User Requirement Specification

Medical Monitoring- Wide-Angle Insights 2.0

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Signatures

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| User Requirements are in compliance with organizational SOP and applicable 21 CFR Part 11 elements. | | |
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| User Requirements are in compliance with the business processes and applicable 21 CFR Part 11 elements | | |
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Revision History

|  |  |
| --- | --- |
| **Version** | Summary of changes |
|  | NA |

Abbreviations

|  |  |
| --- | --- |
| Abbreviation | Full / expanded form |
| CRO | Contract Research Organization |
| DDC | Direct Data Capture synonymous with eSource DDC |
| eCRF | Electronic Case Report Form |
| EDC | Electronic Data Capture |
| MM | Medical Monitoring |
| WAI | Wide-Angle-Insights |

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## Purpose

The purpose of this document is to specify user requirements for business requirements and regulatory features for Wide-Angle-Insights (WAI) – Medical Monitoring system.

## Scope

The scope of this document is to describe user requirements of Wide-Angle-Insights – Medical Monitoring system when used as an integrated with Electronic Data Capture (EDC)/eSource DDC systems.

While verifying the functionality of Medical Monitoring, applicable functionalities of Design Bench, User Management Tool of Wide-Angle Insights used for the support functionality of Medical Monitoring are also part of scope.

## Reference

* CS0101-Computerised System Validation-v.1
* CS0102-Computerised System Validation Plan and Report-v.1
* CS0103-Developing User Requirement Specification-v.1
* EMA Guideline on computerised systems and electronic data in clinical trials 09 Mar 2023
* 21 CFR Part 11

## URS Team Members

***Same as signatories of the document***

## Computer System Introduction and Overview

### Overview of the System

Usually, clinical trial data that must undergo medical review such as Adverse Event (AE), Medical History (MH), Adverse Event of Special Interest (AESI) etc. are scattered across several modules in the electronic Case Report Form (eCRF). For complete review of such data e.g., AE data, the medical reviewer must navigate from one eCRF module to another to look for related information (which is quite cumbersome and time consuming e.g. while reviewing AE data the reviewer may have to refer to MH, vital signs, physical examination, concomitant medications etc. An alternate way to review the study data is to go through listing outputs (usually in the form of excel listings) of the study data which has its own set of challenges (requires navigation across different types of listings, listings stretching over several columns and rows, review tends to be periodic and not real time) making the review process lengthy and time consuming. The WAI – Medical Monitoring system is built to overcome some of these challenges and helps in a smooth and complete data review process in the following manner:

* The desired data entered in different modules of the eCRF is fetched and organized in the Medical Monitoring system in a manner that enables a comprehensive event adjudication/review by bringing all related information required for adjudication of an event on a single screen (or available as pop-up windows).
* The data entered in the eCRF modules in the WAI system is available for review in the Medical Monitoring system on a real-time basis thus enabling identification of trends and issues in a timely manner.

### Intended Use of the System

|  |
| --- |
| **Integrated System**   * There should exist an interface with the Electronic Data Capture (EDC)/eSource DDC systems from where the required records can be made available for review in the medical monitoring portal. Thus, the WAI Medical Monitoring system only works as an integrated model and is not a standalone system. * The data that flows into the medical monitoring portal from the EDC/eSource DDC in a real time manner. The data flowing into the Medical Monitoring system is read-only data and no alternation of the data is possible in the medical monitoring system (only queries and comments made on a record in Medical Monitoring system may be made available in the EDC/eSource DDC systems) * The queries raised by the by data managers in the EDC)/eSource DDC systems or the system generated queries in the EDC/eSource DDC systems is visible to the medical reviewer. * The system has the provision to organize the associated data required for review of an event in a single screen or available in pop-up windows (e.g., to review adverse event data, the concerned MH data, vital and physical examination data can be organized on the same screen or in a pop-up window) * The reviewers can segregate reviewed and unreviewed records. * The reviewers can view the system based/EDC based queries and can add additional medical queries as desired which can be made available in the EDC system for data manager to take further actions. * The reviewers can view the query responses provided by the site and take appropriate action. * Complete patient summaries can be reviewed in the Medical Monitoring system on a single screen. The Patient profile can be designed to view limited patient data or complete patient data as desired. * The system provides real time metrics of various data such as Total AE, reviewed AE, total SAE etc. * The system provides review status such as total reviewed records, unreviewed records, total records with queries, status of queries etc. * The reviewer can view and download listings, listings with queries and query reports. |

### Business Process

* The overall business objective of the WAI medical monitoring system is to ensure a complete and meaningful review of the accumulating study data from a medical perspective to ensure appropriateness and correctness of the data that is entered.
* Review the data in order to identify trends and safety concerns in a timely manner.

### System Features

The Medical Monitoring system is a Real Time Integrated Medical Review platform that helps medical monitors to review safety and efficacy data in a clinical trial in a meaningful, organized, and comprehensive manner by bringing all the related information required for medical adjudication of a possible signal at one single place.

**Figure 1 Medical Monitoring System**

A diagram of a medical overview

Description automatically generated

* Event Adjudication: Complete, comprehensive, real-time review of safety and efficacy data
* Early identification of Trends
* Focused review of critical study data. Highlight Critical Information for quick identification e.g., related/fatal/AESI, efficacy endpoint achievers.
* Availability of Patient profiles for comprehensive review
* Query management within the system
* Real time, Customizable Dashboard that displays desired metrics e.g., AEs/SAEs, related or events, fatal events.

### Users Roles

### User Requirements Specification

| **Role** | **Functions** |
| --- | --- |
| Safety Reviewer (Sponsor/CRO Medical team) | Generate queries; override queries; edit queries; delete queries; add comments; close query |
| Medical Reviewer (Sponsor/CRO Medical team) | Generate queries; override queries; edit queries; delete queries; add comments; close query; Publish/push the queries to the eCRF |
| Medical Coder | Code the adverse events (including adverse events of special interest and SAEs) and medical history using MedDRA dictionary; Code medications using the WHO DD Dictionary |
| Medical Code Approver | Code the adverse events (including adverse events of special interest and SAEs) and medical history using MedDRA dictionary; Code medications using the WHO DD Dictionary; Approve or Disapprove the coded records |

#### *User Requirement Specification (URS) from Business Owner*

**DESIGN BENCH**

The listings and reports are designed/published in Design bench. Design Bench Features that would be used for Medical Monitoring system are listed below.

| **URS ID** | **User Requirement Specification** | **Reference**  **(if Applicable)** |
| --- | --- | --- |
| **DB\_UR\_01** | **User Roles and access** |  |
| DB\_UR\_01.01 | System shall have user groups as Designer, Reviewer and Approver with their respective rights & Privileges defined.  *To be deleted: Anish confirmed during demo that the designer, reviewer and approver concept is not applicable for MM portal.* |  |
| DB\_UR\_01.02 | System shall allow to assign user groups to individual users (who can perform activities as defined for respective user group)  *To be deleted: Anish confirmed during demo that the designer, reviewer and approver concept is not applicable for MM portal* |  |
| DB\_UR\_01.03 | System shall allow to nominate users including cross functional users for review and approve forms designed.  *To be deleted: Anish confirmed during demo that this UR is not applicable for MM portal* |  |
| DB\_UR\_01.05 | System shall be able to define rights and roles for users to perform data entry, query generation, query closure, SDV, access to reports and listings, perform medical review, download/generate reports, publish regulatory reports, closure of SAEs, etc. |  |
| DB\_UR\_01.06 | System shall allow site-wise access to reports and listings  *To be deleted: This UR is not applicable for MM system* |  |
| **DB\_UR\_02** | **Configuration Process Flow** |  |
| DB\_UR\_02.02 | System shall allow review by the user other than the designer of respective form to review the form with fields as required by the protocol. This review shall be recorded in the system. |  |
| System shall allow other system owners to view the forms designed by CDM team in read only format during review  *To be deleted: This UR is not applicable for MM system* |  |
| DB\_UR\_02.03 | System shall allow user other than the designer of respective system to approve the form with fields.  *To be deleted: Anish confirmed during demo that the designer, reviewer and approver concept is not applicable for MM portal.* |  |
| DB\_UR\_02.04 | System shall freeze/lock the approved form in Design bench (i.e., no changes will be allowed to be made on an approved form) |  |
| System shall allow authorized user to unfreeze/unlock the approved form for edits. |  |
| System shall maintain the audit trail / event log for activities executed and changes made to the form  *To be deleted: Form designing is not applicable for MM portal* |  |
| **DB\_UR\_10** | **Manage Listing** |  |
| DB\_UR\_10.01 | The system must have provision to create data listings (module wise or cross-modules) and publish them to the different systems as required.  Use Case.  Demography as single module listing  AE-CM for cross module listing |  |
| DB\_UR\_10.02 | The listing shall have following attributes:   1. Subject/Participant Review: The system shall allow user to review data subject wise by displaying in listing format in a single window.   Use case:  User shall be able to select one subject and the data shall be displayed from different listings E.g. Demography, Informed Consent, Dosing, AE, MH, CM for the subject i.e., an entire subject/ profile should be available. |  |
| DB\_UR\_10.03 | System shall display:   1. Site wise Review status summary of the listings (Performance Metrics). 2. Desired metrics on dashboard in the form of figures or graphs based on the requirement.   Use case:  System shall display total and site wise records of No. of total events, No. of open (to be reviewed) events, No. of reviewed events, No. of open and closed queries.  Use case:  System shall display desired data captured in a listing site wise in graph format. E.g. Display totals number of AEs, Solicited AEs, Unsolicited AEs, AESIs, Serious AEs, Related AEs, Fatal AEs, Severe AEs, Serious Adverse Events, etc. |  |
| DB\_UR\_10.04 | The system shall allow the user to export the listing with desired fields with the queries generated by medical monitoring group |  |
| DB\_UR\_10.05 | System shall allow desired data to be reviewed subject-wise across visits for trends.  Use Case:  E.g. Weight, Blood Pressure, Pulse, Blood Sugar level of a subject/participant across all visits |  |
| DB\_UR\_10.06 | The system shall allow users to create views. This view would then enable users to flag any discrepancies in the listing data.  Use Case  System shall allow user to review data Critical Data/Important Data to be reviewed for study objectives.  System shall allow to create focused listings such as related AE/fatal AE/AEs of Grade 3 and Grade 4 severity, etc. |  |
| DB\_UR\_10.07 | System shall allow user to choose the desired fields for listing in desired sequence.  System shall allow user to add derived fields in the listing.  Use case:   * Age: based on date of birth and date of visit   No. of days between AE start date and AE end date. |  |
| DB\_UR\_10.08 | Users shall be able to set Filters in the listing.  Use Case  The user shall be able to filter based on desired parameter e.g. Hemoglobin or Neutrophil count or any other parameter from Lab listings. Similarly, filter similar type of events from AE listing e.g., all events of Gastroenteritis or Pneumonia |  |
| DB\_UR\_10.09 | Users shall be able to match fields between multiple listings.  Use Case   * For AE-CM listing: Event Code from AE module must be matching with Event Code in CM module.   For AE without CM listing: Where Event Code of AE is not available in Event Code of CM. |  |
| DB\_UR\_10.10 | System shall allow user to review relevant data from more than one listing for efficient review.   * By clicking/selecting on Adverse Event (AE Listing) system shall allow user to review Concomitant Medications (CM Listing) given for selected Adverse Event for a given subject. (Linking two Listings)   In addition to this, the system shall show multiple desired listings on the same.  By clicking/selecting on AESI/Adverse Event (AE Listing) system shall allow user to review Concomitant Medications (CM Listing), Medical History (MH Listing), Prior Medications (CM Listing), Dosing Details given for selected Adverse Event for a given subject. (Display of five listing |  |
| DB\_UR\_10.11 | System shall be able to highlight critical field in a record based on value.  Use Case  E.g., Highlight related event or fatal event in a AE record |  |
| **DB\_UR\_14** | **Exports** |  |
| DB\_UR\_14.01 | System shall have provision to export the Audit Trail Report and Event Logs |  |
| DB\_UR\_14.02 | System shall have provision to provide configuration specifications in an excel format. |  |
| DB\_UR\_14.03 | System shall have the provision to decommission the study database and provide the deployment package for archival |  |

**WAI –** **MEDICAL MONITORING SYSTEM**

Review of study data is performed in the WAI – Medical Monitoring System. The user requirements for WAI – Medical Monitoring system are listed below.

| **URS ID** | | **User Requirement Specification** | **Reference**  **(if Applicable)** |
| --- | --- | --- | --- |
| **MM\_UR\_01** | | **Availability of Data for Review** |  |
| MM\_UR\_01.01 | | System shall have a provision to fetch data from eCRF in the Medical Monitoring Platform under appropriate listings/ patient profiles for review |  |
| MM\_UR\_01.02 | | System shall have a provision to fetch data from eCRF in the Medical Monitoring Platform in a real time manner |  |
| **MM\_UR\_02** | | **Identifying Reviewed Data** |  |
| MM\_UR\_02.01 | | System shall have a provision to mark a record as 'reviewed' after completion of review for any reviewer. |  |
| MM\_UR\_02.02 | | System shall allow every user to differentiate between the records that have been reviewed by the user role and those that are unreviewed.  Use Case  The record reviewed by safety reviewer must appear as reviewed by safety associate to the medical reviewer and vice versa. |  |
| MM\_UR\_02.03 | | System shall indicate to the user if a record is reviewed in another listing.  Use Case:  If a reviewer has checked review for an Adverse event in 'Ongoing AEs' listing, then it should appear as reviewed in all AE listing such as Related AE and overall AE listing. |  |
| MM\_UR\_02.04 | | System should allow to identify any updates made by site to the records which were marked as reviewed by medical and safety reviewer |  |
| **MM\_UR\_03** | | **Data Review and Query Process** |  |
| MM\_UR\_03.01 | | System shall allow the reviewers to filter the records/listings (multiple filters)  Use Case  To be filtered based on Patient ID, event name, Lab test name |  |
| MM\_UR\_03.02 | | System shall have provision to sort records (multiple sort) |  |
| MM\_UR\_03.03 | | System shall have the provision to review data in an organized manner and easily retrievable manner for adjudication/review of an event |  |
| MM\_UR\_03.04 | | System should allow focused medical review of listings based on predefined criteria such as related AEs or Ongoing AEs etc. |  |
| MM\_UR\_03.05 | | System shall allow every user to raise queries for any record in listings/patient profiles |  |
| MM\_UR\_03.06 | | System shall allow every user to add comments for any record in listings/ patient profiles |  |
| MM\_UR\_03.07 | | System shall have a provision for every reviewer to view the queries/comments raised by another reviewer on any record |  |
| MM\_UR\_03.08 | | System shall allow the reviewers to view queries, query status and responses already present in eCRF. |  |
| MM\_UR\_03.09 | | System shall allow the reviewers to edit, delete queries |  |
| MM\_UR\_03.10 | | System should have a provision to allow viewing of patient Profiles by fetching data from the desired eCRF modules in the Medical Portal in a single window |  |
| MM\_UR\_03.11 | | System shall allow queries/comments to be added for a record in patient profile |  |
| **MM\_UR\_04** | | **Event Log** |  |
| MM\_UR\_04.01 | | System shall allow to view a history of review performed, comments and queries raised for every record (reviewed in listings and patient profiles) |  |
| **MM\_UR\_05** | | **Reports** |  |
| MM\_UR\_05.01 | | The system shall have provision to generate and download query report with elements including Query ID, site ID, subject ID, Module name, Visit ID, Date when query was raised, Query raised by, Query text, Date when query was pushed to DM, Query Pushed by, Query resolution, Edited Query, Query Edited by and Date of Edit, Deleted Query. Date Query Deleted, Query Deleted By, Reason for Deletion and query status" |  |
| MM\_UR\_05.02 | | System shall have a provision to download listings and listings with queries as an excel listing |  |
| MM\_UR\_05.03 | | The system shall have provision to generate comment report including the name of the person who raised comment and date when comment was raised |  |
| **MM\_UR\_06** | | **Protocol Deviations** |  |
| MM\_UR\_06.01 | | System shall have provision to categorize and classify Protocol Deviations entered via primary source and system should maintain an audit trail of updates |  |
| **MM\_UR\_07** | **Others** | |  |
| MM\_UR\_07.01 | System shall have provision to have a dashboard which reflects desired metrics in a real time manner.  Use Case  Totals of AE, Solicited AE, Unsolicited AE, AESI, Related AE, Fatal AE, Severe AE, Serious Adverse Events | |  |
| MM\_UR\_07.02 | System shall have a status (total and site wise) report to indicate reviewed and unreviewed status, answered query and unanswered status | |  |

#### User Requirement Specification with respect to Regulatory Requirement

Regulatory requirements can be tested / demonstrated while testing the business process URS and / or as part of functionality testing.

| ***URS ID*** | ***User Requirement Specification*** | ***Reference to Applicable Regulations or Guidelines*** |
| --- | --- | --- |
| **REG\_UR\_01** | **ALCOA++** | *EMA Guideline on computerised systems and electronic data in clinical trials 09 Mar 2023.(6.2.1)*  *EMA Reflection paper on eSource and data capture in CT 09 June 2010 - 6.2* |
| **Data Accuracy during transfer**  System should allow data to transfer from one system to other either automatically or upon confirmation from data owner of primary / source system.  System should notify user "Transfer Successful" OR "Transfer Failure" as the case may be.  System shall retain the data, its attributes (format, units etc.) and the audit trail while transfer |
| **Attributable during Data transfer**  If this data is transferred / integrated to other system, audit trail should show data element identifier of original source |
| **Legibility**  Data entered should be in human readable form  1] in the fields and forms as the data is entered  2] During view  3] In audit trail  4] Upon download  5] Upon print  6] When processed  7] changes to data, such as compression, encryption and coding should be completely reversible |
| **Contemporaneous**  System shall have audit trail that captures information if data is captured by a person or the system with date and time stamp.  Use Case  System generated Date of Report |
| **Original**  Data should be the original first generation/capture of the observation. Certified copies can replace original data. Information that is originally captured in a dynamic state should remain available in that state. |
| **Attributable**  Data should be attributable to the person and/or system generating the data. Based on the criticality of the data, it should also be traceable to the system/device, in which the data were generated/captured.  Audit trail with date and time (Local time of user . server time) for data (Add, modify, delete)  System should generate reports for the following in addition to audit trail  1] Date and Time of log-in, Log-out  3] Inactivity time and locked out  4] Number of times log-in attempts with outcomes Successful / unsuccessful  5] Last log-in  6] Dormant accounts list (User issued log-in details but never logged-in, Last log-in since X days as per company policy) |
| **Complete**  System shall have audit trail of the data and tracking tools (e.g. event Log) to reconstruct and fully understand an event, data should be a complete representation of the observation made. This includes the associated metadata and audit trail and may require preserving the original context. |
| **Consistency**  System shall have provision to assist user during data capture by the use of features such as drop-down lists, online help text, check boxes and branching of questions or data entry fields based on entries. |
| **REG\_UR\_02** | **Audit trail** |
| Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying. |
| **Capture of Audit Trail**  1] System shall maintain secure, computer generated, time stamped audit trail. Dates and times include the year, month, day, hour, and minute format.  Note: Implement time stamps with a clear understanding of the time zone reference used. System documentation explain time zone references as well as zone acronyms or other naming conventions.  2] System shall have provision to capture date and time of user actions linked to external standard (e.g. UTC) |
| Original electronic entries are visible or accessible (e.g. in the audit trail) to ensure the changes are traceable. |
| Audit trails should be visible at data-point level in the live system for review and as a cumulative log / report. |
| **Extract of Audit Trail**  1] System shall have provision to export the entire audit trail as a dynamic data file to allow for the identification of systematic patterns or concerns in data across trial participants, sites, etc. |
| **Audit Trail Storage**  The audit trail should be stored within the system itself |
| Audit trail documentation should be retained as long as the subject electronic records. Audit trails need to be readable. |
| **REG\_UR\_03** | **Copying, Print and Download** |  |
| The system should allow accurate and complete copies of records in both human readable format. The records should contain metadata as well as audit trails. | 21 CFR Part 11.10.b |
| System shall have provision to  Allow user to specify listings/ reports to print / download as required | *EMA Reflection paper on eSource and data capturein CT 09 June 2010 - 6.2* |
| System shall have provision to mention name, date and time of print & download in footer of the record printed / downloaded. |

#### Other Requirements

**User Management Tool (UMT)**

|  |  |  |
| --- | --- | --- |
| **URS ID** | **URS Description** | **Reference**  **(If applicable)** |
| UMT\_UR\_06.01 | The system shall have provision to assign a study id, sponsor and therapeutic area on deployment by Super User via a link | - |
| UMT\_UR\_06.02 | System should be able to create deployment package for UAT and same package should be pushed to LIVE | - |
| UMT\_UR\_06.03 | System should be able to create 3 different instances for UAT/TRN/LIVE | - |

#### Appendix A: Glossary

***Definitions***

|  |  |
| --- | --- |
| TERM | Definition |
| Primary Source | The term is used to describe the first place in the WAI system where data is captured. The primary source may mean the EDC/eSource |
| Sponsor/CRO Medical | This includes the medical team members at the sponsor/CRO teams. This may include the Medical reviewers or safety reviewers. The functions that may be performed by the Sponsor/CRO medical reviewer and safety reviewers is defined in User Roles above in the document.  *Note: Sponsor/CRO medical & safety team are also referred to as Sponsor/CRO team or medal/safety reviewer, sponsor medical/safety reviewer etc*. |

#### Appendix B: List of Attachment/s

None