**753 – EDC RAVE**

**2019.2.2**

**PDA SME HANDBOOK V2.0**

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# Introduction

## Purpose

The purpose of this document is to provide information and functionalities in Rave. This handbook provides the necessary definitions, guidance, and process and shall be used as a single point of reference for the support provided to rave application for Abbott Vascular.

## Responsibilities

| Function | Responsibility |
| --- | --- |
| 1. Rave Application Access Requests - Non Production 2. Rave Report Access 3. Rave – DB and FTP Access requests 4. Rave - CTMS Integration setup 5. Rave - RECON Integration setup 6. Rave Custom Report Implementation 7. Rave Code PUSH/Move (PROD and DEV) 8. Rave IxRS/Lab data integration Testing 9. Rave System Core Configuration 10. Rave - Clinical Systems integration issues (ClinDART, ClinDEV, RECON, CTMS, CDRT) 11. Rave other issues (User Admin, Site Admin, Report Admin, Core Config etc) 12. Rave System downtime | **Clinical IT (Support Team)** |
| 1. Rave Architect Issues including Amendment Manager 2. Rave EDC Issues including Clinical Views 3. Rave Report Issues including Boxi, JReview, SOS 4. Rave TSDV Issues 5. Rave - PER Requests 6. Rave CRF instruction implementation 7. Rave Publish Checks | **Clinical Programming Group (Abbott Vascular)** |

# Functions - Clinical IT:

## *Rave Application Access Requests*

Refer to **Rave User Management.doc** present in below location

/SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/11 Production Support/Rave IT Process Documents.

## *Rave Report Access*

* Rave Reports access can be requested by the users who have access rights to the Reporter Module in Rave
* User Group higher than EDC and DDE will have access to Reporter module in Rave. E.g. EDC and Reporter, Study Designer, Super User, Administrator.
* Access can be requested by email or ITSM ticket. Ensure to create ticket if by email.
* Check if the user requiring access has permissions to Reporter module
* If the access is per development reports such as BOXI, J-Review, Script Utility etc. ensure the requester has proper training for it and request for records.
* Provide access as below.
  + 1. Navigate to Report Administration module in Rave
    2. Click on Report Assignment
    3. Select the Report Name that you want to provide access to.
    4. Type the Login id in the ‘Assign To Users’ box
    5. Click on pencil mark first and then click the Search box
    6. Select the checkbox for the user and click on the ‘eye’ icon
    7. Then click on ‘Update Report Assignments’
  + Inform the user and update the ticket

## *Rave DB & FTP Access Requests*

Access request form is present in the documentum path,

*Medidata Rave/11 Production Support/Access Request*

Access users list and Sample forms are present in the documentum path,

*Medidata Rave/11 Production Support/Rave Database and FTP Access List*

* Users to create an ITSM request or email the request by obtaining the approval from Application owner/Business Relationship Manager for Rave System
* Review the request and complete the access request form accordingly, ensure Database names are appropriate and that PROD database does not have Read/Write access.
* For FTP access request, ensure the correct folder paths are specified.
* Complete the signature sections
* Send mail to Medidata Project Manager 'Michael Chou' [mchou@mdsol.com](mailto:mchou@mdsol.com) to create a Work Order for the database access. Ensure to get the signed copy back and load to documentum.
* Check with the user after one week (5 working days form the creation of WO by Medidata) to see if they have received the activation mail. If not, follow-up with Medidata.
* Resolve the ticket and update the **Secure\_Data\_Access\_List** with the user details.
* Follow the same process to revoke DB or FTP acces.

## *Rave - CTMS Integration setup*

Refer to **Rave CTMS Integration Process.doc** present in below location

/SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/11 Production Support/Rave IT Process Documents

## *Rave - RECON Integration setup*

* Clinical IT PM to intimate IT 1 week prior to sending the specifications for RECON.
* IT to send the timeline to Medidata with schedule for development and Go-Live and get the confirmation for dates.
* When RECON study spec is ready, IT to update Medidata RECON specification and load to documentum.
* IT to send the specification and spec signoff documents to Medidata ('Michael Chou' [mchou@mdsol.com](mailto:mchou@mdsol.com)) to create a WR with the timelines. (Medidata requires 5 days to complete the development and 3 days for QC)
* Medidata to create a WR and send the spec signoff back to AV - IT.
* Medidata to intimate IT once the implementation is completed in avdev URL
* IT to communicate the release to Trial PM.
* Any issues in UAT to follow-up with Medidata.
* Once the study completes successful QC/UAT, PM will intimate for PROD implementation after completing the SDLC documentation.
* CPG to updated the FogBugz ticket and assign to IT for PROD implementation
* IT to send the request to Medidata to implement RECON in PROD
* Medidata to create CO, Test plan, Test execution summary and send to IT for signoff
* IT to verify and obtain the signatures of IT Manager (BRM) for Change Order and forward them to Medidata. Ensure to receive a signed copy back for upload to documentum.
* Once Medidata completes the implementation in PROD notify the study PM to proceed with PROD IV and RV execution.

## *Rave Custom Reports Implementation*

Custom reports are created at study level or URL level. These reports are to be developed by Clinical **IT or Clinical Programmers and have to be validated in DEV URL before implementing in PROD.**

* Requester to create a ITSM/FogBugz ticket for the request and provide the necessary details along with custom report query to be implemented in DEV URL
  + Report Type: New/Updated
  + Report Name:
  + Report Parameters:
  + VSS path for spec and code:
  + Study name (if applicable):
  + Expected UAT date:
* Once ticket is created, CPG to send email notification to EdcRavesupport [EdcRavesupport@abbott.com](mailto:EdcRavesupport@abbott.com) with Subject: **FogBugz – Rave Report.** Note: One ticket should be created for each report
* Clinical IT will review the code for,
  + General header information:
  + Author: Name of the original author
  + Date: original date of code creation
  + Description:
  + Revision history: modifier, description
  + General coding practice:
  + Meaningful naming convention
  + Meaningful inline comments for objects and code segments
  + Readability: proper grouping, flow and indentation

Note: **Logic will not be reviewed**/ validated. IT will contact CPG for any clarifications/issues

* Clinical IT will Send request to **Medidata to implement the code in avdev URL** and Follow-up within 3 business days to ensure the **code is loaded to avdev URL**
* Once communication is received from Medidata **the report should be Published in avdev by using the details provided in FogBugz ticket** (Name, Parameters, Study) and ensure the report is executed without implementation errors and Release for UAT
  + In case of errors with the code, notify CPG
  + In case of file error (not loaded) contact Medidata
* Once CPG confirms **the testing is completed and requests to publish in PROD** URL, below steps has to be followed.
  + Review the UAT and spec signoff documents from VSS.
* Request Medidata to implement the files in **AVPROD database in all 3** databases.
  + Abbottvascular
  + abbottvascularReport
  + abbottvascularBE
* **Publish the report by using the same** configurations used for **avdev URL** and ensure the report is executed without implementation errors

Once the report is **implemented in PROD URL**, update the ITMS/FogBugz ticket and notify CPG

## *Rave Code PUSH/Move (PROD and DEV)*

Code PUSH to PROD will be executed as per the IV and RV for the study in Rave. This activity will be coordinated by trial IT – PM

For Rave Code move refer to **Rave Code Move Process and Test Case.doc** present in below location

/SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/11 Production Support/Rave IT Process Documents

## *Rave IxRS/Lab data integration Testing*

For Rave IxRS Integration refer to **Rave IxRS Integration Process.doc** present in below location

/SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/11 Production Support/Rave IT Process Documents

For Batch Upload integration (Lab data), follow test cases for ABSORB II RCT study (BU is outdated and RWS should be used for all inbound integrations).

/SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/12 Trial Development/10-393 ABSORB II RCT/05 Testing

## *Rave System Core Configuration*

For Rave Core Configuration follow the **Core Configuration Change Checklist.doc** present in below documentum path

*/SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/11 Production Support/Configuration Specification*

## *Rave - Clinical Systems integration issues*

* Clinical Systems involve ClinDART, ClinDEV, RECON, CTMS, CDRT etc., for which data flows from Rave system.
* Integration involves study to study configuration setup individually
* Issues will be raised by the study teams to respective Clinical system owners
* Individual IT persons handling the issue will reach to Rave IT for issues/clarifications related to Rave system.
* These issues are real time and follow the support SLA response and resolution.
* Review the issue and notify the teams accordingly. Contact Medidata in case of system issues.

## *Rave other issues (User Admin, Site Admin, Report Admin, Core Config etc)*

* Analyze the issue before reporting to Medidata, seek more information from user if required.
* Report to Helpdesk (helpdesk@mdsol.com) with details to contact and priority. In case of high priority, call the helpdesk immediately.
* Keep ([mchou@mdsol.com](mailto:mchou@mdsol.com)) and Judy/Phalguni/Sudheer in loop

## *Rave System downtime*

* Analyze the issue before reporting to Medidata, seek more information from user if required.
* Report to Helpdesk (helpdesk@mdsol.com) with details to contact and priority. In case of high priority, call the helpdesk immediately.
* Keep ([mchou@mdsol.com](mailto:mchou@mdsol.com)) and Judy/Phalguni/Sudheer in loop.

## Definitions and Acronyms

|  |  |
| --- | --- |
| Acronym | Description |
| EDC | Electronic data capture |
| Medidata | Rave software is owned by the vendor Medidata. Medidata hosts Rave development and production environments at their hosting facility. |
| Production URL | The highest level in a Rave environment hierarchy is a URL. There can be multiple environments (Dev, Val, etc.) under each URL. Production URL contains Production environment. |
| Integrations | Integrations refer to the Clinical systems that are integrated with Rave. The systems that are integrated with Rave are: Recon, ClinDART, PER, CTMS and CDRT |
| CTMS | Clinical Trial Management System |
| CDRT | Clinical Data Reporting Tool |
| ClinDART | Clinical Reporting application that is used to report on EDC data |
| RECON | Safety Management system that enables the Clinicals & Product Performance Group (PPG) group to assess, evaluate & reconcile adverse events and device malfunctions. |
| PER | Product Experience Reports |
| CRIS | Clinical Research Information System |
| CRIS IT | CRIS Information Technology |
| CDM / DM | Clinical Data Management Group / Data Management Group |
| CDM | Clinical Data Manager |
| CDMS | Clinical Data Management System |
| AV IT | Abbott Vascular Information Technology |
| BRM | Business Relationship manager |
| FTP | File Transfer Protocol |

# Application Overview

## Business Process Overview

|  |
| --- |
| Business Process Workflow |
| Rave EDC is Software as a Service (SaaS) web-based EDC solution with an intuitive user interface that facilitates the capture and cleaning of data. It is comparable to a collection of Electronic Case Report Forms (eCRF). All data related to studies, sites, and subjects collected during a clinical trial are entered and modified in EDC. Specific privileges and functionality that you have and can access, such as, answering queries and viewing audit trails, is dependent on the user roles and permission in Rave EDC. Likewise, the display of specific pages—for example, a single study, a single site, multiple studies, or multiple sites—is dependent on how Rave EDC is configured.  Some key features of Rave EDC include:   * Real-time task lists and visit calendars * Real-time data availability * Real-time cross-panel and cross-visit edit checking * Real-time ability to monitor, query, code, and obtain reports and view of study data * Quick navigation to recently accessed subjects and forms * Access to [Rave Reporter](https://learn.mdsol.com/display/RAVEREPORTSprd) * Electronic signature capability that is compliant with 21 CFR Part 11 * Local and central lab capture and batch data loading * Compliance with regulatory Clinical Data Interchange Standards Consortium (CDISC) requirements through comprehensive and easy-to-use audit trails * Optimized for ease of use by clinical investigators who can access, train, and communicate with the life science company sponsoring the trial. |

## 2.2 Module Description

|  |
| --- |
| Below module are in the scope of description   * [Architect](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/Architect/Architect.aspx&I=2) * [User Administration](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/UserAdmin/UsersPage.aspx&I=3) * [Site Administration](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/SiteAdmin/Sites.aspx&I=4) * [Reporter](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/Reporting/ReportsPage.aspx&I=5) * [Configuration](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/Configuration/WorkflowConfig.aspx&I=7) * [Report Administration](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/ReportAdmin/Default.aspx&I=8) * [Lab Administration](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/LabAdmin/AnalytesPage.aspx&I=9) * [DDE](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/DDE/DDEHomePage.aspx&I=10) * [Translation Workbench](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/Translations/TranslationWorkbench.aspx&I=11) * [PDF Generator](https://avdev.mdsol.com/MedidataRave/(S(x4ew3xsw4zdrbxvjh5knvllk))/LaunchModule.aspx?M=~/Modules/PDF/FileRequests.aspx&I=12) * [Query Management](https://avdev.mdsol.com/MedidataRave/(S(xznm2mdc2wiwlwylnzujjvvk))/LaunchModule.aspx?M=~/Modules/DCF/DCFQueries.aspx&I=14)   Important modules are explained below.  **Architect**: The Architect Module enables users to develop electronic case report forms (eCRFs), Edit checks within a study. Studies must be built and configured in the Architect in order to be viewed in the electronic data capture (EDC) module.  **Site Administration:** The Site Administration module allows system administrators to manage site records for single or multiple studies, as applicable. Users have the ability to create and maintain a list of Site Group levels, Site Groups, Sites, Study settings and User associations.  **User Administration:** The User Administration module allows administrative personnel access to: manage User IDs, grant or deny module access, associate Users with one or more studies and or sites, manage Principle Investigators, indicate sponsor approval and training dates for system access, associate Users with roles, and initiate the account activation process. The User administration module also includes access to optional contact information for the User, including email address, telephone and mailing address  **Reporter and Reporter Administration:** Reporter module allows users to pull reports from Rave system. Reporter administration allows users to assign reports to study/roles within study  **Configuration**: The Configuration Module is used to create and specify information that is used throughout the Rave modules. The permissions and settings granted at this level are applicable to every study and every environment loaded within the specific URL domain.  For detailed description please refer section 9.0 Architect manuals for more details. |

## 2.3 User Roles & Privileges

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Roles** | **Privileges** | **Security Group** | **Department & Location** | **No of Users** | | | a\_EDC | Limited access | NA | AVD,GLOBAL | 105 | | a\_EDC and Reporter | Limited access | NA | AVD,GLOBAL | 46 | | Administrator | Full Access | NA | AVD,GLOBAL | 19 | | Batch Upload | Limited access | NA | AVD,GLOBAL | 7 | | Coder Import Group | Limited access | NA | AVD,GLOBAL | 1 | | EDC | Limited access | NA | AVD,GLOBAL | 1161 | | EDC and DDE | Limited access | NA | AVD,GLOBAL | 2 | | EDC and Reporter | Limited access | NA | AVD,GLOBAL | 467 | | Reporter | Limited access | NA | AVD,GLOBAL | 5 | | RS - Administrator | Full Access | NA | AVD,GLOBAL | 56 | | RS - Help Desk | Limited access | NA | AVD,GLOBAL | 86 | | RS - MnM Group | Limited access | NA | AVD,GLOBAL | 1 | | RS - Outputs | Limited access | NA | AVD,GLOBAL | 1 | | RS - QC | Limited access | NA | AVD,GLOBAL | 1 | | RS - Reports | Limited access | NA | AVD,GLOBAL | 1 | | Study Designer | Limited access | NA | AVD,GLOBAL | 34 | | Superuser | Full Access | NA | AVD,GLOBAL | 10 | | SystemUserGroup | Limited access | NA | AVD,GLOBAL | 1 | | UMT Desk | Limited access | NA | AVD,GLOBAL | 2 | |

## 2.4 Assumptions, Dependencies and Risks

|  |
| --- |
| For issues related to Rave system or database, vendor (Medidata) support will be required. |

## 2.5 Business Critical Events

|  |  |  |  |
| --- | --- | --- | --- |
| Business Activities | Target Timelines | Impacted Applications | Business Groups involved |
| RAVE patch upgrade | Yearly once | N/A | N/A |
| Security Patching | Quarterly | N/A | N/A |
| Server Patching | Quarterly | Clindart, CDRT,  Recon | N/A |
| User Recertification | Yearly | N/A | N/A |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2.6 Service Requirements  |  |  | | --- | --- | | Service Requirements | Requirement Details | | Users Groups or Department | 19 | | No. of Users using the applications | 2006 | | Location of the users | GLOBAL | | No. of Sites where users are using the application | GLOBAL | | No. of Concurrent users during the application | 100 | |

## 2.7 Drawbacks/ Constraints/ Known Issues

|  |
| --- |
| All the known issues list will be published in <https://learn.mdsol.com> for each year .We can download to look for the known issues. Please contact Michael Chou [mchou@mdsol.com](mailto:mchou@mdsol.com) or mail to Medidata Helpdesk [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com) for more details on the known issues list |



### P1 & P2 Ticket Details

No Such P1 & P2 Tickets are there in recent times.

### Root Cause Analysis (RCA) Details

No RCAs are available.

## Key Standard and Ad hoc Service Requests

No such requests are received.

## Key Precaution/Lessons Learnt

* + 1. Application URL monitoring should be done properly
    2. Need to check FTP daily load regularly in a timely manner
    3. Need to co-ordinate with the vendor for any anomaly.
    4. Keep all the application relation documents in proper SLC repository.

## Key Enhancement

Please follow below table for RAVE key enhancement.

|  |  |  |
| --- | --- | --- |
| Environment | URL | Enhancement Date |
| Prod | <https://abbottvascular.mdsol.com/> | 23-Aug-2020 |
| DEV | <https://avdev.mdsol.com/> | 28-Jul-2020 |
| Test | <https://avtest.mdsol.com/> | 2019 |

# System Architecture

## Application Architecture

Not Applicable as the system is externally hosted at the vendor’s hosting facility. Please contact Michael Chou [mchou@mdsol.com](mailto:mchou@mdsol.com) or mail to Medidata Helpdesk [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com) for more details

## Environment Details

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Environment & URL | Server Name & Type | Description | Category | Location |
| <https://avdev.mdsol.com> - Dev | Central Server | Externally hosted and maintained by vendor | N/A | New York, USA |
| <https://abbottvascular.mdsol.com> – Prod | Central Server | Externally hosted and maintained by vendor | N/A | New York, USA |
| <https://avtest.mdsol.com/> --- Test | Central Server | Externally hosted and maintained by vendor | N/A | New York, USA |

## Hardware Architecture

Not Applicable as the system is externally hosted at the vendor’s hosting facility. Please contact Michael Chou [mchou@mdsol.com](mailto:mchou@mdsol.com) or mail to Medidata Helpdesk [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com) for more details

## Software Architecture

Not Applicable as the system is externally hosted at the vendor’s hosting facility. Please contact Michael Chou [mchou@mdsol.com](mailto:mchou@mdsol.com) or mail to Medidata Helpdesk [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com) for more details

## Database model

All the database activities in Rave are taken care by vendor (Medidata).If any details required related to database please contact Medidata Project Manager Michael Chou [mchou@mdsol.com](mailto:mchou@mdsol.com)

1. System Requirements

## User Characteristics

Active users list and corresponding role details can be downloaded from User Administration ->Download in abbottvascular.mdsol.com.

## External Interface Specifications

|  |  |
| --- | --- |
| **Processes** | **Inbound/Outbound Path** |
| FTP file path – XML file for Recon application | /abbottftp/abbottvascular.mdsol.com/RECON\_Archive |
| BIZLINK – Middleware | Picks XML file from FTP and post it in MQ |
| Messaging Queue – MQ | XML file will be picked by Recon application service |

## Performance Requirements

Rave system performance is dependent on the number of real time users accessing the system and the number of process running in parallel and support will be provided by Medidata. To maintain the performance, need to adhere to Medidata.

## System Recovery Procedures

Not Applicable as the System Recovery details are maintained by vendor.

## Disaster Recovery

Details regarding the disaster recovery, criticality, availability, maintainability, stability of the system are maintained by vendor.

## Regulatory and Compliance Parameters

|  |  |
| --- | --- |
| GxP Regulations | |
| Is it GxP application (GMP, GLP, GCP)? | **GxP \_\_\_\_\_\_\_\_\_**  **Non-GxP** |
| If GxP, GAMP 5 Categories (1/3/4/5)? | Infrastructure Only (Category 1)  Standard System (Non-Configurable) (Category 3)  Configurable System (Category 4)  Custom or Bespoke System (Category 5) |
| Availability of ‘System Risk Assessment Report’ or Compliance Determination Document (Yes/No).  If yes, please provide the document path. | Yes.  Please refer DOP1268-50 in view point for more details |
| The location/path of all validation documents (Infrastructure qualification documents, application level validation documents (IQ, OQ, PQ – all versions + user manual, etc.)) | Documentum: SDS Projects/Clinical Data Management (CRIS)/Medidata Rave/08 Training/Manuals |
| As part of the maintenance and support activities, before applying a change/upgrade to a GxP system, if you identify that the existing infrastructure or application is not validated, how do you proceed with the required change or upgrade?  Define Change. | The respective team will be contacted to create qualification documents; on completion and approval of such qualification, the current change or upgrade will be performed.  There is no such check points being followed.  Any other alternate process: \_\_\_\_\_\_\_\_\_\_\_ |
| Additional Comments | The system is validated and a defined change/upgrade process is in practice. |
| SOX Regulations | |
| Does the Application need to be SOX Compliant? | Yes  **No** |
| If yes, the availability of SOX control objectives |  |
| Additional Comments |  |
| Statements on Standards for Attestation Engagements (SSAE) | |
| Does the application come under SSAE purview? | Yes  No |
| If yes, the availability of SSAE related documentations |  |
| Additional Comments |  |
| Any other regulations or controls to be complied with? | Yes  No |
| If yes, list. | 1.  2. |

## Process and Procedures

|  |  |  |
| --- | --- | --- |
| Reference of Process and Application Documents | | |
| Name | Version | Location |
| Incident Management Process Handbook | QC10.21 Incident Management Process | ISO train |
| Problem Management Process Handbook | QC10.23 GIS Problem Management Process | ISO train |
| Change Management Process Handbook | As such, handbook is not available for problem management process, however, we can create a change request and get it approved from CSM and then it can be done. | Not Applicable |
| Release Management Process Handbook | N/A | N/A |
| Business Process Understanding Handbook | N/A | N/A |
| Application Process Handbook | N/A | N/A |
| Application Architecture Document | N/A | N/A |
| Application Design Document | N/A | Will be available to the vendor |
| Application Regression Pack | N/A | N/A |
| Configuration Management | Not Applicable | Perforce: //CRIT/CRIS Global Documents/Configuration Management Plan/CRIS Configuration Management Plan-approved.pdf |
| Defect Management | No such documents on that, however it is tracked by the tool FogBugz | Not Applicable |
| Archival & Retention Policy (or period) | N/A | N/A |

## Third Party Components

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 3rd Party Product | Name of Vendor | Contact details | Application Hosted by Vendor | Application supported by Vendor | Expiry of License | SLA |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |

# Specifications of Rave

## Application Categorization

#### Online Application details

|  |  |  |
| --- | --- | --- |
| **Source** | **Description** | **Frequency** |
| N/A | N/A | N/A |

#### Batch

#### Application details

| **Job Name** | **Reference (Data Set / Table / Reports)** | **Source** | **Description** | **Frequency** |
| --- | --- | --- | --- | --- |
| N/A | N/A | N/A | N/A | N/A |

## Application Component Inventory

External systems that will interface the Rave application are mentioned below .

1) Recon

2) CLINDART

3) CDRT – Clinical Data Reporting Tool

Recon - Recon application is web-based application that will help Clinical & Product Performance Group to reconcile clinical AEs & DMs from RAVE trials .Please refer Recon Application Handbook for more details.

CLINDART - Abbott Vascular needs to track and manage numerous activities related to clinical studies, including adverse events, Clinical Events Committee payment activities, monitoring visits, protocol deviations, and data cleaning. The Clindart application was developed to facilitate this process. The CLINDART application uses the clinical views data from Rave database to generate reports. Please refer CLINDART Application Handbook for more details.

CDRT – CDRT uses the views from Rave database as a source to manage and customize the clinical data using Informatica tool and generates reports .Please refer CDRT Application Handbook for more details.

## User Authentication Scheme

To access the application user can login to Internet Explorer and type on the URL which he wants to access (<https://abbottvascular.mdsol.com> or <https://avdev.mdsol.com>). System will request for User Name and Password. Provide the details to login and access the modules within Rave.

To access Medidata Rave, activation of rave account is needed which can be completed by using an **Activation code** provided by Rave administrator. Those who have completed the Rave training will be able to request for Rave access.

## Scheduled Tasks/ Batch Process

N/A

## Process Flow

Please refer section 5.7 which provides more details on how the Rave application is integrated with other applications like Recon,CDRT, ClinDart etc

## Program flow

N/A

## Data flow

The Rave application is integrated with many applications like Recon, Clindart, CDRT and CTMS.

Please see the below tabular column and the data flow diagram for more details.

|  |  |
| --- | --- |
| Integrations | Type of data |
| Clindart | Adverse event patient data |
| CTMS | Patient visit data |
| CDRT | Payments details |
| Recon | Adverse event ,device deficiency and subject details |



Please refer section 9.0 Production Support Manual – Integrations for more details.

## Folder Structure

|  |
| --- |
| N/A. Maintained by vendor. |

## Configuration Information

|  |  |
| --- | --- |
| Log into Rave, Go to Configuration-> [Configuration Loader](https://abbottvascular.mdsol.com/MedidataRave/(S(olwbczyzfmtlhmqhnnur05ui))/Modules/Configuration/ConfigurationLoader.aspx)-> Download Configuration Settings->Get file.  All the configuration settings can be downloaded in excel format. |  |

## Application Interfaces

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type (Online / Batch)** | **User Interface** | **Hardware Interface** | **Software Interface** | **Communication Interface** |
| Batch | Recon | N/A | N/A | BIZLINK/Messaging Queue |

## Application Repository

SaaS Application. Deployed and maintained by vendor.

# Platform

## Custom Frameworks

N/A. Deployed and maintained by vendor.

## 6.2 Client/Cognizant Team Information

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | **Name** | **Business Phone** | **Job Title** | **Email Address** | **Business**  **/IT** | | --- | --- | --- | --- | --- | | Ham, Judy M | +1 408-845-3485 | Business Relationship Manager - AV | judy.ham@abbott.com | Business - AV | | Baddam, Phalguni R | +1 (408) 845-1572 | Senior IT Analyst - AV | phalguni.baddam@abbott.com | IT - AV | | Chandran, Sachin | +1 (951) 914-3104 | BSS RUN – PDA Domain Lead -CTS | sachin.chandran@abbott.com | IT-CTS | | Sujeesh T K | +91 95-0005-1380 | Offshore Lead | sujeesh.thattankandy@abbott.com | IT-CTS | |

## 6.3 Development and Build Utilities

|  |
| --- |
| N/A |

# Support and Maintenance Information

Scheduled maintenance will take place during non-business hours (unless otherwise agreed by the customer) with a minimum of 24 hours prior notice to customer of any required downtime and appropriate messaging provided to Authorized users (which may take the form of either an email notification, a message on the sites or both) . The scheduled maintenance window is Saturdays from 7PM to 10PM CT.

## Application onboarding

|  |
| --- |
| Application Level Training Application level training will be a classroom Rave EDC training (Instructor led) and once the training is completed, the person can request for the relevant access. Application Access & Onboarding Requester submits a request in ITSM; ITSM ticket created and assigned to **ADM-GLBL-COG Product Dev & Approval Critical App Support** queue for avdev.mdsol.com and avtest.mdsool.com access. Production related access requests are no longer supported by cognizant. Please contact BRM if more details are required.  **To log in to Rave using Rave URL**   1. Access a working Internet connection of choice. 2. Enter the URL for the study you are working on.   This should be “abbottvasculcar.mdsol.com” for production  “avtest.mdsol.com” for testing  “avdev.mdsol.com” for development   1. Press **Enter** or **Return**. 2. Enter **User Name** and **Password**. User names and Passwords are case sensitive      1. Click **Enter**.   You will be directed to the **Rave Home** page or the **eLearning Home** page.   1. Once the eLearning’s are completed, based on the privilege of access, the module inside the rave URL can be accessed. |

## Support Schedule

|  |  |  |
| --- | --- | --- |
| Site | Support Hours(IST) | |
| Global | 11:30 PM – 8:30 AM, 5 days a week | |
|  | | |

## Application Build & Deployment Strategy

|  |
| --- |
| N/A. Application developed and maintained by vendor |

## 7.4 Configuration Management

|  |
| --- |
| Please refer **Perforce:** //CRIT/CRIS Global Documents/Configuration Management Plan/CRIS Configuration Management Plan-approved.pdf for configuration management details. |

## 7.5 Change Management & Rollout Strategy

|  |
| --- |
| Change management is comprised of the raising and recording of changes, assessing the impact, justification, and risk of proposed changes, and obtaining plan reviews/approval, managing and coordinating change implementation, documenting implementation and closing change requests. |

## 7.6 Coding Standards

|  |
| --- |
| N/A. |

## 7.7 Existing Support Process

|  |
| --- |
| Please refer section 9.0 Rave Production Support Plan for more details |

## 7.8 Existing Service Level Agreements

|  |
| --- |
|  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Impact /  Urgency | Extensive / Widespread | Significant/  Large | Moderate Limited | Minor Localized |
| **Response time during Primary time** | | | | |
| **Critical** | 30 Minutes | 30 Minutes | 60 Minutes | 60 Minutes |
| **High** | 30 Minutes | 60 Minutes | 60 Minutes | 4 Hours |
| **Medium** | 60 Minutes | 4 Hours | 4 Hours | 4 Hours |
| **Low** | 9 Hours | 9 Hours | 9 Hours | 9 Hours |
| **Response time during Secondary time** | | | | |
| **Critical** | 60 Minutes | 60 Minutes | 90 Minutes | 90 Minutes |
| **High** | 60 Minutes | 90 Minutes | 90 Minutes | 4 Hours |
| **Medium** | 90 Minutes | 4 Hours | 4 Hours | 8 Hours |
| **Low** | 8 Hours | 8 Hours | 8 Hours | 8 Hours |

## 7.9 Frequently Occurring Issues & Remedies

|  |
| --- |
| No frequently occurring issues in Rave. |

## 7.10 Application Monitoring Details

|  |
| --- |
| Scheduled job Web-INT\_abbottvascular   running on machine GISULCV850707N is monitoring the application URL (abbottvascular.mdsol.com) every five minutes.If the URL goes down alert will be send to group email address edcravesupport@abbott.com. |

## 7.11 Vendor Support Agreements

|  |
| --- |
|  |
| 7.11.1 Vendor Support Process If vendor involvement is needed application support team submits a request to Medidata Support and provides response to the requester OR application support team . The request is submitted through mail to [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com) or for urgent issues can call the customer care **866-633-4328**  **7.11.2 Vendor Support Contact Details**  General support and requests:  [helpdesk@mdsol.com](file:///C:\Users\241673\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\2AZFNNAN\helpdesk@mdsol.com)  Vendor main point of contact: Louis Riozzi  [lriozzi@mdsol.com|](mailto:lriozzi@mdsol.com|)  Contact number - [+1 732 767 4357](tel:%2B1%20732%20767%204357)  Vendor, Project manager : Michael Chou  Contact number - +1 646 276 2954  mchou@mdsol.com 7.12 User Management and Recertification **Recertification:** On yearly basis user recertification is carried for critical system .Rave is considered as a critical system.  **User management:** Novella Clinical Site Support group assumed responsibility for all Rave user and site management in production on Monday March 14, 2016. As of this date, user/site requests should no longer be sent to the Abbott Vascular EDC Support email box and ITSM tickets no longer need to be generated.  All requests for new users or changes to existing users must be sent to the project-specific Project manager or Clinical Research Associate who will review the request and forward it to the Site Support group.  If a new sponsor user requires access to multiple studies, the requestor can send the initial request to Site Support and copy each project-specific authorized requestor so that access to their study can be provided.  After reviewing the request, the project-authorized requestor will send the request to the Site Support group who will process the request within 8 hours.  When a request is processed by Site Support for a new Rave user, the user can expect two emails; one from the Rave system (noreply@mdsol.com) that contains the activation code and user ID and one from Site Support that contains the activation PIN and URL (https://abbottvascular.mdsol.com).  Rave user access for non-prod will be provided by CTS support team Rave administrator. Please follow the below process for non-prod access request. |
|  |

|  |  |
| --- | --- |
| **New Users:**  Fill in the “Sponsor Account Activation Form” as per the guidelines and get the supervisor signature approval. Once the signature is obtained the user/supervisor will raise an ITSM ticket with the details of user and attach the account activation form along with training records (if applicable).  **Existing Users:**  User/supervisor to raise an ITSM ticket with the details of userid, study, environment and role required.  In case of role upgrade (change in user group) fill in the “Sponsor Account Activation Form” and attach the required training records.  *Note: One user can be assigned to one User Group. Training records are required for* User Group *Study Designer, Superuser, Administrator and Batch Upload.*  *For requesting access to Generic Accounts, the same process will be followed depending on the account is New or Existing.* | **Responsible:** Sponsor User |
| Ensure the ticket is assigned to “**ADM-GLBL-COG Product Dev & Approval Critical App Support** “group in ITSM. | Responsible: Sponsor User |
| Review the ITSM request and ensure the required details are appropriate.  For module access other than EDC, request the user for training records *(if not provided)* | Responsible: Rave Administrator |
| Provide access as per the request and communicate to the user. In case of New user, Sign the sponsor approval form, scan, upload to Documentum and send the Activation Pin to the user.  Record the user details in the “Rave User Administration Details” present in the Perforce/Documentum | Responsible: Rave Administrator |
| Update the ITSM ticket with the details and assign the ticket back to the requester. | Responsible: Rave Administrator |
| Verify for the access and resolve the ticket | **Responsible:** Sponsor User |

# Application Dependency Matrix

No dependencies.

# References

|  |
| --- |
| Upgrade Installation Verification & Release Validation - All the recent upgrade related documents will be stored in WNDCHILL.  PATH:- /Computer Systems Life Cycle/AV EDC RAVE  Production Support Manual – Integrations - Perforce: //CRIT/Medidata RAVE/09 Production Support/RAVE Production Support Plan-approved.pdf  Architect manual - Will be available to the vendor.  Access request forms - Will be available to the RAVE ADMINISTRATOR. |

# Change Log

Please note that this table needs to be maintained even if separate Change item status log is maintained in the tool / document and the version history needs to be given here. But reference can be given to details of the changes if it is not given here.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Version Number | Changes Made | | | |
| V1.0 | Initial baseline created on <dd-Mon-yy> by <Name of Author> | | | |
| V1.1 | <Please refer the configuration control tool / change item status form if the details of changes are maintained separately. If not, the template given below needs to be followed> | | | |
| **Section No.** | **Changed By** | **Effective Date** | **Changes Effected** |
|  |  |  |  |

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