TRIAL MASTER FILE
TMF
REFERENCE MODEL

Release Notes v3.2.0

Release Date 2-NOV-2020

Identification

Authors

Name	Organization
Joanne Malia	Regeneron Pharmaceuticals

Contributing Change Control Board Members

Name	Organization
Kelley Robinson	Odonate Therapeutics
Kristen Bretzius	Syneos Health
Gift-Tafadzwa Chareka	UZ-UCSF-Collaborative Research
JP Miceli	Advanced Clinical
Kate Santoro	bluebird bio
Laurel Ann Schrader	Transperfect Translation
Melissa Maberry	Veeva
Ashley Villa	Theradex Oncology
Katherine Firth	GSK
Allison Grosik	LMK Clinical Research Consulting
Carla Calitri	PRA Health Sciences
Mary Ann Brooks	Baxter Healthcare

Leila Ponce	Seattle Genetics
Jennifer Eberhardt	Sarepta Therapeutics
Noreen Bouchard	Astellas
Lisa Mulcahy Steering Committee Liaison	Mulcahy Consulting
Marie Christine Poisson-Carvajal Steering Committee Liaison	Pfizer

Version History

Version	Steering Committee Approval Date	Changes
1.0	19-OCT-2020	N/A

Table of Contents

1 Introduction

These Release Notes relate to TMF Reference Model v3.2.0, the second minor update to TMF Reference Model v3.0. Version 3.1.0 was released in September 2018.

A minor update is defined as a substantial change to the content of the TMF Reference Model, but the changes are unlikely to cause incompatibility issues with the previous version of the TMF Reference Model and/or no significant technical changes to implement the update for electronic TMF solutions

Examples of changes that would require a minor release include:

- Inclusion of an additional optional element to the Model
- Changes to the alignment of artifacts with filing level (study, country and site)
- Attribute updates or attribute additions
- Attribute deletions that are unlikely to cause incompatibility issues

This minor release also includes maintenance changes, defined as no significant impact on adoption or implementation of the Model. Examples of changes that would require a maintenance release include:

- Changes to the definition/purpose text that do not substantially modify the meaning e.g. additional text for clarification
- Inclusion or deletion of example sub-artifacts, as sub-artifacts are specific to a Company's needs and are not utilized globally
- Addition or modification of regulatory guidance references
- Correction of typographical errors

2 General Changes

The 3.2.0 version of the TMF Reference Model includes extensive updates to the sub-artifacts column (column I) and may be found in Section 7. These recommendations, or suggestions, are intended to assist companies in more readily using the Zone > Section> Artifact taxonomy of the TMF Reference Model.

Sub-artifacts are types of records that may be commonly created in addition to the artifact or records that make up the artifact. This does not include Artifact "progeny" records such as signature pages or translation records which are not identified in the Model as they belong to and/or filed with the associated artifact. Sub-artifacts are intended to provide a means to list company-specific records that a company would expect to file under a given artifact. Examples are provided in this new version of the model but may be overridden as part of a company's adoption of the TMF Reference Model.

Some companies are already using sub-artifacts in their TMFs. The sub-artifacts provided as part of this release are not exhaustive and should be viewed as recommendations for companies to consider as they implement or update their company's TMF Index which is based on the TMF Reference Model (if they use sub-artifacts)

Definitions:

Artifact: Type of *records or documents which one would expect to find in a TMF, at either Sponsor or Investigator site or both.*

Sub-Artifact*: Type of records that may be commonly created in* ***addition to*** *the artifact or records that make up the artifact, when the artifact does not refer to a single document type e.g. Meeting Materials*

Alternate Name: *A term equivalent to the Artifact Name, that may be commonly known in different facets or geographies of the clinical development industry. The alternate name column overlapped somewhat with the previous Sub-artifacts column - it was often confusing to users of the TMF Reference Model and no longer appeared to serve a useful purpose. It was, therefore retired and replaced by the new recommended Sub-artifacts column. Individual companies may choose to retain this column for alternate names that may exist across divisions or with partners.*

3 New Artifacts

06.05.04 Non-IP Storage Documentation

Previous text	New text
N/A	Non-IP Storage Documentation
Reason for change: To document the unique storage conditions of the Non-IP supplies at the sponsor (if sponsor is distributing), distribution center, depot, trial site and in transit, if required by the available stability requirements of the non-IP supplies. To record excursions for non-IP supplies, from the acceptable pre-defined condition range either during transit or storage at a distribution center, depot and/or trial site.	

4 Changes to Artifact Name

Artifact 04.01.02 IRB or IEC Approval

Previous text	**New text**
IRB or IEC Approval	IRB / IEC Decision
Reason for change: The TMF artifact 04.01.02 may contain both positive and negative responses. The previous name indicated only approvals were required.	

Artifact 06.04.03 Maintenance Logs

Previous text	**New text**
Maintenance Logs (Device)	Maintenance Logs ~~(Device)~~
Reason for change: Consistency within the TMF Reference Model	

Artifact 10.03.01 Database Specifications

Previous text	**New text**
Database Specifications	Database Requirements
Reason for change: 'Specifications' is often interpreted fairly narrowly whereas the artifact covers more than just a specifications document. Requirements is a more general term.	

Artifact 10.04.03 Validation Documents

Previous text	**New text**
Validation Documents	Validation Documentation
Reason for change: Consistency	

5 Changes to Filing Level

Artifact 01.01.08 Monitoring Plan

TMF Level – Site Level Document

Previous text	New text
-	X
Reason for change: Clarification	

6 Changes to Artifact Definition/Purpose, Milestones, Glossary, Model Overview and ICH Code

Artifact 01.01.08 Monitoring Plan

Definition/Purpose

Previous text	New text
To describe how monitoring will be implemented during the trial, including strategy for source data verification. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc	To describe how monitoring will be implemented during the trial, including strategy for source data verification and risk-based monitoring (if applicable). Artifact can include any trial level evidence of plan execution including, but not limited to plan, reports, checklists, etc. Note: Individual Monitoring Visit Reports are filed in Zone 5.
Reason for change: Clarification and alignment with ICH E6 R2.	

Artifact 01.01.11 Debarment Statement

Trial Level Milestone/ Event

Previous text	New text
03 Site Live / Ready / Open for Enrollment	~~03 Site Live / Ready / Open for Enrollment~~ #2 Clinical Infrastructure Ready
Reason for change: Clarification	

Artifact 01.01.17: Vendor Management Plan

Definition/Purpose

Previous text	New text
To describe the overall management strategy for vendors used to conduct trial-related activities. May include assignment of responsibilities for vendor oversight, performance indicators, monitoring activities	To describe the overall management strategy for third party vendors used to conduct trial-related activities. May include assignment of responsibilities for third party vendor oversight, performance indicators, monitoring

and schedules, issue escalation and resolution process, technology and documentation transfer and business continuity plan. Artifact can include any evidence of plan execution including, but not limited to: plan, reports, checklists, etc.	activities and schedules, issue escalation and resolution process, technology and documentation transfer and business continuity plan. Artifacts providing evidence of plan execution including, but not limited to reports, checklists, etc. and other records demonstrating oversight of a specific third party vendor should be filed in the appropriate artifacts in Zone 09.
Reason for change: Clarification between vendors and third-party vendors	

Artifact 01.04.04 Trial Team Evidence of Training

Definition/Purpose

Previous text	**New text**
To document completion of trial team training, including certification or evidence of training (attendance sheets). Includes EDC training.	To document completion of study-specific trial team training, including certification or evidence of training (attendance sheets). Includes EDC training. Does not include each individual's education, training and experience to perform his/her role. This should be documented in the company learning management system.
Reason for change: Clarification	

Artifact 02.01.04 Protocol Amendments

Definition/Purpose

Previous text	**New text**
To describe description of change(s) to or formal clarification of a protocol. Includes justification for a non-substantial amendment, such as administrative changes.	Subsequent versions of the original protocol as well as supporting documentation that may include description of change(s) to or formal clarification of a protocol. Includes justification for a non-substantial amendment, such as administrative changes
Reason for change:	

Clarification

Artifact 04.01.02 IRB or IEC Decision

Definition/Purpose

Previous text	**New text**
Documentation received from IRB/IEC in response to submission indicating approval/acknowledgement of trial and any specifications or modifications. Records referenced by the approval (such as a Protocol that has been approved) should be filed elsewhere in the TMF, as appropriate, as long as there is identification of the approved record within the IRB/IEC letter or acknowledgement.	Documentation received from IRB/IEC in response to submission indicating decision of the trial and any specifications or modifications. Records referenced by the approval (such as a Protocol that has been approved) should be filed elsewhere in the TMF, as appropriate, as long as there is identification of the approved record within the IRB/IEC letter.
Reason for change: Clarification to align with new name (can include both positive and negative decisions)	

Artifact 06.04.03 Maintenance Logs

Definition/Purpose

Previous text	**New text**
To record activities and times when quality of condition of IP, Non-IP, and other trial supplies is assessed over period of use and any maintenance performed, including software logs and certificates of calibration.	To record activities and times when quality of condition of IP, Non-IP, device, and other trial supplies is assessed over period of use and any maintenance performed, including software logs and certificates of calibration."
Reason for change: Clarification to align with revised artifact name	

Artifact 10.03.01 Database Requirements

Definition/Purpose

Previous text	**New text**

To provide a detailed framework for the database to be built for CRF data capture system.	To provide a detailed design framework for the system(s) used to manage and store subject/patient data captured via a paper CRF or eCRF for the specified trial. Not to be confused with specifications for the Electronic Data Capture (EDC) system (see 10.04.02).
Reason for change: Clarification	

Artifact 10.04.02 Technical Design Document

Definition/Purpose

Previous text	**New text**
Document containing the design elements of the EDC (e.g.: eCRF or ePRO) eCRF including the variables to be collected, the logical arrangement of the variables, navigation among and between the different forms, the logic checks for logical consistency.	A technical planning and tracking document containing all the elements required to build and test the EDC application including the variables to be collected, their logical arrangement, navigation between the different forms, and the checks for logical consistency. May take the form of a spreadsheet created manually by a programmer and uploaded to the EDC application (e.g. to generate the eCRF or ePRO system) or exported from the application after building as a record of its technical design. May include some code for 10.03.03, Edit Check Programming.'
Reason for change: Clarification	

Artifact 11.03.07 Final Analysis Raw Datasets

Definition/Purpose

Previous text	**New text**
The export of raw data for final analysis purposes. This may include CDISC datasets such as Operational Data Model (ODM) or SDTM.	The export of raw data for final analysis purposes. This may include CDISC datasets such as Operational Data Model (ODM), SDTM or Case Report Tabulation (CRT) package.

Reason for change:
Clarification

Glossary Zone 8; Central and Local Testing

Previous text	**New text**
Records related to central and local laboratory's SOPs, certification (and expiration dates), procedure manuals, current normal value ranges and the Laboratory Director's curriculum vitae (CV).	Records related to all specialty testing vendors, including central and local laboratories, on a global study level, a country level or a site level. Records include certification (and expiration dates), procedure manuals, current normal value ranges and the test facility staff curriculum vitae (CV). The content should be modified based on the testing utilized
Reason for change:	
Clarification	

Glossary SDTM definition

Previous text	**New text**
Statistical Time Division Multiplexing	Study Data Tabular Module
Reason for change:	
Correction	

Model Overview: Row 5

Previous text	**New text**
Since its inception, the TMF Reference Model has been developed by a pan-industry, global project team comprising in excess of 800 representatives from more than 300 bio-pharmaceutical companies, contract research organizations (CROs), consultancies,	Since its inception, the TMF Reference Model has been developed by a pan-industry, global project team comprising over 1000 representatives from hundreds of bio-pharmaceutical and medical device companies, contract research organizations

technical vendors, industry groups, healthcare, academia, not-for-profit / NGO and regulatory agencies. The TMF Reference Model is a consensus of the TMF Reference Model Team that includes all essential documents that individually and/or collectively permit the evaluation of the conduct of a study and the quality of the data produced, in accordance with industry opinion and best practices. The model is a reference for the industry and should not be considered mandatory, but rather an opportunity for standardization across the industry. The TMF Reference Model can be adapted to an electronic or paper TMF. It does not endorse, nor, require, any specific technology for application. The model can be downloaded from the DIA website at: http://www.diahome.org/en/News-and-Publications/Publications-and-Research/EDM-Corner.aspx	(CROs), consultancies, technical vendors, industry groups, healthcare, academia, not-for-profit / NGO and regulatory agencies. The TMF Reference Model is a consensus of the TMF Reference Model Team that includes all essential documents that individually and/or collectively permit the evaluation of the conduct of a study and the quality of the data produced, in accordance with industry opinion and best practices. The model is a reference for the industry and should not be considered mandatory, but rather an opportunity for standardization across the industry. The TMF Reference Model can be adapted to an electronic or paper TMF. It does not endorse, nor, require, any specific technology for application. The model can be downloaded from the DIA website at: http://www.diahome.org/en/News-and-Publications/Publications-and-Research/EDM-Corner.aspx
Reason for change: Inclusion of medical device companies and updated numbers regarding TMF Reference Model membership.	

Model Overview; Row 9

Previous text	**New text**
All companies and investigators conducting clinical trials in the pharmaceutical/biotech industry maintain documentation for each clinical trial. Each company has their own unique TMF structure as defined by their SOPs. No comprehensive common model exists for managing TMF documents. Over the conduct of a trial many functions contribute to the TMF, although oversight of the content is usually not one function's responsibility – resulting in a highly inefficient work processes including but not limited to: * All drug development companies and CROs expend considerable resources defining the content of the trial master file for each clinical trial. Consequently, * Investigators have the challenge of adapting to different formats and TMF content organization with each clinical trial.	All companies and investigators conducting clinical trials in the pharmaceutical/biotech and medical device industries maintain documentation for each clinical trial. Each company has their own unique TMF structure as defined by their SOPs. No comprehensive common model exists for managing TMF documents. Over the conduct of a trial many functions contribute to the TMF, although oversight of the content is usually not one function's responsibility – resulting in a highly inefficient work processes including but not limited to: * All drug and medical device development companies and CROs expend considerable resources defining the content of the trial master file for each clinical trial. Consequently: * Investigators have the challenge of adapting to different formats and TMF content organization with each clinical trial.

* The burden is very high on smaller companies that usually have limited document management expertise and limited financial resources. * Records and information exchange between collaborating companies is extremely cumbersome, potentially preventing the joint venture or transfer of an investigational product. * Regulators are challenged with varying terminology and file structures, creating inefficiency and variability during audits	* The burden is very high on smaller companies that usually have limited document management expertise and limited financial resources. * Records and information exchange between collaborating companies is extremely cumbersome, potentially preventing the joint venture or transfer of an investigational product. * Regulators are challenged with varying terminology and file structures, creating inefficiency and variability during audits
Reason for change: Inclusion of medical device companies	

Changes to ICH Code

Artifact 01.01.08 Monitoring Plan

Previous code	New code
5.18.3	5.18.3, 5.18.7
Reason for change: To correct an error	

Artifact 04.03.02 IRB or IEC Progress Report

Previous code	New code
8.3.19, 3.1.4, 3.3.8, 4.4.4, 3.5.2, 4.5.3, 4.10.1, 4.10.2, 8.4.7	8.3.19, 3.1.4, 3.3.8, 4.4, 4.52, 4.54, 4.10.1, 4.10.2, 8.4.7 (Removed 4.4.4, 3.5.2 & 4.5.3)
Reason for change: To correct an error	

Artifact 05.01.03 Feasibility Documentation

Artifact 05.01.04 Pre-Trial Monitoring Report

Artifact 05.01.05 Sites Evaluated but not Selected

Previous code	New code
-	5.6
Reason for change: To correct an error	

Artifact 05.04.13 Subject Eligibility Verification Forms and Worksheets

Previous code	New code
-	8.3.22
Reason for change: To correct an error	

Artifact 09.01.03 Ongoing Third Party Oversight

Previous code	New code
-	5.2.2
Reason for change: To correct an error	

Artifact 11.03.10 Final Analysis Output

Previous code	New code
-	5.22, 8.4.8
Reason for change: To correct an error	

7 New Sub-artifact Set

Sub-artifacts are alphabetically ordered per artifact.

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
01.01.01	Trial Master File Plan	Document Transfer Documentation Evidence of Quality Review Request to Lock TMF Trial Master File Plan Trial Master File Index Trial Master File Report
01.01.02	Trial Management Plan	Clinical Development Plan Project Management Plan Trial Management Plan
01.01.03	Quality Plan	Quality Documentation Quality Plan Quality Report
01.01.04	List of SOPs Current During Trial	List of SOPs Current During Trial SOP Waivers SOP Deviations
01.01.05	Operational Procedure Manual	Operational Procedure Manual
01.01.06	Recruitment Plan	Recruitment Plan Recruitment Progress
01.01.07	Communication Plan	Communication Plan
01.01.08	Monitoring Plan	Monitoring Plan Risk Based Monitoring Plan Risk Based Monitoring Evidence
01.01.09	Medical Monitoring Plan	Medical Monitoring Plan Medical Contact Report Medical Monitoring Decisions
01.01.10	Publication Policy	Publication Policy
01.01.11	Debarment Statement	Debarment Statement Restricted Party Lists
01.01.12	Trial Status Report	Trial Status Report
01.01.13	Investigator Newsletter	Investigator Newsletter
01.01.14	Audit Certificate	Audit Certificate List of Audits
01.01.15	Filenote Master List	Filenote Master List
01.01.16	Risk Management Plan	Risk Management Plan Risk Assessment Risk Log
01.01.17	Vendor Management Plan	Vendor Management Plan
01.01.18	Roles and Responsibility Matrix	Roles and Responsibility Matrix
01.01.19	Transfer of Regulatory Obligations	Transfer of Regulatory Obligations
01.01.20	Operational Oversight	Operational Oversight Plan Operational Oversight Evidence

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
01.02.01	Trial Team Details	Trial Team Details Transition Evidence
01.02.02	Trial Team Curriculum Vitae	Trial Team Curriculum Vitae
01.03.01	Committee Process	Committee Charter Committee Process ~~Document~~
01.03.02	Committee Member List	Committee Member List
01.03.03	Committee Output	Committee Correspondence Committee Data Package Committee Minutes Committee Report
01.03.04	Committee Member Curriculum Vitae	Committee Member Curriculum Vitae Committee Member Medical License Committee Member Training Evidence
01.03.05	Committee Member Financial Disclosure Form	Committee Member Financial Disclosure Form
01.03.06	Committee Member Contract	Committee Member Contract
01.03.07	Committee Member Confidentiality Disclosure Agreement	Committee Member Confidentiality Disclosure Agreement
01.04.01	Kick-off Meeting Material	Kick-off Meeting Agenda Kick-off Meeting Attendance Sheet Kick-off Meeting Presentation Materials Kick-off Meeting Minutes
01.04.02	Trial Team Training Material	Trial Team Training Material
01.04.03	Investigators Meeting Material	Investigators Meeting Agenda Investigators Meeting Attendance Sheet Investigators Meeting Minutes Investigators Meeting Presentation Materials
01.04.04	Trial Team Evidence of Training	Trial Team Training Attendance Sheet Trial Team Training Certificate
01.05.01	Relevant Communications	Relevant Communications
01.05.02	Tracking Information	Tracking Information
01.05.03	Other Meeting Material	Other Meeting Agenda Other Meeting Attendance Sheet Other Meeting Minutes Other Meeting Presentation Materials
01.05.04	Filenote	Filenote
02.01.01	Investigator's Brochure	Investigator's Brochure Investigator's Brochure Addendum Investigator's Brochure Extension Investigator's Brochure Review and Approval Investigator's Brochure Summary of Changes Investigational Medicinal Product Documentation

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
02.01.02	Protocol	Protocol Protocol Review and Approval Clinical Investigation Plan (Devices)
02.01.03	Protocol Synopsis	Protocol Synopsis
02.01.04	Protocol Amendment	Protocol Amendment Protocol Amendment Summary of Changes Protocol Amendment Review and Approval Protocol Amendment Synopsis Protocol Amendment Administrative Changes Justification For a Non-Substantial Amendment
02.01.05	Financial Disclosure Summary	Financial Disclosure Summary
02.01.06	Insurance	Insurance Policy Insurance Certificate
02.01.07	Sample Case Report Form	Sample Case Report Form CRF Summary of Changes CRF Review and Approval
02.01.10	Report of Prior Investigations	Report of Prior Investigations RPI Addendum RPI Summary of Changes RPI Review and Approval
02.01.11	Marketed Product Material	Package Insert Summary of Product Characteristics
02.02.01	Subject Diary	Subject Diary Subject Diary Review and Approval Subject Diary Summary of Changes
02.02.02	Subject Questionnaire	Subject Questionnaire Subject Questionnaire Review and Approval Subject Questionnaire Summary of Changes
02.02.03	Informed Consent Form	Consent to Release Information or HIPAA / Privacy Informed Consent Form ICF Addendum ICF QC Checklist ICF Summary of Changes ICF Review and Approval ICF Summary of Changes
02.02.04	Subject Information Sheet	Subject Information Sheet Subject Information Sheet Addendum Subject Information Sheet Summary of Changes Subject Information Sheet Review and Approval
02.02.05	Subject Participation Card	Subject Participation Card Subject Participation Card Summary of Changes Subject Participation Card Review and Approval
02.02.06	Advertisements for Subject Recruitment	Advertisements for Subject Recruitment Advertisements for Subject Recruitment Review and Approval
02.02.07	Other Information Given to Subjects	Other Information Given to Subjects
02.03.01	Clinical Study Report	Clinical Study Report Clinical Study Report Synopsis Interim Clinical Study Report

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
		Interim Clinical Study Report Synopsis Form FDA 3654 (devices)
02.03.02	Bioanalytical Report	Bioanalytical Report Pharmacokinetic Report
02.04.01	Relevant Communications	Relevant Communications
02.04.02	Tracking Information	Tracking Information
02.04.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
02.04.04	Filenote	Filenote
03.01.01	Regulatory Submission	Cover Letter List of Content Submitted Receipt of Acknowledgement Regulatory Submission Review and Approval of Regulatory Submission
03.01.02	Regulatory Authority Decision	Condition Approval List of Content Approved Regulatory Authority Decision
03.01.03	Notification of Regulatory Identification Number	Notification of Regulatory Identification Number
03.01.04	Public Registration	Public Registration Receipt of Acknowledgement
03.02.01	Import or Export License Application	Import License Application Export License Application
03.02.02	Import or Export Documentation	Import License Export License
03.03.01	Notification of Safety or Trial Information	Evidence of Distribution of Safety Information Evidence of Distribution of Trial Information Notification of Safety Information Notification of Trial Information
03.03.02	Regulatory Progress Report	Regulatory Progress Report
03.03.03	Regulatory Notification of Trial Termination	Regulatory Notification of Trial Termination
03.04.01	Relevant Communications	Relevant Communications
03.04.02	Tracking Information	Tracking Information
03.04.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
03.04.04	Filenote	Filenote
04.01.01	IRB or IEC Submission	Acknowledgement of Submission Receipt IRB or IEC Submission Request for Additional Information Responses

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
04.01.02	IRB or IEC Decision	IRB or IEC Approval IRB or IEC Conditional Approval IRB or IEC Rejection
04.01.03	IRB or IEC Composition	IRB or IEC Composition
04.01.04	IRB or IEC Documentation of Non-Voting Status	IRB or IEC Documentation of Non-Voting Status
04.01.05	IRB or IEC Compliance Documentation	IRB or IEC Compliance Documentation
04.02.01	Other Submissions	Other Approval Committee Submissions
04.02.02	Other Approvals	Other Approval Committee Decisions
04.03.01	Notification to IRB or IEC of Safety Information	Evidence of Distribution of Safety Information Notification to IRB or IEC of Safety Information
04.03.02	IRB or IEC Progress Report	Evidence of Distribution of Progress Report IRB or IEC Progress Report
04.03.03	IRB or IEC Notification of Trial Termination	IRB or IEC Notification of Site Closure IRB or IEC Notification of Trial Termination
04.04.01	Relevant Communications	Relevant Communications
04.04.02	Tracking Information	Tracking Information
04.04.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
04.04.04	Filenote	Filenote
05.01.01	Site Contact Details	Site Contact Details
05.01.02	Confidentiality Agreement	Confidentiality Agreement
05.01.03	Feasibility Documentation	Feasibility Documentation Feasibility Questionnaire Site Selection Documentation Technical Capabilities Questionnaire
05.01.04	Pre Trial Monitoring Report	Pre Trial Monitoring Report Pre Trial Visit Confirmation Letter Pre Trial Visit Follow Up Letter Pre Trial Visit Waiver Site Selection Letter
05.01.05	Sites Evaluated but not Selected	Sites Evaluated but not Selected
05.02.01	Acceptance of Investigator Brochure	Acceptance of Investigator Brochure Evidence of Investigator Brochure Distribution Evidence of Reference Safety Information Distribution
05.02.02	Protocol Signature Page	Protocol Signature Page
05.02.03	Protocol Amendment Signature Page	Protocol Amendment Signature Page

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
05.02.04	Principal Investigator Curriculum Vitae	Principal Investigator Affiliation Form Principal Investigator Biographical Sketch Principal Investigator Curriculum Vitae
05.02.05	Sub-Investigator Curriculum Vitae	Sub-Investigator Affiliation Form Sub-Investigator Biographical Sketch Sub-Investigator Curriculum Vitae
05.02.06	Other Curriculum Vitae	Other Affiliation Form Other Biographical Sketch Other Curriculum Vitae
05.02.07	Site Staff Qualification Supporting Information	DEA License Evidence of Registration ICH-GCP Evidence of Training IATA Certification Medical License Medical Qualification Professional License Site Staff Qualification Supporting Information
05.02.08	Form FDA 1572	Form FDA 1572
05.02.09	Investigator Regulatory Agreement	Clinical Trial Site Information Form Investigator Regulatory Agreement Qualified Investigator Undertaking Form
05.02.10	Financial Disclosure Form	Financial Disclosure Form
05.02.11	Data Privacy Agreement	Data Privacy Agreement
05.02.12	Clinical Trial Agreement	Clinical Trial Agreement Clinical Trial Agreement with Investigator Clinical Trial Agreement with Investigator and Site Clinical Trial Agreement with Site Termination Agreement
05.02.13	Indemnity	Indemnity
05.02.14	Other Financial Agreement	Laboratory Agreement Other Financial Agreement Pharmacy Agreement
05.02.17	IP Site Release Documentation	IP Site Release Checklist IP Site Release Documentation IP Site Release Notification
05.02.18	Site Signature Sheet	Delegation of Authority Log Site Signature Sheet
05.02.19	Investigators Agreement (Device)	Investigators Agreement (Device)
05.02.20	Coordinating Investigator Documentation	Coordinating Investigator Clinical Trial Agreement Coordinating Investigator Confidentiality Agreement Coordinating Investigator Curriculum Vitae Coordinating Investigator Documentation Coordinating Investigator Financial Disclosure Form Coordinating Investigator GCP Training Coordinating Investigator Indemnity Coordinating Investigator Medical License Coordinating Investigator Personal Data Consent
05.03.01	Trial Initiation Monitoring Report	Trial Initiation Monitoring Report Trial Initiation Visit Confirmation Letter Trial Initiation Visit Follow Up Letter Trial Initiation Visit Waiver
05.03.02	Site Training Material	Site Training Material

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
05.03.03	Site Evidence of Training	Site Evidence of Training Site Training Attendance Sheet Site Training Certificate
05.04.01	Subject Log	Subject Consenting Tracker Subject Enrollment Log Subject Log Subject Screening Log Subject Visit Log
05.04.02	Source Data Verification	Source Data Specification and Agreement Source Data Verification
05.04.03	Monitoring Visit Report	Co-Monitoring Visit Report Monitoring Visit Confirmation Letter Monitoring Visit Follow Up Letter Monitoring Visit Report Monitoring Visit Waiver
05.04.04	Visit Log	Site Visit Log
05.04.05	Additional Monitoring Activity	Additional Monitoring Activity Non-Routine Visit Report Non-Routine Visit Report Confirmation Letter Non-Routine Visit Report Follow Up Letter Oversight Monitoring Visit Report Oversight Monitoring Visit Report Confirmation Letter Oversight Monitoring Visit Report Follow Up Letter Site Improvement Plan
05.04.06	Protocol Deviations	Protocol Deviations Protocol Deviation Logs Protocol Deviation Report
05.04.07	Financial Documentation	Financial Documentation Financial Summary Tracker Invoices Payments Receipts
05.04.08	Final Trial Close Out Monitoring Report	Close Out Visit Confirmation Letter Close Out Visit Follow-Up Letter Close Out Visit Waiver Final Trial Close Out Monitoring Report
05.04.09	Notification to Investigators of Safety Information	Evidence of Safety Information Distribution Notification to Investigators of Safety Information
05.04.10	Subject Identification Log	Subject Identification Log
05.04.11	Source Data	Source Data Site Level Source Data Worksheets
05.04.12	Monitoring Visit Follow-up Documentation	Monitoring Visit Follow-up Documentation
05.04.13	Subject Eligibility Verification Forms and Worksheets	Subject Eligibility Verification Forms and Worksheets
05.05.01	Relevant Communications	Relevant Communications
05.05.02	Tracking Information	Tracking Information
05.05.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
05.05.04	Filenote	Filenote
06.01.01	IP Supply Plan	IP Supply Plan Placebo Justification Statement

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
06.01.02	IP Instructions for Handling	Device User Manual IP Directions for Use IP Instructions for Handling IP Manual Pharmacy Manual
06.01.03	IP Sample Label	IP Master Label IP Sample Label
06.01.04	IP Shipment Documentation	Acknowledgement of Receipt Approval to Ship Invoice IP Shipment Documentation Packaging Order Shipment Request Form Temperature (TempTale) Monitoring
06.01.05	IP Accountability Documentation	Drug Accountability Log IP Accountability Documentation
06.01.06	IP Transfer Documentation	Evidence of IP Transfer IP Transfer Documentation IP Transfer Plan Notification of IP Transfer
06.01.07	IP Re-labeling Documentation	Evidence of IP Relabeling IP Relabeling Documentation IP Relabeling Plan Notification of IP Relabeling
06.01.08	IP Recall Documentation	Evidence of Recall IP Recall Documentation IP Recall Plan Notification of IP Recall
06.01.09	IP Quality Complaint Form	IP Quality Complaint Form
06.01.10	IP Return Documentation	Acknowledgement of Return IP Return Documentation IP Return Form
06.01.11	IP Certificate of Destruction	IP Certificate of Destruction IP Destruction Documentation
06.01.12	IP Retest and Expiry Documentation	Expiry Extension IP Retest and Expiry Documentation Stability Confirmation
06.02.01	QP (Qualified Person) Certification	QP (Qualified Person) Certification
06.02.02	IP Regulatory Release Documentation	IP Regulatory Release Documentation
06.02.03	IP Verification Statements	Controlled IP Storage DEA 223 GMP Certificate GMP Manufacturer's License GMP Statement IP Verification Statements Manufacturing Authorization TSE Certificate
06.02.04	Certificate of Analysis	Batch Records Certificate of Analysis Certificate of Conformance
06.03.01	IP Treatment Allocation Documentation	IP Treatment Allocation Documentation Kit List Randomization Envelopes Randomization List

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
06.03.02	IP Unblinding Plan	IP Unblinding Plan Unblinding Procedure
06.03.03	IP Treatment Decoding Documentation	Emergency Decoding Authorization Document IP Treatment Decoding Documentation Treatment Decoding Form
06.04.01	IP Storage Condition Documentation	IP Storage Condition Documentation Temperature Logs
06.04.02	IP Storage Condition Excursion Documentation	Approval For Use (following temp excursion) IP Storage Condition Excursion Documentation TempTale Documentation Temperature Excursion Form
06.04.03	Maintenance Logs (Device)	Calibration Certificate Calibration Log Maintenance Logs
06.05.01	Non-IP Supply Plan	Non-IP Supply Plan
06.05.02	Non-IP Shipment Documentation	Acknowledgement of Receipt Approval to Ship Invoice Non-IP Shipment Documentation Packaging Order Shipment Request Form
06.05.03	Non-IP Return Documentation	Acknowledgement of Return Non-IP Return Documentation Non-IP Return Form
06.05.04	Non-IP Storage Documentation	Non-IP Storage Documentation Non-IP Storage Condition Excursion Documentation
06.06.01	IRT User Requirement Specification	IRT User Requirement Specification
06.06.02	IRT Validation Certification	IRT Validation Certification
06.06.03	IRT User Acceptance Testing (UAT) Certification	IRT UAT Certification IRT UAT Executed Scripts IRT UAT Sign Off IRT User Acceptance Testing (UAT) Certification
06.06.04	IRT User Manual	IRT Quick Reference Card IRT User Manual
06.06.05	IRT User Account Management	IRT User Account Management Summary of IRT Access Report
06.07.01	Relevant Communications	Relevant Communications
06.07.02	Tracking Information	Tracking Information
06.07.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
06.07.04	Filenote	Filenote
07.01.01	Safety Management Plan	Reference Safety Information Approval Form Safety Management Plan Safety Reporting Plan Safety Reporting Templates
07.01.02	Pharmacovigilance Database Line Listing	Annual Safety Report (ASR) Development Safety Update Report (DSUR) Pharmacovigilance Database Line Listing

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
07.02.01	Expedited Safety Report	Expedited Safety Report
07.02.02	SAE Report	SAE Report
07.02.03	Pregnancy Report	Pregnancy Report
07.02.04	Special Events of Interest	Special Events of Interest
07.03.01	Relevant Communications	Relevant Communications
07.03.02	Tracking Information	Tracking Information
07.03.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
07.03.04	Filenote	Filenote
08.01.01	Certification or Accreditation	Certification or Accreditation CAP Certificate CLIA Certificate ISO Certification Other Certification or Accreditation
08.01.02	Laboratory Validation Documentation	Laboratory Validation Documentation Laboratory System Specifications Laboratory Kit Assembly Specifications
08.01.03	Laboratory Results Documentation	Biochemical Testing Imaging Uploads Independent Rater Data Laboratory Results Documentation
08.01.04	Normal Ranges	Normal Ranges
08.01.05	Manual	Imaging Manual Laboratory Manual Manual Other Manual
08.01.06	Supply Import Documentation	Biologic Supply Import Biosafety Statements Customs Statements Proforma Invoices Secure Handling of Material and Data Supply Import Documentation Supply Import Licenses
08.01.07	Head of Facility Curriculum Vitae	Head of Facility Curriculum Vitae
08.01.08	Standardization Methods	Analytical Method Report Interlaboratory Comparison Testing Standardization Methods
08.02.01	Specimen Label	Specimen Label
08.02.02	Shipment Records	Specimen Shipment Records
08.02.03	Sample Storage Condition Log	Sample Storage Condition Log
08.02.04	Sample Import or Export Documentation	Sample Import or Export Documentation Specimen Export Documentation Specimen Import Documentation
08.02.05	Record of Retained Samples	Biorepository Destruction Records Dispatch Form Inventory From Lab Record of Retained Samples

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
08.03.01	Relevant Communications	Relevant Communications
08.03.02	Tracking Information	Tracking Information
08.03.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
08.03.04	Filenote	Filenote
09.01.01	Qualification and Compliance	Evidence of Third Party Qualification Third Party Audit Certificate
09.01.02	Third Party Curriculum Vitae	Third Party Curriculum Vitae
09.01.03	Ongoing Third Party Oversight	Ongoing Third Party Oversight
09.02.01	Confidentiality Agreement	Third Party Confidentiality Agreement
09.02.02	Vendor Selection	Vendor Evaluation Vendor Decision
09.02.03	Contractual Agreement	Authorization To Proceed Budget Contract Change Order Data Privacy Agreements Indemnification
09.03.01	Relevant Communications	Relevant Communications
09.03.02	Tracking Information	Tracking Information
09.03.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
09.03.04	Filenote	Filenote
10.01.01	Data Management Plan	Data Management Plan
10.02.01	CRF Completion Requirements	CRF Completion Requirements
10.02.02	Annotated CRF	Annotated CRF Annotated CRF Electronic Data Capture Annotated CRF Study Data Tabulation Model (SDTM)
10.02.04	Documentation of Corrections to Entered Data	Data Clarification Forms Data Query Forms Documentation of Corrections to Entered Data
10.02.05	Final Subject Data	Final Subject Data Site Receipt of Final Subject Data
10.03.01	Database Requirements	Database Requirements
10.03.02	Edit Check Plan	Edit Check Plan Edit Check specifications
10.03.03	Edit Check Programming	Edit Check Programming
10.03.04	Edit Check Testing	Edit Check Testing
10.03.05	Approval for Database Activation	Approval for Database Activation

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
10.03.06	External Data Transfer Specifications	External Data Transfer Authorization External Data Transfer Specifications External Data Transfer Testing Documentation
10.03.07	Data Entry Guidelines (Paper)	Data Entry Guidelines (Paper)
10.03.08	SAE Reconciliation	SAE Reconciliation SAE Reconciliation Approval SAE Reconciliation Report
10.03.09	Dictionary Coding	Dictionary Coding Medical Coding Approval Medical Coding Consistency Report Medical Coding Guidelines
10.03.10	Data Review Documentation	Data Review Documentation Data Review Plan Data Validation Plan DB Audit Specification Third Party Vendor Reconciliation Report
10.03.11	Database Lock and Unlock Approval	Database Interim Lock Approval Database Lock and Approval Database Lock and Unlock Approval Database Unlock Approval
10.03.12	Database Change Control	Database Change Control Data Model Difference Report Database Modification Approval
10.04.01	System Account Management	EDC User Authorization Documentation EDC User Report Electronic Signature Authorization Form System Account Management
10.04.02	Technical Design Document	Technical Design Document
10.04.03	Validation Documentation	Validation Certificate Validation Executed Scripts Validation Plan Validation Report Other Validation Documents
10.05.01	Relevant Communications	Relevant Communications
10.05.02	Tracking Information	Tracking Information
10.05.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
10.05.04	Filenote	Filenote
11.01.01	Statistical Analysis Plan	Analysis Convention Document Interim Analysis SAP SAP Approval SPP Approval Statistical Analysis Plan (SAP) Statistical Programming Plan (SPP)
11.01.02	Sample Size Calculation	Sample Size Calculation Sample Size Validation
11.02.01	Randomization Plan	Randomization Plan
11.02.02	Randomization Procedure	Randomization Procedure Randomization Specification
11.02.03	Master Randomization List	Master Randomization List

Artifact #	Artifact name	Recommended Sub-artifacts - Documents/documentation recommended to be filed to the artifact.
11.02.04	Randomization Programming	Randomization Programming
11.02.05	Randomization Sign Off	Randomization Sign Off
11.02.06	End of Trial or Interim Unblinding	Administrative Interim Unblinding Request Form End of Trial or Interim Unblinding Results Release Authorization Memorandum
11.03.01	Data Definitions for Analysis Datasets	Data Definitions for Analysis Datasets
11.03.02	Analysis QC Documentation	Analysis QC Documentation Validation Documentation Approval Validation Plan Validation Report
11.03.03	Interim Analysis Raw Datasets	Interim Analysis Raw Datasets
11.03.04	Interim Analysis Programs	Interim Analysis Programs Interim Analysis Datasets Programs Interim Analysis Macros
11.03.05	Interim Analysis Datasets	Interim Analysis Datasets
11.03.06	Interim Analysis Output	Interim Analysis Graphs Interim Analysis Figures Interim Analysis Listings Interim Analysis Statistics Approval Interim Analysis Tables
11.03.07	Final Analysis Raw Datasets	Final Analysis Raw Datasets
11.03.08	Final Analysis Programs	Final Analysis Datasets Programs Final Analysis Macros Final Analysis Programs
11.03.09	Final Analysis Datasets	Final Analysis Datasets
11.03.10	Final Analysis Output	Final Analysis Graphs Final Analysis Figures Final Analysis Listings Final Analysis Statistics Approval Final Analysis Tables
11.03.11	Subject Evaluability Criteria and Subject Classification	Final Protocol Deviation Report Population Definition Criteria Protocol Deviation Listing Subject Evaluability Criteria and Subject Classification
11.04.01	Interim Statistical Report(s)	Interim Statistical Report(s)
11.04.02	Statistical Report	Statistical Report
11.05.01	Relevant Communications	Relevant Communications
11.05.02	Tracking Information	Tracking Information
11.05.03	Meeting Material	Agenda Attendance Sheet Minutes Presentation Materials
11.05.04	Filenote	Filenote