

REALTIME ReDOCS

REGULATORY DOCUMENT MANAGEMENT AT ITS BEST

MONITOR USER MANUAL

A FULLY VALIDATED AND PART 11 COMPLIANT ELECTRONIC DOCUMENT MANAGEMENT
SYSTEM FOR RESEARCH SITES, STUDIES AND PERSONNEL.

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INTRODUCTION

RealTime-eDOCS™ is a fully validated, Part 11 compliant, electronic document management system. RealTime-eDOCS™ is designed to create efficiencies when managing electronic regulatory records. This manual will guide sponsor monitors/CRAs when reviewing electronic records through the monitor portal issued by the research site.

The monitor portal allows sponsor CRAs/monitors access to their assigned study records. All records may be reviewed, tracked and downloaded as needed by the monitor. This portal is unique to each user and only reveals records specific to the user's study assignment and records can't be altered through this portal.

OBTAINING ACCESS TO THE MONITOR PORTAL

The investigator site will control access to the monitor portal. To maintain confidentiality, monitors will only receive access to the studies they are assigned. Once the investigator site sets up a monitor portal, the monitor will receive an email notification granting access and providing a temporary password to log in. Please keep the following in mind:

1. The monitor must provide the investigator site with a valid email address before receiving portal access.
2. For security reasons, the investigator site will create the monitor's username and provide it to the monitor separately from the temporary password email.
3. If you have any issues with gaining access to the monitor portal, always contact your investigator site.

GENERAL NAVIGATION

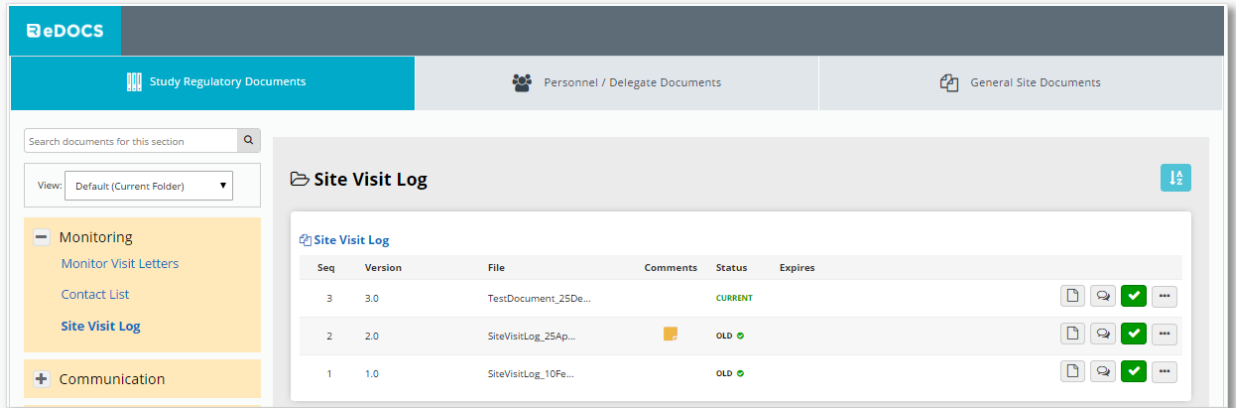
RealTime-eDOCS™ is designed to provide quick and easy access to study records utilizing simple and intuitive navigation. It is important to understand that RealTime-eDOCS™ is a web-based application; therefore, any additions, deletions or modifications that are made to data must be saved by clicking the 'Update/Save' button. Navigating away from a page containing new or edited data without clicking the 'Update/Save' button may result in loss of data.

There are two main areas of the RealTime-eDOCS™ monitor portal:

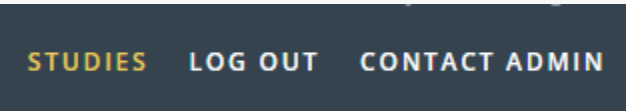
Home Page



Documents Section



All sections of the monitor portal will have the main header bar with the following links:




The **Studies** link will always bring the user back to the Home Page where their assigned studies are listed. Clicking the RealTime logo in the top left corner will bring the user to the Home Page also.

The **Log Out** link will log the user out of the system.

The **Contact Admin** link will allow the user to send a direct email to the system administrator at the investigator site.

HOME PAGE (STUDY LIST)

When first logging into the system, the monitor will be able to view a list of all studies assigned to their username. Simply click the appropriate study to start reviewing records or click the  icon.

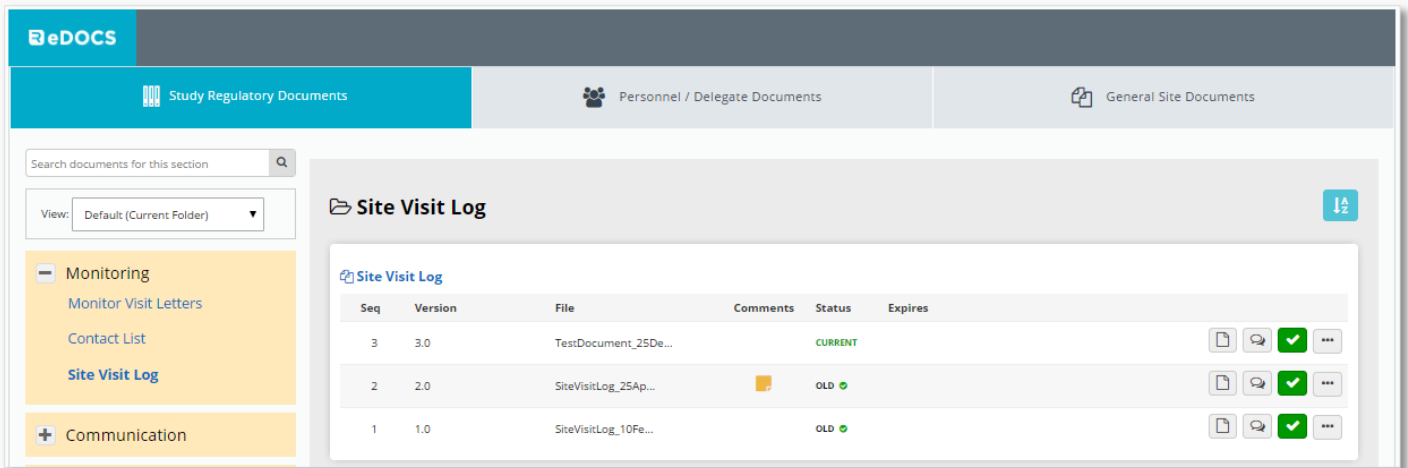


The screenshot shows the REALTIME ReDOCS interface. The header includes the logo, user name 'Welcome Tracy Test', and 'Log Out'. Navigation links for 'STUDIES', 'LOG OUT', and 'CONTACT ADMIN' are present. The main content area is titled 'Clinical Studies' and contains a table with the following data:













SPONSOR	CLINICAL DESCRIPTION	PROTOCOL	STATUS	OPTIONS
BigPharma Healthcare	Test Docs Study	ABC-123	Enrolling	
XYZ Pharma	Atopic Dermatitis	123ABC	Enrolling	

STUDY DOCUMENTS


After accessing a study, the Study Regulatory Documents section under the eDOCS tab will be where most study records are viewed by the monitor. To promote consistency and efficiency, this section will be organized according to the investigator site's standard operating procedure.

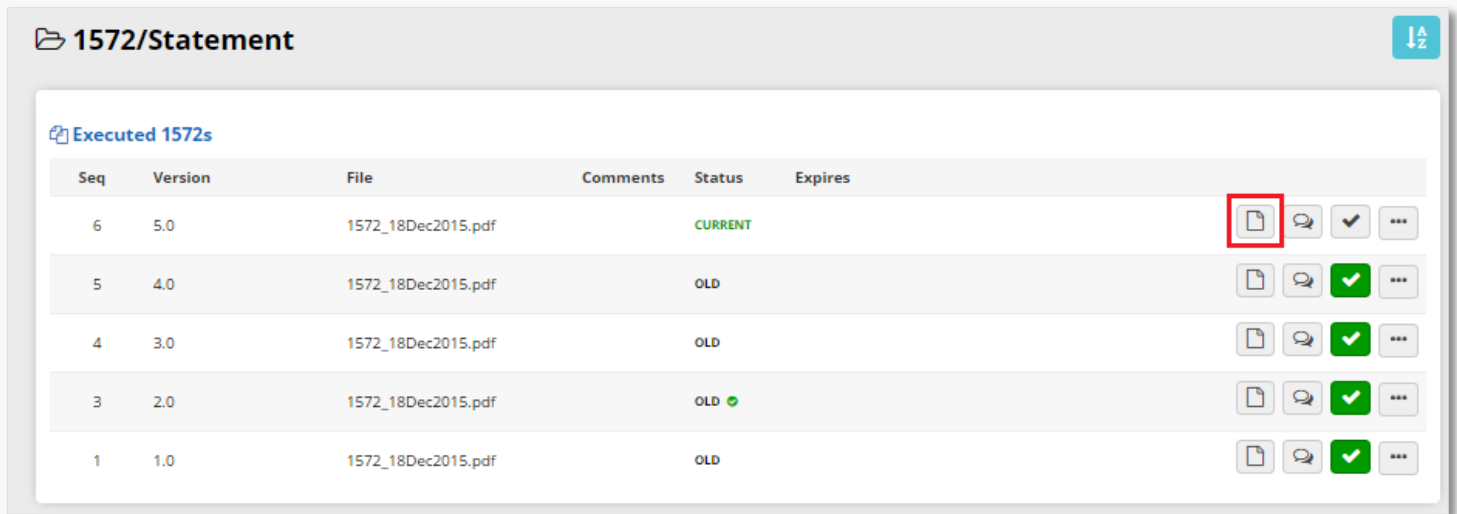


The screenshot shows the 'Study Regulatory Documents' section in the REALTIME ReDOCS interface. It features a search bar, a view dropdown set to 'Default (Current Folder)', and a sidebar with categories: Monitoring (Monitor Visit Letters, Contact List, Site Visit Log), and Communication. The main content area displays a 'Site Visit Log' table with the following data:

Seq	Version	File	Comments	Status	Expires	Actions
3	3.0	TestDocument_25De...		CURRENT		   
2	2.0	SiteVisitLog_25Ap...		OLD		   
1	1.0	SiteVisitLog_10Fe...		OLD		   






















REVIEWING DOCUMENTS

Monitors will be able to view all records uploaded to the system for their assigned studies clicking the  icon to the right of each document.





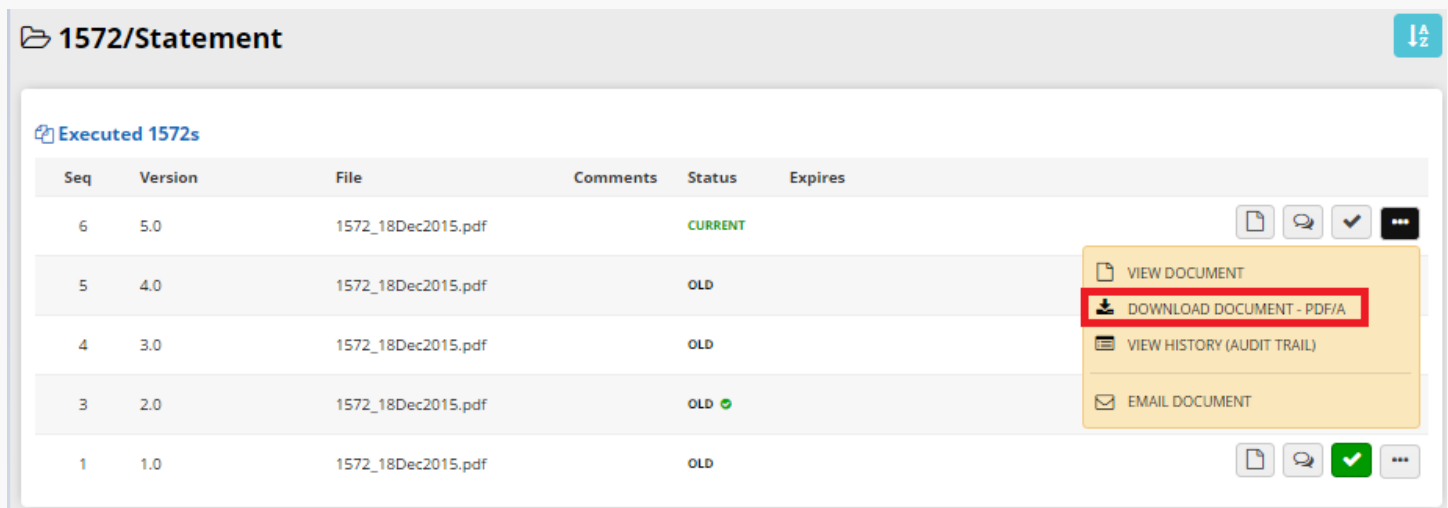
1572/Statement

Executed 1572s

Seq	Version	File	Comments	Status	Expires	
6	5.0	1572_18Dec2015.pdf		CURRENT		   
5	4.0	1572_18Dec2015.pdf		OLD		   
4	3.0	1572_18Dec2015.pdf		OLD		   
3	2.0	1572_18Dec2015.pdf		OLD 		   
1	1.0	1572_18Dec2015.pdf		OLD		   






















DOWNLOADING DOCUMENTS

Records can be downloaded by the monitor to print/file within the sponsor trial master file. To download a record, simply locate the file and click the  icon. Next, click the  icon to download the document.



1572/Statement

Executed 1572s

Seq	Version	File	Comments	Status	Expires	
6	5.0	1572_18Dec2015.pdf		CURRENT		   
5	4.0	1572_18Dec2015.pdf		OLD		   
4	3.0	1572_18Dec2015.pdf		OLD		   
3	2.0	1572_18Dec2015.pdf		OLD 		   
1	1.0	1572_18Dec2015.pdf		OLD		   

- VIEW DOCUMENT
- DOWNLOAD DOCUMENT - PDF/A**
- VIEW HISTORY (AUDIT TRAIL)
- EMAIL DOCUMENT

Depending on the browser, the download status should appear at the bottom of the browser. For example, the Google Chrome browser will show all downloads at the bottom of your screen. To view and save this document on your computer (or other drive), click on the download at the bottom of the screen. The record will open in a separate browser window and allow the user to save or print the file.



FILTERING

Records can be filtered to assist monitors in their review of study records. Records can be filtered using the drop-down menu at the top left corner to assist monitors in their review of study records.

A screenshot of the eDOCS web application interface. The top navigation bar includes 'eDOCS' and three tabs: 'Study Regulatory Documents', 'Personnel / Delegate Documents', and 'General Site Documents'. Below the navigation is a search bar and a 'View: Default (Current Folder)' dropdown menu, which is highlighted with a red box. The main content area shows a folder view for '1572/Statement' with a sub-section titled 'Executed 1572s'. This section contains a table with the following data:

Seq	Version	File	Comments	Status	Expires
6	5.0	1572_18Dec2015.pdf		CURRENT	
5	4.0	1572_18Dec2015.pdf		OLD	
4	3.0	1572_18Dec2015.pdf		OLD	
3	2.0	1572_18Dec2015.pdf		OLD	
1	1.0	1572_18Dec2015.pdf		OLD	

Each row in the table has a set of action icons on the right, including a document icon, a comment icon, a checkmark icon, and a three-dot menu icon.

Filtering options include:


Default (Current Folder)

- Allows the user to view all documents within a given folder.


All Documents in this Section

- Allows the user to view all records within a given section. There may be multiple folders within a section.


Reviewed Documents

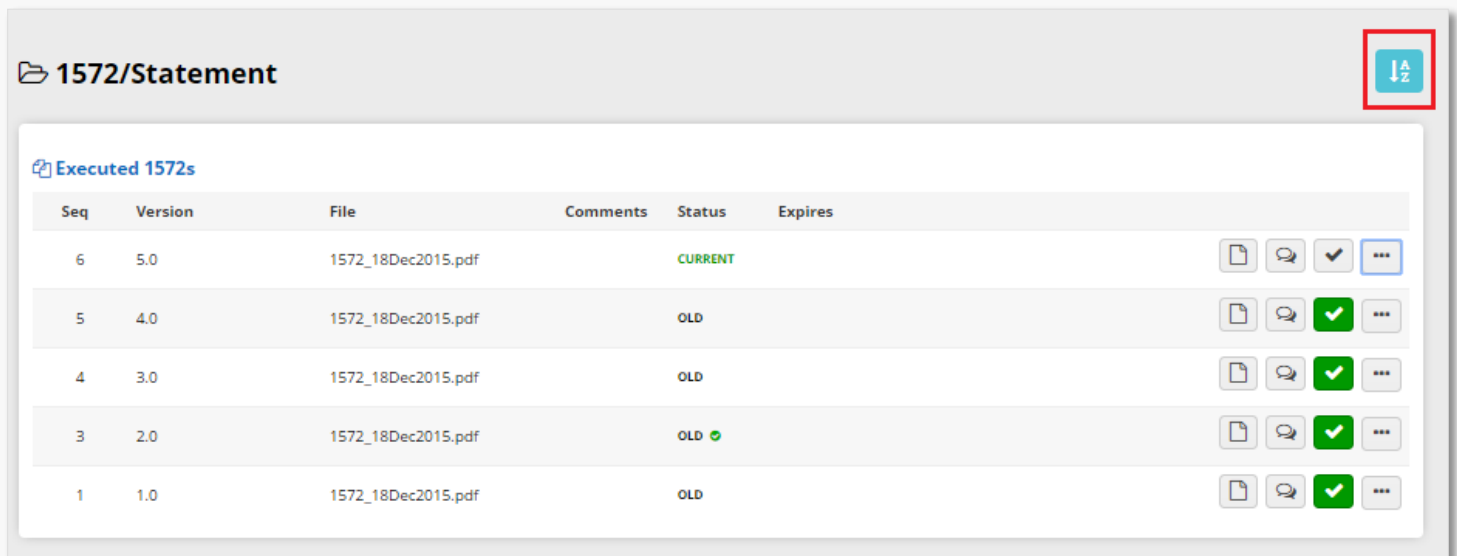
- Allows the user to view all records that have been reviewed and approved by the monitor. Reviewed records are indicated with the  icon.

Review Pending Documents

- Allows the user to view all records that require review and approval by the monitor. Pending records are indicated by the  icon.
-

SORTING RECORDS

Records can also be sorted using the  icon at the top right of the screen. Records can be sorted based on document title, the date the document was uploaded, the date the record was updated, or by the record's expiration/renewal date.



1572/Statement

Executed 1572s

Seq	Version	File	Comments	Status	Expires
6	5.0	1572_18Dec2015.pdf		CURRENT	
5	4.0	1572_18Dec2015.pdf		OLD	
4	3.0	1572_18Dec2015.pdf		OLD	
3	2.0	1572_18Dec2015.pdf		OLD	
1	1.0	1572_18Dec2015.pdf		OLD	

PERSONNEL AND DELEGATES

The Personnel and Delegates section will allow monitors to review training and qualification records for each staff member assigned to a study. The investigator site can add/remove individuals as needed.

The screenshot shows the eDOCS interface for the 'Personnel / Delegate Documents' section. The top navigation bar includes 'Study Regulatory Documents', 'Personnel / Delegate Documents' (highlighted), and 'General Site Documents'. A search bar is located above the left sidebar. The sidebar contains expandable categories: 'Principal Investigator', 'Sub Investigators', 'Site Staff' (with a count of 1), and 'Other Personnel / Delegates'. Under 'Site Staff', 'Nathan Levens' is listed with a count of 1. The main content area is titled 'Nathan Levens' and contains two document sections: 'Company CV' and 'License - DEA'. Each section has a table with columns for Seq, Version, File, Comments, Status, and Expires. Action icons (document, comment, checkmark, and more) are visible for each row.

Company CV

Seq	Version	File	Comments	Status	Expires	
4	4.0	TestDocument_04No...		CURRENT	Expires 11/JUL/2019	[Document] [Comment] [Checkmark] [More]
3	3.0	TestDocument_04No...		OLD	Expires 11/JUL/2019	[Document] [Comment] [Checkmark] [More]
2	2.0	CVTest.pdf		OLD	Expires 09/DEC/2018	[Document] [Comment] [Checkmark] [More]
1	1.0	CVTest_25Dec2015...		OLD	Expired 07/JAN/2016	[Document] [Comment] [Checkmark] [More]

License - DEA

Seq	Version	File	Comments	Status	Expires	
2	2.0	LicenseTest_18Dec...		CURRENT	Expires 17/JUL/2019	[Document] [Comment] [Checkmark] [More]
1	1.0	LicenseTest_18Dec...		OLD	Expires 18/DEC/2017	[Document] [Comment] [Checkmark] [More]

GENERAL SITE DOCUMENTS

The General Site Documents section is where monitors will find records that apply to the entire investigator site, not just one particular study. For example, an investigator site may upload equipment calibration records, CLIA certificates and certain temperature logs to this section.

BeDOCS

Study Regulatory Documents

Personnel / Delegate Documents

General Site Documents

Search documents for this section

+ Site Calibrations 1

- Temperature Logs

Temp Logs - Downtown Location

Temp Logs - Main Street Locations

+ Lab Certifications

+ SOPs









Temp Logs - Downtown Location

Temp Log - Main Drug Room - DT

Seq	Version	File	Comments	Status	Expires
4	4.0	TestDocument_04No...		CURRENT	
3	3.0	ProtocolDeviation...		OLD	
2	2.0	Temp Logs - Main ...		OLD	
1	1.0	Temp Logs - Main ...		OLD	

DOCUMENT OPTIONS

Once a document is uploaded into the system, the user will have a few options to choose from:


1. The  icon allows users to view the document.
2. The  icon allows users to message (or issue queries) to the investigator.
3. The  icon allows the user to indicate that a document has been reviewed and approved by the monitor.
4. The  icon offers an extended list of options, which includes the ability to:
 - a.  Download the document from the system.
 - b.  View the history (Audit Trail).
 - c.  Message Study Staff/Delegates.
 - d.  Email document using secure Document Link

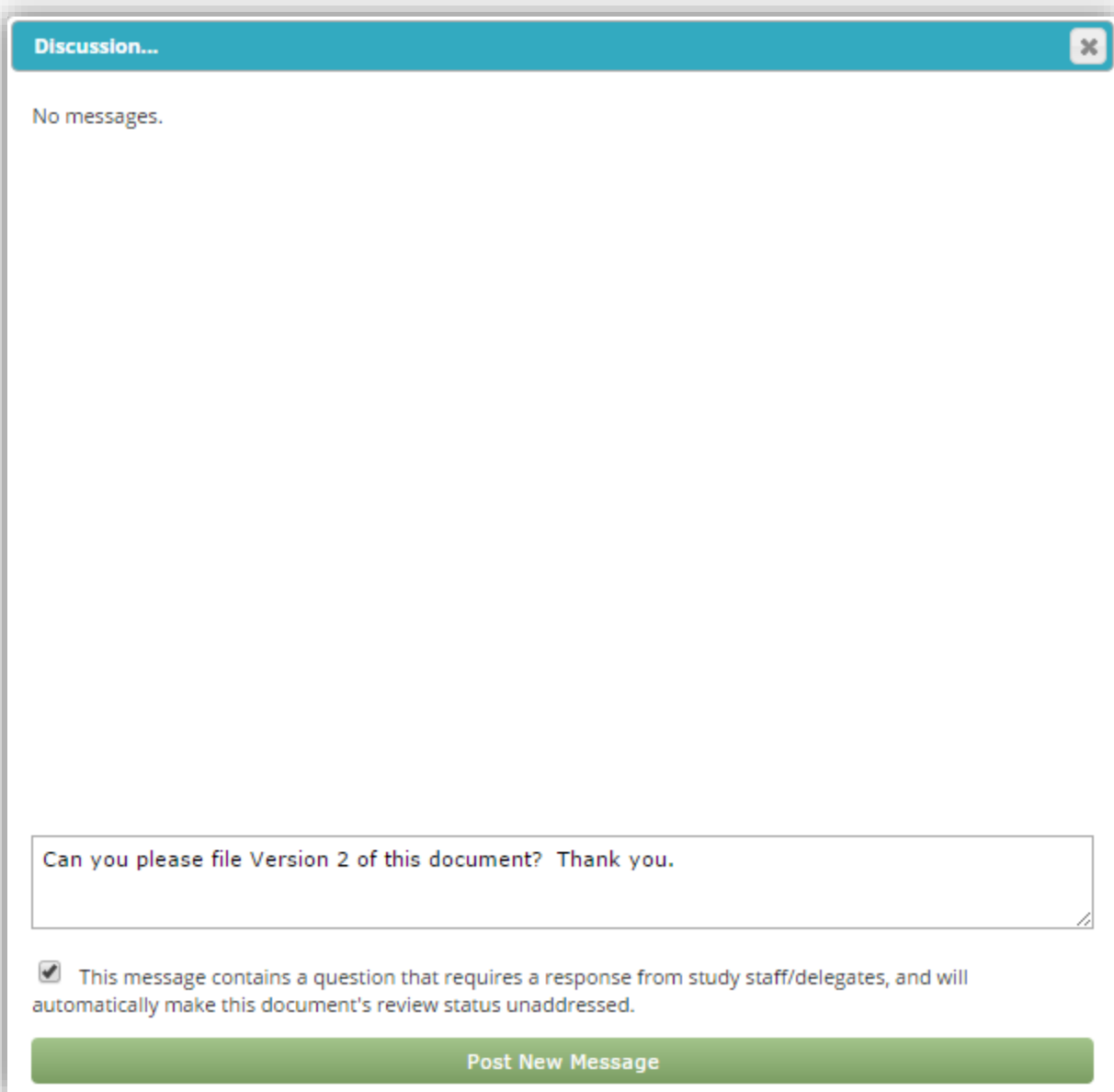
Temp Log - Main Drug Room - DT

Seq	Version	File	Comments	Status	Expires
4	4.0	TestDocument_04No...		CURRENT	
3	3.0	ProtocolDeviation...		OLD	
2	2.0	Temp Logs - Main ...		OLD	
1	1.0	Temp Logs - Main ...		OLD	

- VIEW DOCUMENT
- DOWNLOAD DOCUMENT - PDF/A
- VIEW HISTORY (AUDIT TRAIL)
- EMAIL DOCUMENT

ISSUING MONITOR QUERIES

Monitors can issue queries through the monitor portal using the  button located to the right of each record. This button activates a discussion board.



Discussion...



No messages.

Can you please file Version 2 of this document? Thank you.


This message contains a question that requires a response from study staff/delegates, and will automatically make this document's review status unaddressed.






Post New Message


To post a query, ensure that the checkbox at the bottom indicates that the message requires a response from the site before clicking the **Post New Message** button. To post a message without requiring the site to respond to the query, simply uncheck the box . This feature allows the monitor to write notes about a record without asking for a formal response from the investigator site.

Once the message is posted and the monitor requests a formal response to a query, the site will be notified of an open query and the document icon will turn red . Also, anytime comments are added to a record, the  icon will show up in the Comments column indicating that comments have been documented.


Contact List ↓ A Z











Sponsor/CRO Contact List 




Sequence	Version	File	Comments	Status	
3		ContactList_08Jan2015.docx		CURRENT 	   

Once the investigator site addresses the query, the document notification will turn yellow . Yellow indicates that the query is ready to be verified by the monitor.


Contact List ↓ A Z











Sponsor/CRO Contact List 

Sequence	Version	File	Comments	Status	
3		ContactList_08Jan2015.docx		CURRENT 	   
2	2.0	ContactList_08Jan2015.docx		OLD	   

The monitor will click the  icon to view the site's response. If the response is sufficient, the monitor simply clicks the  icon to change it to  indicating that the query is closed out and the record is approved as filed.

Contact List ↓ A Z

Sponsor/CRO Contact List 

Sequence	Version	File	Comments	Status	
3		ContactList_08Jan2015.docx		CURRENT 	   
2	2.0	ContactList_08Jan2015.docx		OLD	   

If the response is not sufficient, simply post another comment to restart the query process.

ELECTRONIC SIGNATURES

The investigator site may utilize electronic signatures when signing records. When electronic signatures are utilized, the monitor will see an attached digital stamp that includes a username of the person that signed the document and the date and time in which the record was signed. Electronic signatures within the RealTime-eDOCS™ system are Part 11 compliant and cannot be removed or modified.

This is a representation of an electronic record that was signed electronically.

This page is a manifestation of the electronic signature and was added Jan 11, 2016 9:08 AM CST

Document Name: 1572 - Version 1.0

Document ID: 206

Study: Aastrom Biosciences - Test Docs Study - TEST-134

Statement of Testament: I have reviewed and approve the document

Electronic Signature for: Nathan Levens

Electronically Signed by: nlevens

Date & Time: Jan 11, 2016 9:08 AM CST

IP Address: 71.42.199.146

CERTIFIED COPIES OF ORIGINAL DOCUMENTS

RealTime-eDOCS™ allows investigator sites to upload certified copies of original documents. This feature is mostly used to scan and upload “wet ink” documents to the system for electronic record keeping. Original paper documents are maintained with the investigator per site operating procedures. All certified copies within RealTime-eDOCS™ are considered exact copies of the original record.

Certified copies will include a digital stamp attached directly to the electronic record. This stamp will indicate the username of the person that certified the record and include a date and time that the record was certified.

This page is the manifestation of an electronic signature certifying that I have reviewed the electronic copy of this document and certify that it is an exact copy having all of the same attributes and information as the original document.

Document Name: Sponsor/CRO Contact List

Document ID: 232

Study: BigPharma Healthcare - Test Docs Study - ABC-123

Electronic Signature for: Site Administrator


Electronically Signed by: admin

Date & Time: 12/May/2016 2:33 PM CDT

IP Address: 71.42.199.146

AUDIT TRAIL

RealTime-eDOCS™ maintains a secure, computer generated, time-stamped audit trail of all user actions that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record. The investigator site maintains access to a complete audit history of each record within the system. Activities in the monitor portal will be included in the audit history for each record.

Viewing the audit history of a particular electronic record is simple. To view the audit trail for a particular document, simply click the audit trail icon  for the document under review and the complete history will appear in a pop-up window. The audit history may be filtered by Action Type and/or User.

1572

Sequence	Version	File	Comments	Status
1	1.0	1572_18Dec2015.pdf		CURRENT

- VIEW DOCUMENT
- DOWNLOAD DOCUMENT - PDF/A
- VIEW HISTORY (AUDIT TRAIL)**
- MESSAGE STUDY STAFF/DELEGATES

Audit Trail: 1572

Action Type ▼ User ▼

- Viewed by Tracy Test on 12/MAY/2016 9:46 AM / 71.42.199.146
- Viewed by Nathan Levens on 06/MAY/2016 12:55 PM / 71.42.199.146
- +** Updated by Tracy Test on 25/APR/2016 9:49 AM / 71.42.199.146
- +** Updated by Tracy Test on 25/APR/2016 9:46 AM / 71.42.199.146
- Viewed by Tracy Test on 25/APR/2016 9:46 AM / 71.42.199.146
- Viewed by Nathan Levens on 25/APR/2016 9:29 AM / 71.42.199.146
- Viewed by Nathan Levens on 25/APR/2016 9:26 AM / 71.42.199.146
- +** Created by Nathan Levens on 25/APR/2016 9:26 AM / 71.42.199.146

ARCHIVAL OF RECORDS

Records saved within the RealTime-eDOCS™ system are archived on multiple servers and backed up on at least a daily basis. All records are saved as a PDF/A file. PDF/A is an ISO-standardized version of the PDF specialized for digital preservation of electronic records. Sponsors, CROs, IRBs and the FDA can be granted access to archived records by the investigator site at any time.