

REDCap eDocs Module User Requirements Specification

University of Vanderbilt
(VUMC)

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Signature Page

Prepared by:

I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

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Revision History

Date	Version	Description
11-Feb-2020	001	Original Release, New Document

1 Introduction

1.1 Objective

The purpose of this User Requirements Specification (URS) is to define the various user requirements for the eDocs Module of REDCap system. The requirements will be tested and/or verified in the execution of the test scripts or implemented by procedure.

Validation is a process that provides a high degree of assurance that the system and/or utilities/facilities are performing reliably and consistently. This URS is the controlling document that includes requirements for eDocs Module within REDCap system and serves to guide validation testing activities needed to retrospectively and prospectively validate the eDocs module.

Project specific information such as scope, responsibilities, validation deliverables as well as other project information can be found in the eDocs Validation Plan.

1.2 Rationale

It is the practice of University of Vanderbilt, located in Nashville, Tennessee to assure that all regulated computerized systems perform according to predetermined specifications in an accurate, reliable and repeatable manner. These activities are designed and executed to ensure that the system and related procedures comply with Good Clinical Regulations and Guidance and 21 CFR Part 11.

1.3 Requirements

The following requirements apply to the system being retrospectively validated. These requirements include all activities and standards which must be met prior to releasing the system into the production environment. Each requirement will include a proposed verification mechanism. This will be identified in the 'Verification' column below. Verification methods include:

- P - Procedural controls will be implemented to meet the requirements.
- T - Formal testing will be executed to document that these requirements are satisfied.
- V - Verification will be performed (including but not limited to tester testimonial and / or objective evidence and documented to meet the requirements.
- N/A - Requirement may not be verified in the current scope of this project.

Some requirements may have multiple verification methods.

This section shall state the requirements: installation, system, security, regulatory, user/functional, instrument interface and risk mitigation (if necessary). The contents of this section shall define the environment in which the system must operate, the interface, data and reporting, as applicable.

A set of criteria will also be applied resulting in a prioritization of each user requirement on a scale from 1-3.

The priority levels are defined as:

- Priority (3): the user requirement is mandatory and must be implemented in the scope of the project. Essential to business operations; a mandatory function or requirement.
- Priority (2): the user requirement is strongly expected and may be implemented after this project or highly desirable to business operations; would provide significantly enhanced benefit but is not critical.
- Priority (1): the user requirement is "Optional" and may not be implemented nor tested in the scope of the project ("Nice to have" requirement) or for future business operations; nice to have feature or requirement.

Priority 3 requirements are critical process requirement, and a functional solution must satisfy the requirement.

Priority 2 or 1 requirements are general user requirements, which are optional and do not need to be tested or satisfied in this retrospective validation effort.

The Requirement ID number (Req ID #) number must be unique and user must allow considerable empty numbers for future changes to requirements document.

1.4 System Context

eDocs is being developed to provide functionality that will allow secure part 11 compliant document uploads in a basic data collection instrument as a module of the REDCap system at University of Vanderbilt Medical. As such, the application will leverage some core functionality from REDCap, which will be tested in part during the validation of eDocs. eDocs will be implemented to allow for the creation of a file upload in a basic data collection instrument. The file will be uploaded by the users and system will ask to confirm that the file is correct while uploading and additionally ask the user to enter the REDCap ID and password for the verification process. The system allows versions whenever the new document is updated and all the version will be stored in the data history if deleted the versions will still be maintained in the Vault storage, which is a SFTP write once read many file storage locations.

Additionally, due to the nature and content of the records managed by eDocs, a validation effort including regulated requirements will be conducted to provide the appropriate evidence and documentation to support use for clinical research submission to regulatory authorities.

2 Requirements

The below functional requirements will reflect the functional requirements defined for this release of the eDocs application.

Req#	Requirement	Verification	Priority	Traceability
3	Data Requirements			
3.1	System shall allow a file upload size up to a maximum of 50 mb The file upload will generally have a size requirement of 10-100kb but can be as large as 50 mb.	T	3	PQ-eDocs Steps 4 and 5
4	eDocs Core Functionality			
4.1	Basic Demographic form Development			
4.1.1	System shall permit inclusion of eDoc file upload process in any data collection instrument. System will allow for the inclusion of the eDocs file upload process in any data collection instrument created within the system framework.	T	3	PQ-eDocs Step 5
4.2	eDocs File Versioning			
4.2.1	System shall maintain version history of a file upload field or a form on the survey. File version history shall maintain previous version(s) of a file upload field or a form on the survey.	T	3	PQ-eDocs step 40
4.2.2	System shall allow a user to delete file from the data collection field. NOTE: This is an administrative function. The file will be deleted on REDCap instance but retained in the 'Vault'.	T	3	PQ-eDocs step 42

Req#	Requirement	Verification	Priority	Traceability
4.2.3	System shall allow a user to overwrite and upload a new version of the current file while maintaining the current version in the file upload field.	T	3	PQ-eDocs step 40
4.2.4	System shall provide an ability to download files from previous versions of an uploaded file.	T	3	PQ-eDocs step 41
4.2.5	System shall create a version of a file only when the file is saved.	T	3	PQ eDocs step 26
4.2.6	System shall maintain version history for files that will be Uploaded.	T	3	PQ-eDocs step 40
4.2.7	<p>System shall maintain a version history which shall include the following:</p> <ul style="list-style-type: none"> • Date/Time of Upload • User • File Uploaded • File Version • Information / Action <p>NOTE: <i>Information / Action includes information about deleted files</i></p>	T	3	PQ-eDocs step 40
4.2.8	<p>Logging history shall include the following:</p> <ul style="list-style-type: none"> • Date and time of the activity • Username performing the action • File information and action block 	T	3	<p>PQ eDocs step 21</p> <p>PQ-eDocs step 47</p> <p>PQ-eDocs step 48</p>
4.2.9	System shall allow a user to download a file from the file history in the Information / action field.	T	3	PQ-eDocs step 41
4.2.10	System shall allow a user to delete a file from the file history in the Information / action field.	T	3	PQ-eDocs step 41
4.2.11	System shall retain deleted eDocs from REDCap database into the vault storage,	T	3	<p>PQ eDocs step 14</p> <p>PQ-eDocs step 44</p>
4.2.12	System shall enforce a mechanism to provide a reason for deletion prior to deletion of file.	T	3	<p>PQ eDocs step 21</p> <p>PQ-eDocs step 41</p>
4.2.13	System shall store date and time of the deleted file.	T	3	<p>PQ eDocs step 21</p> <p>PQ-eDocs step 42</p>
4.2.14	System shall retain reason of deletion of the deleted file.	T	3	<p>PQ eDocs step 21</p> <p>PQ-eDocs step 48</p>
4.2.15	System shall be able to export entire data collection instrument into a CSV file format.	T	2	PQ eDocs step 27

Req#	Requirement	Verification	Priority	Traceability
4.2.16	System shall provide a capability to download documents from eDocs module from Data Exports, Reports, and Stats.	T	2	PQ-eDocs step 49 PQ-eDocs step 50 PQ-eDocs step 51
4.2.17	System shall provide a capability to upload documents into eDocs module from Data Exports, Reports, and Stats.	T	2	PQ-eDocs step 52
4.2.18	System shall be capable of performing the following: <ul style="list-style-type: none"> • Upload New File • Remove File • Send file as an email 	T	3	PQ eDocs step 4 PQ eDocs step 7 PQ eDocs step 9
4.3	Password verification & automatic external file storage			
4.3.1	The system will allow any given project to utilize extra functionality regarding the use of file upload fields in the project.	T	3	PQ eDocs step 4
4.3.2	The system will ask to confirm that the file is correct while uploading and additionally ask the user to enter the REDCap password for the verification process	T	3	PQ eDocs step 5
4.3.4	The system will notify to save the changes or leave without saving the changes or stay on the page if the user proceeds without saving the record.	T	3	PQ eDocs step 28
4.4	4.4. Post Signature Form Updates and Versioning			
4.4.1	All versions of the files will be maintained within the project "vault."	T	3	PQ eDocs step 14
4.4.2	System shall maintain all versions of the files on REDCap servers	T	3	PQ-eDocs step 53
4.5	Executed eDocs Storage			
4.5.1	An appropriate "vault" will be set-up for each project.	T	3	IQ-eDocs Step 8 PQ eDocs step 14
4.5.2	The Vault will have limited access only to administrators of the Local Network.	T	3	IQ-eDocs Step 11
4.5.3	The Vault will have write once read many configurations.	T	3	IQ-eDocs Step 11
4.5.4	The Vault environment will be backed up daily.	T	3	IQ-eDocs Step 12
4.5.5	The Vault will have data encryption enabled.	T	3	IQ-eDocs Step 13
4.6	SFTP storage			
4.6.1	eDocs will interface with an SFTP storage location.	T	3	IQ-eDocs Step 10
4.6.2	eDocs will not interface with any other systems directly other than the storage SFTP or "vault."	T	3	IQ-eDocs Step 9
Non-Functional Requirements				
All non-functional requirements not specified in this document are defined by data and application architectures and SOPs.				
Regulatory Information				



User Requirement Specification of eDocs Module in REDCap application

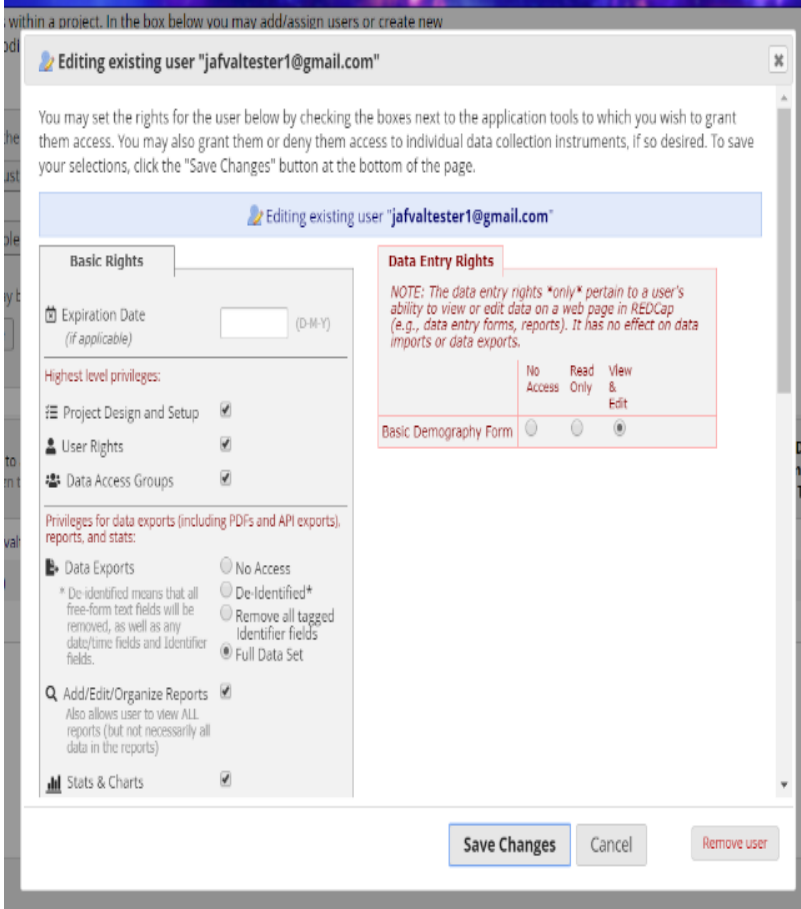
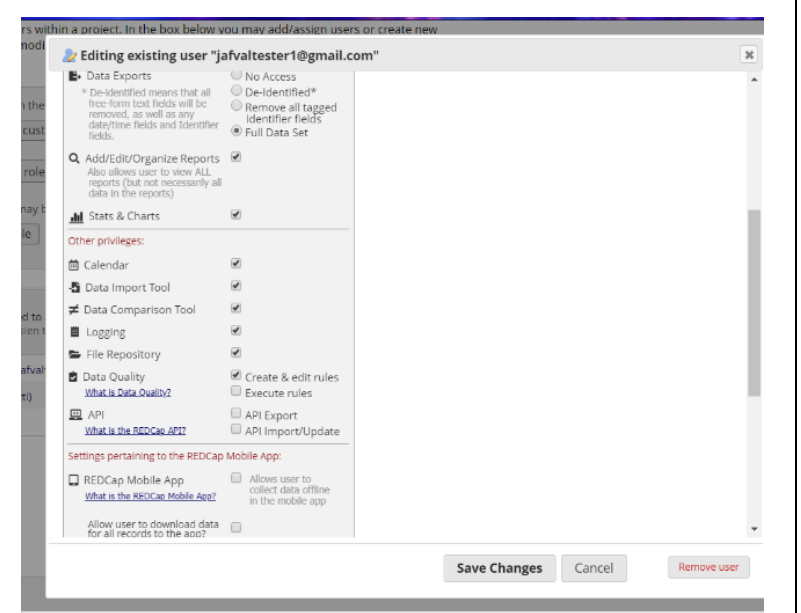
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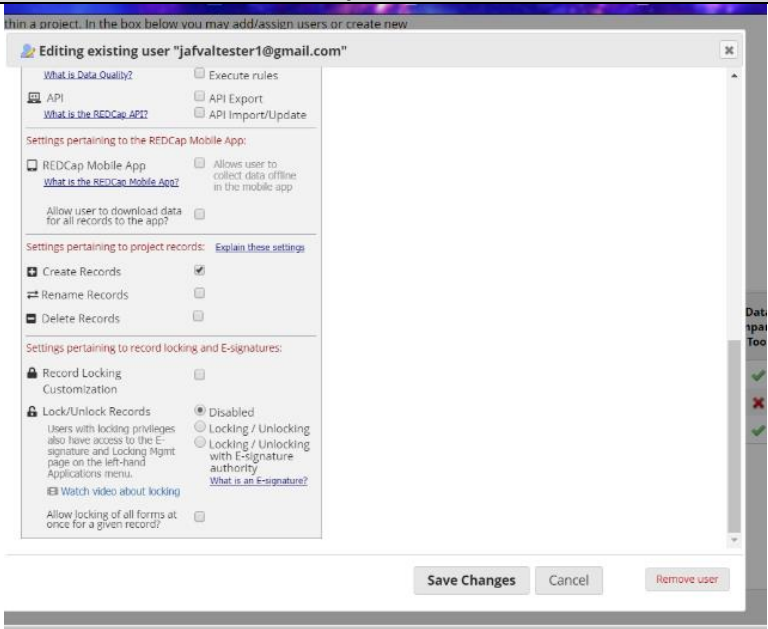
Req#	Requirement	Verification	Priority	Traceability
4.6.3	This system is subject to FDA 21 CFR Part 11, Electronic Records; Electronic Signatures and other global system regulations.	T / P	3	PQ-eDocs Step 3 & 6 Operation SOP Section 1 step 7
4.7	Special Remote Use			
4.7.1	eDocs does not allow for off-line usage.	T	3	PQ-eDocs Step 34
4.8	Documentation and Training			
4.8.1	The eDocs validation documentation will be maintained by Stride program at Vanderbilt University.	V	3	Validation Plan
4.8.2	The eDocs validation package will provide the basic design and associated functionality and testing to demonstrate that the application performs in an accurate and reliable manner.	V	3	Validation Plan
4.8.3	Training for eventual users of the eDocs module will be provided in association with the REDCap training modules.	V	3	PQ-eDocs Step 36
4.8.4	There WILL BE training on regulated use of the eDocs and configuration considerations necessary for compliant use and control of the product.	V	3	PQ-eDocs Step 36
4.9	Availability and Recoverability			
4.9.1	Disaster recovery and business continuity planning along with testing evidence will be developed and executed for the eDocs system and environment, effectively demonstrating the ability to recover and not lose data in the event of an outage or issues with the system or hosting environment.	T	2	IQ and PQ REDCap Database backup and restore procedure
4.10	Performance			
4.10.1	There are no known performance risks or limitations with the eDocs module within the REDCap application. The system supports concurrent users.	V	3	Administration SOP Section 5
4.11	Capacity			
4.11.1	eDocs storage and performance, because it is leveraging REDCap system and functionality, will be based on the REDCap system performance. The system will allow for concurrent users within the system without degradation of system performance.	V	3	Administration SOP Section 5
4.12	Installation Considerations			
4.12.1	For all supporting infrastructure or hardware (both for test and production implementation), a formal Installation Qualification including any noted configuration points will be executed to document the infrastructure and associated components necessary to run the application.	T	3	IQ Test Protocol
FDA 21 CFR Part 11 and Associated Global Regulatory Requirements				
4.13	Security			Verification

Req#	Requirement	Verification	Priority	Traceability
4.13.1	21 CFR Part 11 (g) The system should have effectively defined roles and access controls. Access should be granted to the system via appropriate entry of an acceptable User ID and password combination.	T / P	3	PQ eDocs Step 31 PQ eDocs Step 32 PQ eDocs Step 33 Administration SOP section 1 and 2
4.13.2	21 CFR Part 11 (g) (d) The system will enforce role-based authorization to various parts of the system. Refer to the matrix below for a list of roles supported by the system and the activities that each role is authorized to perform. Roles will have effective checks and balances on use, as well as, a process for granting access with appropriate authorization (may be non-testable, but confirmed with procedures).	T / P	3	PQ eDocs Step 31 PQ eDocs Step 32 PQ eDocs Step 33 Administration SOP section 1 and 2
4.13.3	User Roles and Permissions: eDocs User Roles are based on Data entry so every user regardless of the roles and permission can view and edit the records.	T / P	3	Administration SOP section 1 and 2
4.14	Audit Trail			
4.14.1	21 CFR Part 11 (g) (e) Actions performed within the system should be recorded within the audit trail and the role/user performing the action is included within the audit trail record.	T / P	3	PQ-eDocs step 40 PQ-eDocs step 46 Administration SOP section 1 and 2
4.14.2	eDocs will leverage the Logging, history and audit trail capabilities of the REDCap application framework.	T	3	PQ-eDocs step 21 PQ-eDocs step 40 PQ-eDocs step 46
4.14.3	21 CFR Part 11 (e) The system will provide secure, computer-generated audit trails to independently record all changes made to electronic records. The audit trail must contain the date and time of operator entries, the action performed (create, update, delete), the username of the operator performing the action, and the data elements affected. Record changes will not obscure previously recorded information.	T	3	PQ-eDocs step 21 PQ-eDocs step 48

Req#	Requirement	Verification	Priority	Traceability
4.14.4	An audit trail record will be created for every data process entry in the system.	T	3	PQ-eDocs step 21 PQ-eDocs step 40 PQ-eDocs step 46 PQ-eDocs step 48
4.14.5	Audit trail documentation will be retained and will be available for review and export.	T	3	PQ-eDocs step 21
4.14.6	Audit trail can be maintained with the data records for the length of the data retention requirements.	T	3	PQ-eDocs step 21
4.15	Process or Procedural Control			
4.15.1	All user interactions with the system will occur over an encrypted channel.	T	3	IQ-eDocs Step 14
4.15.2	21 CFR Part 11.30 For open systems, the application will demonstrate that an appropriate encryption standard is employed.	T	3	IQ-eDocs step 14
4.15.3	CFR Part 11.30 Systems should demonstrate that encryption is in effect for data in transit and while at rest.	T	3	IQ-eDocs step 14
4.15.4	Encryption Keys are maintained by VUMC	T	3	TBD
5	Hardware and Software Requirements			
5.1	A standard installation qualification document, defining the version of the software, the additional software and hardware components (i.e. PDF rendering software, etc.) and versions leveraged for the system to work, will be executed to capture these requirements.	V	1	IQ and PQ
6	User Groups			
6.1.1	User Groups and accounts for eDocs are managed per project and utilize functionality associated with the REDCap application. The associated screen shots included here is of the REDCap User Rights module, which will be utilized for eDocs account and role set-up:	T / P	N/A	Administration SOP section 1 and 2

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6.1.2	<div>User Roles and Permissions Matrix for e-Docs:</div> <table><tr><th>Activity</th><th>Administrator</th><th>Principle Investigator</th><th>Site Coordinator</th><th>Monitor / Auditor</th></tr><tr><td>Development of e-Docs Form</td><td>X</td><td>X</td><td>X</td><td></td></tr><tr><td>e-Docs Form Execution</td><td>X</td><td>X</td><td>X</td><td></td></tr><tr><td>Vaulting of Executed e-Consent Form</td><td>X</td><td>X</td><td>X</td><td></td></tr><tr><td>Read Only access to review e-Docs forms</td><td></td><td></td><td></td><td>X</td></tr></table>	Activity	Administrator	Principle Investigator	Site Coordinator	Monitor / Auditor	Development of e-Docs Form	X	X	X		e-Docs Form Execution	X	X	X		Vaulting of Executed e-Consent Form	X	X	X		Read Only access to review e-Docs forms				X	T	3	PQ e-Docs Step 31 PQ e-Docs Step 32 PQ e-Docs Step 33																																																																																																											
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6.1.3	<table><tr><th>Role name <small>(click role name to edit role)</small></th><th>Username or users assigned to a role <small>(click username to edit or assign to role)</small></th><th>Expiration <small>(click expiration to edit)</small></th><th>Project Design and Setup</th><th>User Rights</th><th>Data Access Groups</th><th>Data Export Tool</th><th>Reports & Report Builder</th><th>Graphical Data View & Stats</th><th>Calendar</th><th>Data Import Tool</th><th>Data Comparison Tool</th></tr><tr><td>—</td><td>gkumar@jafconsulting.com (G Kumar)</td><td>never</td><td>✓</td><td>✓</td><td>✓</td><td>Full Data Set</td><td>✓</td><td>✓</td><td>✓</td><td>✗</td><td>✗</td></tr><tr><td>—</td><td>jafvaltester1@gmail.com (jafvaltester 1)</td><td>never</td><td>✓</td><td>✓</td><td>✓</td><td>Full Data Set</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr><tr><td>—</td><td>jafvaltester2@gmail.com (jafvaltester 2)</td><td>never</td><td>✗</td><td>✗</td><td>✗</td><td>De-identified</td><td>✓</td><td>✓</td><td>✓</td><td>✗</td><td>✗</td></tr><tr><td>—</td><td>joe_franchetti (Joe Franchetti)</td><td>never</td><td>✓</td><td>✓</td><td>✓</td><td>Full Data Set</td><td>✓</td><td>✓</td><td>✓</td><td>✗</td><td>✗</td></tr><tr><td>—</td><td>taylor4 (Rob Taylor)</td><td>never</td><td>✓</td><td>✓</td><td>✓</td><td>Full Data Set</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr><tr><td>Administrator</td><td>[No users assigned]</td><td></td><td>✓</td><td>✓</td><td>✓</td><td>Full Data Set</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr><tr><td>Auditor / Monitor</td><td>[No users assigned]</td><td></td><td>✗</td><td>✗</td><td>✗</td><td>De-identified</td><td>✓</td><td>✓</td><td>✓</td><td>✗</td><td>✗</td></tr><tr><td>Data Entry Analyst</td><td>[No users assigned]</td><td></td><td>✗</td><td>✗</td><td>✗</td><td>✗</td><td>✗</td><td>✗</td><td>✗</td><td>✗</td><td>✗</td></tr><tr><td>Principle Investigator</td><td>[No users assigned]</td><td></td><td>✓</td><td>✓</td><td>✗</td><td>De-identified</td><td>✓</td><td>✓</td><td>✓</td><td>✗</td><td>✓</td></tr><tr><td>Study Coordinator</td><td>[No users assigned]</td><td></td><td>✗</td><td>✗</td><td>✗</td><td>De-identified</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td><td>✓</td></tr></table>	Role name <small>(click role name to edit role)</small>	Username or users assigned to a role <small>(click username to edit or assign to role)</small>	Expiration <small>(click expiration to edit)</small>	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder	Graphical Data View & Stats	Calendar	Data Import Tool	Data Comparison Tool	—	gkumar@jafconsulting.com (G Kumar)	never	✓	✓	✓	Full Data Set	✓	✓	✓	✗	✗	—	jafvaltester1@gmail.com (jafvaltester 1)	never	✓	✓	✓	Full Data Set	✓	✓	✓	✓	✓	—	jafvaltester2@gmail.com (jafvaltester 2)	never	✗	✗	✗	De-identified	✓	✓	✓	✗	✗	—	joe_franchetti (Joe Franchetti)	never	✓	✓	✓	Full Data Set	✓	✓	✓	✗	✗	—	taylor4 (Rob Taylor)	never	✓	✓	✓	Full Data Set	✓	✓	✓	✓	✓	Administrator	[No users assigned]		✓	✓	✓	Full Data Set	✓	✓	✓	✓	✓	Auditor / Monitor	[No users assigned]		✗	✗	✗	De-identified	✓	✓	✓	✗	✗	Data Entry Analyst	[No users assigned]		✗	✗	✗	✗	✗	✗	✗	✗	✗	Principle Investigator	[No users assigned]		✓	✓	✗	De-identified	✓	✓	✓	✗	✓	Study Coordinator	[No users assigned]		✗	✗	✗	De-identified	✓	✓	✓	✓	✓	T / P	3	PQ e-Docs Step 31 PQ e-Docs Step 32 PQ e-Docs Step 33 Administration SOP section 1 and 2
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6.1.4		T / P	3	Administration SOP section 1 and 2
6.1.5		T / P	3	Administration SOP section 1 and 2

Req#	Requirement	Verification	Priority	Traceability
6.1.6		T / P	3	Administration SOP section 1 and 2
7	Other Requirements			
7.1	There shall be an operation and administration procedure	V	1	Operation and Administration SOP
7.2	Computing Environment			
7.2.1	System shall be developed and validated in test environment	V	1	PQ-eDocs step 36