

*Because traceability requires attribution, the DMP should list or reference procedures for assignment of and tracking access to and privileges in data systems including the time period for which the access and privileges are active during the study and training requirements prior to system access. User account creation, expiration and roles may be recorded in a separate user log or within the EDC system itself.*

*It is usual to assign users to different roles within an EDC system, with privileges based on role as shown in the sample table below.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Role | Project design and setup | Create Reports | Form Viewing | Form Editing | Raise Queries | Data Export |
| Administrator | Y | Y | Y |  | Y | Y |
| Monitor |  | Y | Y |  | Y |  |
| Site data entry |  | Y | Y | Y |  |  |
| Laboratory |  | Y | Biochem |  | Y |  |
| Safety Review |  |  | Y | AE/SAE |  |  |

*For more complex projects where, for instance, there are different roles for blinded and unblinded users, it may be necessary to specify role-based read and write privileges on a form-by-form basis.*

# Data systems used

*All systems used to collect and process data for the study should be listed in or referenced by the DMP along with the location of the instance where appropriate. e.g:*

|  |  |  |  |
| --- | --- | --- | --- |
| System | Purpose | Version | Hosted |
| REDCap – Vanderbilt University  | Primary trial EDC, including eCRFs, upload of central lab data, PRO surveys | Current - 13.10.6, periodically updated within 6 weeks of new version being released by vendor | MCRI  |
| Florence eBinders™ | eConsent, trial document management including ISF, TMF | Current - 83.0.1, updated by vendor | Cloud |
| Microsoft 365, including OneDrive, SharePoint | Storage of working and analysis files | Updated as per institutional licence | Cloud hosted in Melbourne as outlined in MCRI Data Storage Proceedure |
| EPIC EMR | Electronic Medical Record | Updated as per RCH schedule | Royal Children’s Hospital, Melbourne |
| Study Symptom App – Curve Tomorrow | Participant entered symptom diary – data imported directly into REDCap | Current - 2.0.4 |  |

# Software Development Lifecycle procedures

*If there are specific applications created for use in the Trial (such as app or web-based participant reporting tools), the procedures for development, vendor assessment/selection, integration, testing, installation, and change control of these systems and related activities should be described in or referenced by the DMP where relevant. The scope of validation of all systems used in the study should be stated in the DMP.*

# Instrumentation, Calibration and Maintenance

*Instrumentation used for data collection or processing used for a clinical study should be documented in the DMP where relevant. Procedures for selection, testing, distribution, training on operation, calibration, maintenance, and acquisition of data from instrumentation and personal or medical devices should be described in or referenced by the DMP. This may range from ECG machines provided to trial sites to sponsor-supplied wearables.*

# Privacy and Confidentiality

*Protection of human subjects’ right to privacy and organizational procedures for maintaining confidentiality are required by multiple regulations applicable to clinical studies including the General Data Protection Regulation (GDPR), the Health Insurance Portability and Accountability Act (HIPAA) security rule 45CFR160 and 45CFR164(A) and (E), The Common Rule 45CFR46, 21CFR Part 50 (Protection of Human Subjects) and Part 56 (Institutional Review Boards).*

*The DMP should describe or reference procedures for protecting privacy of human subjects. e.g*

All data for the trial will be processed and stored according to MCRI Data Protection Policy and Information Security Classification Policy, all other institutional data policies and all relevant national and international legislation.

## Data Protection Impact Assessment

*The General Data Protection Regulation (GDPR) require privacy to be by design. Information needs to be protected against intentional and accidental disclosure, destruction, disruption, tampering or unauthorised access by identifying and protecting against risks. For trials with sites in the EU and/or the UK a data privacy impact assessment (DPIA) should be completed at the start of the trial (prior to data collection), to help identify and minimise data protection risk where possible. The DMP should record that the DPIA has taken place and its location in the TMF.*

# Change Control

*All post-release changes in computerised systems used in clinical studies should be implemented in a controlled manner, most commonly through a database change log. It is good practice to perform validation and user acceptance testing on a test copy of the trial EDC before implementing changes in the live project(s).*

*Suggested columns for such a log are:*

* *Database (for trials with more than one data entry project: eCRF, safety database etc)*
* *CRF/Form Name*
* *Requestor Name*
* *Date of Request*
* *Change Description*
* *Variable(s) to be Changed or Added*
* *Reason for Change*
* *Completed By (trial database programmer)*
* *Validation/UAT Performed By*
* *Release Approved By*
* *Date & Time of Upload to live project*

*A sample change log is provided in Annex B. The DMP should document change management processes (i.e. the procedures for requesting, testing, approving and documenting changes) and where any change logs are stored.*

# Back-up and recovery

*The DMP shall include a brief description of data back-up and recovery, or a reference should be made to the appropriate documents if documented outside the DMP.*

e.g.

An incremental backup of all MCRI file servers is made nightly, allowing IT services to perform recovery of data rapidly. A full backup is performed monthly with tapes being stored off-site for 7 years.

The Florence eBinders™ platform is hosted using an Amazon Web Services (AWS) infrastructure. Data hosting is via AWS’s EU-Central-1 facility. As per the Florence eBinders™ Security Overview SOP, the Florence eBinders™ databases are backed up according to the following schedule:

* Three (3) daily incremental backups maintained for one (1) week
* One (1) daily full backup maintained for two (2) months; and
* One (1) monthly full backup maintained for one (1) year.

# Data Quality Control

*E6 R2 section 5.1.3 states that, “quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly."*

*The process, tools, and reports that will be used to monitor data quality, should be described or referenced by the DMP, including aspects of data quality to be measured, the measures used, how data quality will be measured and reported, and any acceptance criteria. This is usually recorded in a separate Data Validation Plan. Such a plan will cover:*

1. *Required fields for each form*
2. *On entry data checks for data type and within expected ranges*
3. *Source documents collected and variables in EDC checked against source*
4. *Post entry checks cross-referencing multiple forms/data in different projects, any listing reviews, and any specialised review reports*
5. *Manual post entry checks for data coherence, e.g. reconciling reported adverse events against concomitant medications*
6. *Metrics reporting of data completeness, computational trend monitoring etc*

*The DMP should outline the mechanisms for raising queries and approving responses/alterations, both within the EDC and other logged methods (e.g. via email). The DMP should also outline any automated alerts such as safety event detection, protocol deviation detection and handling, medical coding procedures (e.g. adverse events MedDRA coded and confirmed with medical monitor)*

# Database Clean

*Prior to database lock (either interim or final), all data should be confirmed as ‘clean’. This is usually recorded in a “Completion of Data Cleaning Confirmation” form. This is a document that confirms that all trial data required for analysis has been verified and cleaned, there are no outstanding unresolved data queries, all SAEs have been reconciled, the data is ready for final export and that the trial database is now ready to be hard-locked. No further edits or additions to the dataset should be made prior to the hard lock being completed.*

# Database Lock and Unlock

*The DMP should describe or reference procedures for database lock and unlock including study specific criteria for locking and unlocking the database including forms to record:*

1. *Nature of lock, e.g. interim or final*
2. *Lock request date and timeline for completion*
3. *Confirmation that:*
	1. *All required data has been entered or imported into the trial database*
	2. *All outstanding data queries or questions to the investigators or site personnel have been resolved and corrections made*
	3. *Any issues that are unable to be resolved (e.g. because site personnel change, potential errors in source documents) have been recorded in a separate listing*
	4. *All reported Adverse Events have been coded (ICH MedDRA is the default dictionary for trials)*
	5. *All SAEs have been reconciled*
	6. *"Completion of Data Cleaning Confirmation" form has been completed and signed*
	7. *All CRFs requiring site investigator sign-off have been*
4. *Date of lock*

*Unlocking a study database to allow changes, particularly after unblinding has occurred, may give cause to question the objectivity of the trial. For this reason, an unlocking form should be created that clearly states:*

1. *Unlocking requestor*
2. *Reason for unlocking request with detailed description of what data is to be changed*
3. *Date of unlock*
4. *Confirmation of changes made to data and that they are in line with the request*
5. *Relocking date*

# Data Archival

*The procedures for data archival should be described or referenced by the DMP. Such procedures include responsibilities for data archival, enumeration of the data to be archived, the data format for archival, how and when data will be transferred for archival as well as how receipt will be acknowledged, and how long data should remain in archival prior to disposal.*

*e.g.*

* Pseudonymized trial data will be stored securely on MCRI servers (restricted access) for at least 25 years after trial completion
* Data stored in Florence eBinders™ will be electronically archived securely within Florence eBinders™ for at least 25 years after trial completion
* Any hardcopy paper documents will be stored offsite in a secure archiving facility for the duration of the retention period agreed with the Sponsor
* After the 25-year minimum archival period, trial data will be anonymised and retained indefinitely for approved future research projects

# Data Reuse and Sharing

*It is common in clinical trials to share data, both with collaborators and via more widely accessible data platforms such as Vivli and Yoda. The DMP should state that all data sharing will be carried out according to (referenced) institutional guidelines and contractual agreements, along with timelines when data will be made available and make reference to study-specific data-sharing SOPs and documents.*

*As sharing is now such a key part of trials, it is common to flesh out the details in a separate Data Sharing Plan. If one is created, this needs to be referenced in the DMP.*

*The DMP should either reference or describe in detail processes that will be performed on shared datasets including:*

1. *Checks performed to ensure consent has been obtained from participants for reuse of data beyond trial analyses*
2. *Anonymisation and “making safe” data for sharing including:*
	1. *The replacement of any direct identifiers e.g. Date of Birth replaced with age at study entry*
	2. *Modification of potential identifiers, e.g. date shifting or date replacement with days from randomization etc.*
3. *Transformation of data to common formats to maximize interoperability, e.g. CDISC SDTM*
4. *Description of metadata to be created for datasets*

*What other documents will accompany shared datasets such as final protocol, final statistical analysis plan*

Appendix A – Sample Data Definition

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Variable | Label | Data Type | Length | Format | Mandatory | Codelist | Origin | Role |
| USUBJID | Unique Subject Identifier | integer | 8 |  | Yes |  | Assigned | Identifier |
| AESEQ | Sequence Number | integer | 8 |  | Yes |  | Assigned | Identifier |
| AETERM | Reported Term for the Adverse Event | text | 156 |  | Yes |  | CRF | Topic |
| AEDECOD | Dictionary-Derived Term | text | 40 |  | Yes | MedDRA | CRF | Synonym Qualifier |
| AEPTCD | Preferred Term Code | integer | 8 |  | No | MedDRA | CRF | Variable Qualifier |
| AESER | Serious Event | text | 1 | Y/N | No |  | CRF | Record Qualifier |
| AEACN | Action Taken with Study Treatment | text | 14 |  | No | DOSE INCREASED, DOSE NOT CHANGED, DOSE RATE REDUCED, DOSE REDUCED, DRUG INTERRUPTED, DRUG WITHDRAWN, NOT APPLICABLE, UNKNOWN | CRF | Record Qualifier |
| AEREL | Causality | text | 16 |  | No | NOT RELATED, UNLIKELY RELATED, POSSIBLY RELATED, PROBABLY RELATED, RELATED | CRF | Record Qualifier |
| AESCONG | Congenital Anomaly or Birth Defect | text | 1 | Y/N | No |  | CRF | Record Qualifier |
| AESDISAB | Persistent or Significant Disability/Incapacity | text | 1 | Y/N | No |  | CRF | Record Qualifier |
| AESDTH | Results in Death | text | 1 | Y/N | No |  | CRF | Record Qualifier |
| AESHOSP | Requires or Prolongs Hospitalization | text | 1 | Y/N | No |  | CRF | Record Qualifier |
| AESLIFE | Is Life Threatening | text | 1 | Y/N | No |  | CRF | Record Qualifier |
| AETOXGR | Standard Toxicity Grade | integer | 1 |  | No | 1.2.3.4.5 | CRF | Record Qualifier |
| AESTDTC | Start Date/Time of Adverse Event | datetime |  | YYYY-MM-DD | No |  | CRF | Timing |
| AEENDTC | End Date/Time of Adverse Event | datetime |  | YYYY-MM-DD | No |  | CRF | Timing |

Appendix B – Sample Change Log

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Database | CRF Name | Requestor Name | Date of Request | Change Description | Variable Changed or Added | Reason for Change | Completed By | Validation/UAT Performed By | Release Approved By | Revision # | Date & Time of Upload |
| Sample Main  | Demographics | Thomas Browder | 01-04-2023 | Constraint to prevent the entering of future dates | BIRTHDAT | Prevention of typos by site | Barry Pincus | Cherilyn Sarkisian | Sylvester Stewart | 4 | 14-04-2023 |