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## Document Information

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**CTMS 2013.1.1**  
**Validation Plan**

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**Revision History**

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## **1 Introduction**

CTMS 2013.1.1 delivers the following functions and features to address some pertinent issues in the application.

### **1.1 System Overview**

Centralized trial management tools can help study managers effectively deploy critical resources, proactively address performance issues and streamline operational workflow representing huge opportunities for budget savings and timeline reductions.

Medidata CTMS provides tools that can make a significant difference in operations today, with a broad and flexible platform to support the business challenges of tomorrow.

Medidata CTMS enables the user to view, update and add information quickly and easily. Medidata CTMS offers cost effective modules to streamline key processes with proven ROI. The solution is web based, enabling you to access the system from anywhere at any time. Simply log onto your system from a web browser in any physical location and you will have access to the same information as you would from your computer in your office.

New Functionalities and Enhancements in this release include:

- Incremental XML Exports
- Study activities display according to due date
- Increase Character Limit for Description on Study Management Page
  
- DB Sync Manual Testing Data Extraction
- Change cross reference back to Questionnaire.
- Allow Configuring Recurring Events As Event Costs
- RMI: Study Specific Attribute: Import Enabled
- Make Site Data Pulls Incremental
- RMI: Subject Screening No should be consistent between Rave & CTMS.
- Make Template Data Pulls Incremental
- Handle large number value for lastTransactionId
- Adjust Subject Visit Due Dates for all Studies When Reference Date Gets Imported from Rave.
  
- Data Mapping Engine for handling foreign keys
- RMI: Property that Toggles RMI Pulls ON/OFF
- CRF Base Template should have the "no generate" flag.
- CRF Base Template should have the "no auto generate" flag.
- CRF Forms should not be generated for Study Assigned Templates if the "no generate" flag is set.
- CRF Forms should not be generated for Study Assigned Templates if the "no auto generate" flag is set.

- CRF Forms should not be generated for Rave Integrated Studies.
- RMI: Rave Subject having new Status should now appear in CTMS
- Sunshine Act Payments Fields: Add Fields to Database Schema
- RMI: For JnJ - Map CTMS Subject Status codes with Rave Subject Status Category.
- Support Import read-only at service Alias level to trump data Object level (Note: There are 5 User stories for this Epic).

Issues Fixes include:

Refer to Section 5.6.2, Issues to be verified below.

## 2 References

### 2.1 Regulatory References

Medidata assures CTMS 2013.1.1 is developed so that it is compliant with regulations/guidelines or sections of those regulations/guidelines that are applicable. In addition, the CTMS 2013.1.1 is designed so that it will support a Sponsor's compliance with regulations/guidelines that they are required to follow.

### 2.2 Documentation References

The following documents are related to this document.

Code	Document Name	Version
POL-RD-001	Software Development Life Cycle Policy	06
SOP-SDLC-013-04	Develop and Release Software Product	04
SOP-RD-004	Develop and Maintain Customer Integration Applications	N/A
WI-RD-008-02	Software Issue Tracking	02
RS	CTMS Application Overview	N/A
DS	CTMS Design Overview	N/A
FORM-SDLC-004-02	Release Completion Form	02

### **3 Validation Overview**

#### **3.1 Validation Objective**

The purpose of this validation is to provide documented evidence that CTMS 2013.1.1 has been developed to the documented requirements and that it operates consistently and in accordance with those requirements.

#### **3.2 Validation Overview**

The Validation of CTMS 2013.1.1 includes the following activities:

- Risk Assessment (documented in section 3.8 “Risk Assessment” within this document)
- Development or update of the IQ Tests and Documents (as needed)
- Development or update of the OQ Tests (as needed)
- Execution of the IQ Tests (as needed)
- Execution of the OQ Tests (as needed)
- Development and finalization of the automated and/or manual Trace of Requirements to OQ tests (as applicable)
- Documentation of Test Exceptions, if any
- Development and finalization of Release Completion Form
- Development and finalization of the Validation Summary
- Development and finalization of the Release Notes
- Generation of Validation Package Portal
- Issuance of the Validation Certificate

#### **3.3 Acceptance Criteria**

The validation of CTMS 2013.1.1 will be considered completed when Tests have been executed; all exceptions have been addressed including a suitable resolution and/or disposition; all executed tests, and all other SDLC documentation deliverables have been reviewed and approved by appropriate personnel. Successful execution means that actual results were equivalent to expected results on executed tests. Successful execution may also mean the system is released with some outstanding Issues, with such Issues clearly identified as such, with documented workarounds and cautionary notes as/if appropriate.

#### **3.4 Responsibilities & Deliverables**

Refer to Appendix -3 in Develop and Release Software Product SOP (*Refer to SOP-SDLC-013*).



### 3.5 Issue Handling

Issue Handling is covered in the Develop and Release Software Product SOP (*Refer to SOP-SDLC-013*) and Software Issue Tracking WI (*Refer to WI-RD-008*).

### 3.6 Documentation Change Control

Once a document is approved and released, it is versioned up to the next version number using whole numbers. For example, if a document was Version 1.0 and was approved, if changes are needed after approval, the new document version will be Version 2.0 and revision history captures who made the changes and what changes were made to the document.

### 3.7 Training

All personnel involved in this validation will be trained on all applicable validation process. Training will be recorded in all personnel's individual eDMS training folder.

### 3.8 Risk Assessment

The extent and scope of the testing of CTMS 2013.1.1 are based on the risk associated with the changes introduced in this version of the software. The following functional areas were identified as requiring testing (and/or regression) for this validation:

Functionality	Risk	Reason	Testing approach
Incremental XML Exports	Medium	The risk is medium because  the functionality is  Localized and involves minimal code changes.	Verify the expected behavior according to the pre-defined user acceptance behavior. Execute the Feature files where applicable.
Study activities display according to due date	Medium	Code changes with expected impact on the study activities due date.	Verify the expected behavior according to the pre-defined user acceptance behavior. Execute the Feature files where applicable.
Increase Character Limit for Description on Study Management Page	Medium	Code changes with expected impact on the study activities due date.	Verify the expected behavior accordingly. Execute the Feature files where applicable.
DB Sync Manual Testing Data Extraction	Medium	Code changes with expected impact on the DB Synch.	Verify the expected behavior accordingly. Execute the Feature files where applicable.

Functionality	Risk	Reason	Testing approach
Change cross reference back to Questionnaire.	Medium	The risk is medium because  the functionality is  Localized and involves minimal code changes.	Verify the expected behavior accordingly. Execute the Feature files where applicable.
Allow Configuring Recurring Events As Event Costs	Medium	The risk is medium because the changes are localized to an existing functionality.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
RMI: Study Specific Attribute: Import Enabled	Medium	The functionality is  Localized and involves minimal code changes around the transaction IDs of RMI studies.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
Make Site Data Pulls Incremental	Medium	The risk is medium because the changes are localized to an existing functionality.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
RMI: Subject Screening No should be consistent between Rave & CTMS.	Medium	The risk is medium because  the functionality is  Localized and involves minimal code changes around the screening number of RMI studies.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
Make Template Data Pulls Incremental	Medium	Introduction of a new functionality and Impact restricted to the major areas of RMI.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
Handle large number value for lastTransactionId	Medium	The functionality is  Localized and involves minimal code changes around the transaction IDs	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable

		of RMI studies.	
Functionality	Risk	Reason	Testing approach
Adjust Subject Visit Due Dates for all Studies When Reference Date Gets Imported from Rave.	Medium	The functionality is  Localized and involves minimal code changes around the Subject visit due dates of RMI studies.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
Data Mapping Engine for handling foreign keys	Medium	Introduction of a new data mapping functionality.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
RMI: Property that Toggles RMI Pulls ON/OFF	Medium	Introduction of a new functionality and Impact restricted to the major areas of RMI.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
CRF Base Template should have the "no generate" flag.	Medium	Introduction of a new functionality and Impact restricted to the CRF templates generation.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
CRF Base Template should have the "no auto generate" flag.	Medium	Introduction of a new functionality and Impact restricted to the CRF templates generation.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
CRF Forms should not be generated for Study Assigned Templates if the "no generate" flag is set.	Medium	Introduction of a new functionality and Impact restricted to the CRF templates generation.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
CRF Forms should not be generated for Study Assigned Templates if the "no auto generate" flag is set.	Medium	Introduction of a new functionality and Impact restricted to the CRF templates generation.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
CRF Forms should not be generated for Rave Integrated Studies.	Medium	Introduction of a new functionality and Impact restricted to the CRF templates generation.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable

RMI: Rave Subject having new Status should now appear in CTMS	Medium	Introduction of a new functionality and Impact restricted to the Subject statuses that are imported.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
Sunshine Act Payments Fields: Add Fields to Database Schema	Medium	Introduction of a new functionality and Impact restricted to the Subject statuses that are imported.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
RMI: For JnJ - Map CTMS Subject Status codes with Rave Subject Status Category.	Medium	Introduction of a new functionality and Impact restricted to the Subject statuses that are imported.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable
Support Import read-only at service Alias level to trump data Object level (Note: There are 5 User stories for this Epic).	Medium	Introduction of a new functionality and Impact restricted to the Subject statuses that are imported.	Verify the expected behavior according to agreed acceptance criteria. Execute the Feature files where applicable

## **4 Validation Testing Approach**

The process for validation testing is described in the SOP: Develop and Release Software Product (*Refer to SOP-SDLC-013*).

Requirements introduced in Medidata CTMS 2013.1.1 and above have been defined as user stories. Each user story has one or more feature files associated with it. The Cucumber testing tool has been used to automate the feature file scenarios. Cucumber reads the scenarios from the feature files and executes the step definitions with matching regular expressions. Cucumber compares actual results to expected results, and the scenarios pass automatically when actual results equal the expected results. SQA personnel will review the results of all scripts to confirm they pass and compile a list of all the scripts and their Source Control Numbers where applicable, as part of the Release Completion Form.

The validation effort will test that Medidata CTMS functions as expected both for existing and new Medidata CTMS clients; these two scenarios will be referred to as 'upgrade path' and 'clean path', respectively.

The 'Upgrade Path' site will be used for testing the upgrade path.

The 'Clean Path' site will be used for testing the clean path.

### **4.1 IQ Plan**

Medidata CTMS software will be configured and installed in the AWS servers.

The application core components will be upgraded to the validation build.

Medidata CTMS will be deployed to two sites. One site will have a clean installation (clean path) and the second one will have an upgrade installation (upgrade path).

CTMS 2013.1.1 will be deployed according to SOP: Change Management [SOP-IT-002]. IQ testing will confirm that the system is properly installed and configured in the Medidata environment. The CTMS 2013.1.1 Production Installation Requirement documents will be created for deployment of CTMS 2013.1.1.

Details of the above installation documents will be captured in the Validation Summary document. All installation documents and results for CTMS 2013.1.1 will be available in the Validation Package Portal for CTMS 2013.1.1. Approvals on the Installation documents/test results (as applicable) are captured via approval of the Validation Summary document by IT Management

The installation of iMedidata and Jasper are out of the scope of this Installation Process.

### **4.2 OQ Plan**

OQ tests will be run on the Operational Qualification Environment (OQE). End-To-End tests will be run on the Cloud Validation Environment (CVE). These tests will confirm that the

system functions in accordance with the functional and user specifications. All tests and test results for

CTMS will be available in the CTMS 2013.1.1 Validation Package Portal by functional area and by feature. Test development and execution will follow WI: Operation Performance Qualification Testing (*Refer to WI-SDLC-003*). List of tests executed, execution status, and any other pertinent information will be captured appropriately in CTMS 2013.1.1 Release Completion Form which will be an attachment to the CTMS 2013.1.1 Validation Summary document. All executed Tests (as applicable) will be reviewed by an SQA Personnel- reviewer name/review date will be captured in the CTMS 2013.1.1 Release Completion Form. Approvals of the OQ tests/results (as applicable) will be captured via approval of the Validation Summary document by SQA Management.

#### 4.2.1 Electronic Records/Electronic Signatures (ERES)

Tests which will be used to verify CTMS 2013.1.1 conformance to applicable ERES regulations will be captured in the Release Completion Form as applicable.

#### 4.2.2 Issues to be verified

The following Issues will be resolved and verified in CTMS 2013.1.1 Validation. Each Issue will include test results as well as a screenshot of the fix, if applicable and necessary. Status of the Issues, test results and other pertinent information will be captured appropriately in Jira and Release Completion Form.

Issues	Short Description
MCC-51340	Datasets are displayed with default name in imported xml
MCC-68854	SFTP imports can't be processed.
MCC-67260	Inactive export parameters are not working
MCC-71240	ERROR: PKV-022: DS=STDY-PROD Record=1 Configuration error - please contact the system administrator. Missing language identifier for message lookup using string identifier: MISSING_REQUIRED_FIELD
MCC-47981	RMI: Rave Keeps Separate GUIDs for Same Subjects in Certain Status Changes
MCC-54838	Metrics Stored Procedure performance improvement
MCC-69240	Reviewer Comments appearing in Action items UI
MCC-57072	Audit Data for eSignature is Not Captured
Issues	Short Description

MCC-69737	OLC Sync throws a duplicate key error when previous sync fail
MCC-55995	Checkboxes in subject_crf_page service to update multiple pages fail in IE8 and IE9
MCC-70792	RMI: Site and Subject data is not pulled if the Site is Inactive.
MCC-70332	INC Research can't save Site Status (IE8)
MCC-47991	RMI: Special Characters in Rave Form Names Blocking Data Flow
MCC-49829	RMI: Purdue UAT RMI Integration Log recording Null Time Stamp
MCC-52872	Cascaded dropdowns do not clear default value when selected
MCC-54169	User Modes - Values don't persist - User Modes (e.g. when option is ticked - value does not persist is lost (2013.1.0))
MCC-59054	Organization and Contact Docs cannot be added
MCC-51888	Mass Add of Documents in a template throwing MISSING_REQUIRED_FIELD error but the field isn't named / nor on the view
MCC-56032	Visit Report CC Email notification SQL Failure. vrPMAApproved Trigger fails to send email if a CC list is defined
MCC-60029	Subject & Site Document Tracking Errors
MCC-57890	Payee Contracts do not generate Payment Costs
MCC-57177	Site documents are not deleted when Site assigned Document templates are deleted.
MCC-57447	RMI Performance Improvement: Metrics Pull
MCC-57940	last transaction id issue in ImpMetrics attribute
MCC-49795	User Modes - UI (Save and Close does not close the Window)
MCC-50326	E-Signature Popup displays at coords 0,0 incorrectly
<b>Issues</b>	<b>Short Description</b>
MCC-48150	CTMS report KPI0100 is failing when the Site's Recruitment Date is set

	to 28 Feb 2013 : Reported by SGS
MCC-45464	New FDA 1572 Report address issue
MCC-47320	CTMS RMI integration can enter an infinite loop if Rave pull fails.
MCC-44224	Site Deviation sub report uses incorrect/misleading term
MCC-52892	Time Out doesn't redirect to the desired page when occurred while changing the page size dropdown
MCC-47087	Able to change the status of the report even if the questions are unanswered
MCC-47243	Pagination not working on some pages
MCC-28689	Costs are generated even when the Payee or Invoicee is inactivated.
MCC-28685	Costs are generated for inactive subjects
MCC-46179	IE-Bar graphs moving upwards away from the box after refreshing the browser
MCC-52794	OLC- The questionnaire numbering in OLC and online application are different if a Visit report is started in OLC
MCC-53479	Page size is cached in some pages
MCC-46250	Pagination Issue: Page URL properties for pagination are carried to other pages

### 4.3 PQ Plan

Based on the impact assessment of the functionalities or enhancements and defect fixes in scope for the release, the performance of CTMS has not been affected, therefore the Performance Qualification testing will be out of scope for the CTMS 2013.1.1 release.



## 5 Validation Environment

### 5.1 Configuration – Host System Requirements

#### 5.1.1 Baseline for IQ/OQ – Val 2 and 5.

The baseline configuration to be used for this validation of CTMS 2013.1.1 will consist of the following components:

Component Name	Description
<b>Host System Requirements Hardware</b>	
Server(s)	Amazon Web Services (AWS)
Workstations and Laptops	iMac, Mac book Pro, Dell Latitude D620, D630, E6420 10 GB Hard Drive (Minimum)
Host OS	Windows- Microsoft Windows 7, Mac OS X v10.5.5
Reporting Software	CTMS, iMedidata
Host Browser Requirements	Microsoft Internet Explorer 7.0, 8.0, 9.0, Safari Firefox 12.0, Firefox 18.0, Chrome v23 and Chrome v 24.
Database Software	MySQL 5.x
Application Framework	Ruby on Rails

## 6 Definitions

Term	Definition
Exploratory Tests	Testing in high risk or high impact areas to challenge the system. Testing is goal-oriented and time-boxed.
Deviation	A departure from one or more steps in an approved document or practice.
End-to-end Tests	Tests conducted on system modules that are integrated, to ensure the interaction across those modules is operating as expected.
Exception	An approved, planned departure from a Quality System Policy, Standard Operating Procedure, or Work Instruction.
Functional Tests	Tests that focus on overall system performance and functionality, stress and boundary testing, and overall data integrity.
Operation Qualification (OQ) Tests	Tests of the functionality of the system. Include manual OQ Test Scripts, OQ Test Scenarios, and System Wide Tests (End to End Tests).
Installation Qualification (IQ) Test	A document which details installation steps for an application or component, as well as test steps that verify that the application was installed correctly.
Integration Tests	Tests that focus on overall data storage and retrieval capabilities, program module interactions, interfaces and interaction with other applications and external data sources, data transfer, security, and cross module functionality.
Issue	A problem which impairs or prevents the software product from functioning or operating as expected and/or as per intended requirements.
Issue Tracking System	A software product used by Medidata to record, manage, and track software issues.
Performance Qualification (PQ) Tests	Tests that focus on the systems limitations in regards to simultaneous users, maximum data quantities, or other performance limitations.
Regression Tests	Tests that confirm the functionality that exists in the previous version of the software is not affected as a result of a new version of the software.
Release Completion Form	A form which is issued upon completion of validation activities. Similar to the Release Candidate Form, it contains all the tests which were actually included in the validation, as well as the documentation deliverables actually included in the Release.
SOP	Standard Operating Procedure.
SDLC	Software Development Life Cycle.
Unit Tests	Tests that focus on the functionality of one program module.

Term	Definition
Validation	The process of evaluating a system or component to determine whether it satisfies specified requirements.