RAVE is an electronic data capture tool (EDC) for capturing, managing and reporting patient data. RAVE is categorized as a critical application and it is hosted by Medidata.

Application SP ID is 753.

**Please note:** Do not use the Application Handbook to identify the latest owners (Application, Support or Business).   For BTS IT Support Owner: Access the application portfolio management tool (HOPEX) for current support owner names.

* 1. Table of Contents

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1.2 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.

1.3 Scope

The scope shall include the following –

* Handle user requests (create new users, inactivate users, provide access to projects)
* Handle Technical issues (RAVE application issues)
* Code Move (Push the study to PROD, Move code to DEV URL).
* Core Configuration maintenance.

1.4 Responsibilities

|  |  |
| --- | --- |
| **Roles** | **Responsibility** |
| Clinical Research IT | 1. RAVE Application Access Requests - Non Production  2. RAVE Report Access  3. Access DB & FTP Access Requests to Medidata  4. RAVE - CTMS Integration setup  5. RAVE - RECON Integration setup  6. RAVE Custom Report Implementation  7. RAVE DTE code Implementation  8. RAVE Code PUSH/Move (PROD and DEV)  9. RAVE System Core Configuration  10. Medidata Handover Requests  11. RAVE - Clinical Systems integration issues  (ClinDART, ClinDEV, RECON, CTMS, CDRT)  12. RAVE other issues (User Admin, Site Admin, Report  Admin, Core Config etc)  13. RAVE System downtime |

Please refer section 4.3 Medidata RAVE Activities Roles & Responsibilities for more details.



**N**ote: The following terms are document specific and are included for reference in this document only.

|  |  |
| --- | --- |
| Term | Definition |
| ASP | Application Service Provider. In an ASP model, the vendor  contracting the service will provide the complete solution. |
| CDRT | Clinical Data Reporting Tool |
| CDM / DM | Clinical Data Management Group / Data Management Group |
| CDM | Clinical Data Manager |
| CDMS | Clinical Data Management System |
| ClinDART | Clinical Reporting application that is used to report on EDC data |
| CRIS | Clinical Research Information System |
| CRIS IT | CRIS Information Technology |
| EAI | Enterprise Application Integration team that supports in  interfacing applications (ex: SAP data is integrated into CDRT  via EAI technology supported by the EAI team) |
| EDC | Electronic data capture |
| GTB | Grow the Business releases include new capital projects of in scope  applications e.g Recon 1.0 |
| 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 |
| Medidata | RAVE software is owned by the vendor Medidata. Medidata  hosts RAVE development and production environments at their  hosting facility. |
| PER | Product Experience Reports |
| 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. |
| RECON | Safety Management system that enables the Clinicals &  Product Performance Group (PPG) group to assess, evaluate &  reconcile adverse events and device malfunctions. |
| RTB | Run the Business releases include bug fixes that are necessary  for running the business applications. e.g: Recon 1.2, CTMS  6.1, Absorb 2.0 |
| STB | Sustain the Business releases include patches, upgrades that  are necessary for sustaining the business applications (as  required or recommended by Vendors, IT Architects , or IT wide  system upgrade initiatives) e.g : MS Windows Server  SP2 patch |



RAVE is hosted and supported by Vendor Medidata. MEDDEV IT serves as liaison between MEDDEV business community and the vendor and is dependent on the Vendor for most of the activities.

* User Access is provided by the RAVE ADMINISTRATOR. The Admin will send the UAR form to the user and upon getting that UAR form fully filled and signed the user can get the access
  1. 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, users need to adhere to Medidata Guidelines

3.2 Service Requirements

|  |  |
| --- | --- |
| Service Requirements | Requirement Details |
| Users Groups or Department | 23 Active user groups |
| No. of Users using the applications | ~2577 users |
| Location of the users | Global |
| No. of Sites where users are using the application | ~860 |
| No. of Concurrent users during the  application | 400 (maximum) |

4 Business Process Overview

4.1 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
* 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.

4.2 Business Module Description

Below module are in the scope of description

* Architect
* Site Administration
* User Administration
* Reporter and Reporter Administration
* Configuration

**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, 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.

**4.3 User Information, Roles & Privileges**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Roles** | **Privileges** | **Security Group** | **Department & Location** | **Approximate 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 |

**4.4 Business Events**

This section shall cover the key Business Events and impact to the business.

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |

5.0 Application Overview

5.1 System Architecture

Not Applicable as the system is externally hosted at the vendor’s hosting facility

5.1.1 Environment Details

|  |  |  |  |
| --- | --- | --- | --- |
| URL | Environment | Server Type | Hosting Location |
| **https://avdev.mdsol.com** | **Development** | **Central**  **Server** | **New York,**  **USA** |
| **https://abbottvascular.mdsol.com** | **Production** | **Central**  **Server** | **New York,**  **USA** |
| **https://avtest.mdsol.com** | **Test** | **Central**  **Server** | **New York,**  **USA** |

5.1.2 Database Model

All the database activities in RAVE are taken care by vendor (Medidata). If any details are required related to database, please contact Medidata Project Manager (mchou@mdsol.com)

RAVE uses Microsoft SQL server 2016 SP1 for DEV and TEST as back end database. For PROD it will be updated to the MS SQL 2016 SP1. Please see the database details below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **URL NAME** | **URL** | **IP**  **Address** | **SQL Server Name** | **SQL Server Database Name** |
| DEV | https://avdev.mdsol.com | 130.36.4  1.204 | HDCU15DVDBSV001 | avdev |
| PRD | https://abbottvascular.m dsol.com | 130.36.4  1.203 | HDCA23PRDBSV002 | AbbottVascular BE |
| Test | https://avtest.mdsol.com | 130.36.4  1.204 | HDCU15DVDBSV001 | avtest |

* + 1. Integration Details

The RAVERAVE application is integrated with many applications like Recon, Clindart, Clindev,

CDRT and CTMS.

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

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



Please refer section 7.7 Production Support Manual – Integrations for more details.

5.1.4 Third Party Components

The application does not have any third-party components.

**5.2 Regulatory & Compliance Parameters**

|  |  |
| --- | --- |
| GxP Regulations | |
| Is it GxPapplication (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  Perforce: //CRIT/Medidata RAVE/01 Planning & Admin/EDC Hazard Risk Analysis-approved.pdf |
| The location/path of all validation documents (Infrastructure qualification documents, application level validation documents (IQ, OQ, PQ – all versions + user manual, etc.)) | Perforce: //CRIT/Medidata RAVE/  The vendor validation documents for RAVE are available on the validation portal provided by the vendor. |
| 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.  Thereis no such check points being followed.  Any other alternate process: \_\_\_\_\_\_\_\_\_\_\_ |
| Additional Comments |  |
| 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. |

* 1. **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 | Not Applicable | Not Applicable |
| Business Process Understanding Handbook | Not Applicable | Not Applicable |
| Application Process Handbook | Not Applicable | Not Applicable |
| Application Architecture Document | Not Applicable | Not Applicable |
| Application Design Document | N/A | Will be available to the vendor |
| Application Regression Pack | Not Applicable | Not Applicable |
| 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) | Not Applicable | Not Applicable |

6.0 Application Onboarding Requirements

6.1 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.

* 1. Application Access & Onboarding

The entire RAVE related user access request and other requests will be sent to RAVE administrator. The user should complete the required trainings to get the RAVE application access.

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

Requester submits a request in ITSM; ITSM ticket created and assigned to **ADM-GLBL-COG Product Dev & Approval Critical App Support** queue for AVDEV and AVTEST access.

Production related access requests are no longer supported by cognizant. Please contact BRM if more details are required.

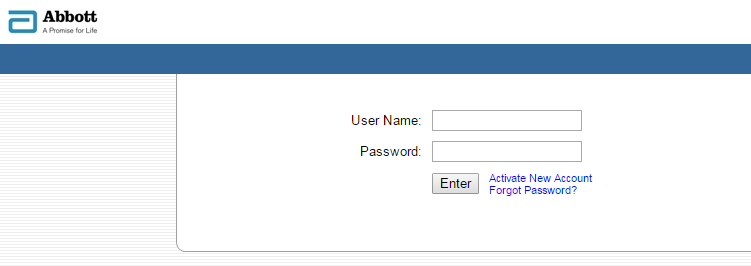
To access Medidata RAVE, activation of RAVE account is needed which can be completed by using an **Activation code** provided by RAVE administrator.

**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.
2. Once the eLearning is completed, based on the privilege of access, the module inside the RAVE URL can be accessed.

All the server access for development and production environments will be requested to vendor. (Medidata)

Please refer section 7.15 for more details

7.0 Scope of Maintenance Operations

7.1 In Scope Activities

* + 1. Incident Management
* All the tickets related to technical and functional issues for RAVE are routed to the below queue

ADM-GLBL-COG Product Dev & Approval Critical App Support

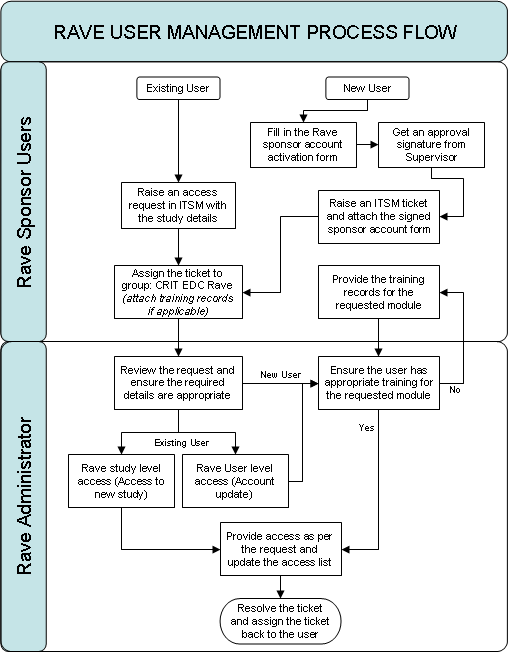
**SLA Details:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SLA/Priority** | **Response SLA** | | **SLA / Priority** | **Resolution SLA** |
| **Priority** | **Primary Hours** | **Secondary Hours** | **Priority** |
| P1 | 15 min | 60 min | P1 | 8 hours |
| P2 | 15 min | 90 min | P2 | 2 days |
| P3 | 2 hours | 4 hours | P3 | 6 days |
| P4 | 4 hours | 8 hours | P4 | 10 days |

* + 1. Change Control

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. We can create a change request and get it approved from CSM and then it can be done.

7.1.5 User Management &Recertification

****

|  |  |
| --- | --- |
| **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 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 |

Note: Please see section 7.7 Access request forms for more details.

User Recertification frequency - Yearly once done by ABBOTT GAA Team

7.1.6 System Backup and Restoration

System backup and restoration details are maintained by vendor.

7.1.7 Disaster Recovery

Not Applicable as the disaster recovery details are maintained by vendor.

7.1.8 Application Monitoring

There’s an automated job in BMC PATROL Portal that runs in every 5mins to check whether url is down or not and sends the alert to the DG-EDCRAVESUPPORT team. From the vendor side the Global Network Operations Teams monitor URL availability 24x7 to check the URLs.

7.1.9 Application Maintenance

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.

7.1.10 Application Patching

Application patching /hot fixes will be taken care by vendor. Once the patching is completed, vendor will

communicate to application support team. Application upgradations are done by vendor as well and is communicated to the support team.

7.1.11 Outage Planning

For emergency maintenance Medidata will provide a minimum of 4 hours of notice to customer and appropriate messaging provided to Authorized users (which may take the form of either an email notification, a message on the sites or both) .For purpose of service levels, emergency maintenance will be considered as maintenance performed outside of scheduled maintenance and not to be counted as available time. With respect to nonproduction environment, Medidata will use commercial best efforts to ensure that scheduled maintenance and emergency maintenance will not exceed 48 consecutive hours.

7.1.12 License Management

The License Management details will be available to the vendor.

7.2 Out of Scope Activities

|  |  |
| --- | --- |
| GTB (Grow the business) releases | Any new Capital Project for new features/enhancements for non-trial applications. |
| GTB (Grow the business) releases of the trials | Any new trial development project |
| RTB / STB releases (that require new funding in addition to operating expenses) | This includes, upgrades that are necessary for sustaining the business applications (as required or recommended by Vendors, IT Architects , or IT- wide system upgrade initiatives) e.g: Siebel Upgrades |
| Services provided as per Infrastructure SLA | Scheduled maintenance, backup and recovery |
| Services provided by the vendor | Vendor hosting services Vendor Helpdesk services |

7.3 Site and Regional Differences

|  |  |
| --- | --- |
| **Site** | **Support Hours(CST)** |
| Global | 1:00AM – 10:30 AM, 5 days a week |

7.4 Vendor Agreements

**7.4.1 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.

Please refer section 7.7 Master Technology and Services Agreement for more details.

**7.4.2 Vendor Support Contact Details**

General support and requests: [helpdesk@mdsol.com](mailto:helpdesk@mdsol.com)

Vendor main point of contact: Mark Millington [mmilington@mdsol.com](mailto:mmilington@mdsol.com)

Vendor, Project manager : Michael Chou [mchou@mdsol.com](mailto:mchou@mdsol.com)

7.5 Support Dependency Matrix

|  |  |  |  |
| --- | --- | --- | --- |
| **Dependent Group or Team** | **Resolver Group** | **Contact Number** | **Email ID** |
| ESB\_SUPPORT | GIS-GLBL-ESB  (Tibco support) |  | [MOREDX4@oneabbott.com](mailto:MOREDX4@oneabbott.com) |
| Database Support | Handled by vendor - Medidata | +1-888-480-6376 | [helpdesk@mdsol.com](file://localhost/C:/Users/SALEMRX1/Desktop/helpdesk%40mdsol.com) |

7.6 Key Contacts

|  |  |  |
| --- | --- | --- |
| **Key Contacts** | **Role** | **eMail Id** |
| RAVE Support team | Application Support | Saha, Saha ( [saikat.saha1@abbott.com](mailto:saikat.saha1@abbott.com) ) |
| BTS IT Support Owner | Support Owner | Access the Application Portfolio Management Tool (HOPEX) for current support owner name |

7.7 Knowledge Repository

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

END OF DOCUMENT