Title: CLUWE Web Tool System Overview

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TITLE: CLUWE WEB TOOL SYSTEM OVERVIEW

Training Requirement

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New Procedure				
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- Meets the requirements of the Lilly Quality Practice: Requirements and Design (LQP302-16)

System Owner

Your electronic signature attests that the system overview is complete and accurate and you understand your responsibility to be able to explain the system overview and the intended use of the computer system relative to regulatory and business requirements.

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TITLE: CLUWE WEB TOOL SYSTEM OVERVIEW

PURPOSE

This System Overview provides high-level information about CLUWE Web Tool.

SCOPE

The following are in scope:

- Job Scheduling
- Versioning
- Electronic Signature (eSignature)
- Re-lock Files
- JReview Integration
- Automated Versioning

The following are out of scope:

- SAS Grid/ SAS GSub Command line tool
- Data Migration
- Data Conversion

ACRONYMS AND DEFINITIONS

The terms and acronyms in this document are defined at their first occurrence.

DOCUMENT REVISION HISTORY

Version	Revision Date	Reason for Revision (Include CR#, if Applicable)	Revised By, Title
5	10 July 2017	Updated per CHG1092912 Changes made to the following sections: Updated scope	J. Jason Rees, IT SME
		1.0 added Automated Versioning	
4	23-May-2017	Added Training grid on the first page.	Priyanka Mehra, Validation Lead
3	5 May 2017	Updated per CHG1074979. Changes made to the following sections: 4.0 Updated Diagram	J. Jason Rees, IT SME
		7.0 Added new section and renumbered remaining	
2	23 Mar 2017	Updated per CHG1057702. Changes made to the following sections:	David Fleig, IT SME
		1.0: Added JReview paragraph	
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1	17 Aug 2016	Updated per CHG0783626. Changes made to following sections:	David Fleig, IT SME
		1.0: Added paragraph, Re-Lock Files	
		4.0: Added bullet point 3, CLUWE Services	
		4.0: Added bullet point 4, Apache ActiveMQ	

Version	Revision Date	Reason for Revision (Include CR#, if Applicable)	Revised By, Title
0	6-Oct-2015	New Document.	David Fleig,
			Execution Lead

Table of Contents

1.	BASIC FUNCTIONS AND FEATURES	5
	SITES AND FACILITIES	
	DATA	
	SYSTEM ARCHITECTURE	
	INTERFACE DIAGRAM	
	ELECTRONIC RECORDS/ELECTRONIC SIGNATURES	
7.	OPEN SOURCE	8
8.	REFERENCES	10

1. BASIC FUNCTIONS AND FEATURES

Lilly's Clinical Users Working Environment (CLUWE) system provides a centralized repository and execution environment that allows Lilly statisticians to analyze clinical research data in a controlled, secure and documented way. The Web Tool component of Lilly's CLUWE system is comprised of applications and services custom developed to meet business requirements which were not met by the Commercial, Off-The-Shelf (COTS) components of CLUWE. These applications and services include the following.

Securing Production Files

Files in the production (prd) branch of the CLUWE repository are automatically changed to read-only by the Lock-in-Place background service. A new file's security is changed to a read-only state after the file has been inactive for 60 minutes. Once changed to a read-only state, the file is not able to be modified by users.

Electronically Signing Files

The Sign application enables the user to electronically sign (eSign), on behalf of themselves or as a delegate, files stored in the production (prd) branch of the CLUWE repository.

Versioning Files

Files in the production (prd) branch of the CLUWE repository are automatically changed to read-only by the system. When a post-production change is required, the existing files must be versioned before replacement files can be re-created. The Version application enables the user to identify and version the files that need replacement.

The version functionality is available to other systems through a set of RESTful web services. The Taffy, M2C and Integration Broker systems all call the version services to version files when needed.

Scheduling SAS Programs to Execute

The Schedule application enables the user to schedule SAS programs for execution on the SAS Grid either for immediate execution or for execution on a specific date and time.

Viewing Information about Files

The Info application enables the user to view a subset of file property information. For files that have been electronically signed, the user is also able to view the electronic signature information.

Re-lock Files

The Business Administrators are able to re-lock files and prior_versions folders on the Isilon whenever they make changes that would change the locked status of a file or prior_versions folder. When selected through an Admin tab only available to Business and IT Administrators, the system will start at the selected root folder and lock files and prior_versions folders recursively.

Permission Export for JReview

The JReview system is unable to directly interpret the CLUWE repository permissions so a process to export permissions from the repository to JReview was established. This process executes every two hours.

Automated Versioning of Files

Automated Versioning enables all output, data and log files to be locked and all TFL and log files to be automatically versioned upon program completion. Automated Versioning is limited only to files written to the output folder, the log folder, and their respective sub-folders. This functionality will be invoked only for programs that are submitted through the Schedule function of the CLUWE Web Tool and reside within the \prd branch of the repository. Files created in the \prd branch of the repository by programs residing outside of the \prd branch of the repository will NOT invoke this functionality.

2. SITES AND FACILITIES

The system is hosted in Indianapolis with the primary components deployed in the 141-2 Data Center at the Lilly Technology Center (LTC) and the backup components at the Lilly MetroHA facility. End users will access the system from the Lilly Intranet as well as through VPN connections at Third Party Organization (TPO) sites.

3. DATA

The system processes clinical trial datasets with an Information Classification of Orange. Additionally, it processes BCI, PI and SPI data.

4. SYSTEM ARCHITECTURE

The primary component of the system is the CLUWE Web Tool application. This custom java application consists of a web site hosted on Linux servers running jBoss Enterprise Application Platform (EAP) and a set of micro-services hosted on Linux servers. An F5 load balancer to distribute traffic between the jBoss EAP servers. The web site provides the user interface and web services for external integrations while the micro-services provide the business logic. Authentication is provided by the Lilly Active Directory (AD) Lightweight Directory Access Protocol (LDAP) service with authorization performed by the application based on AD group membership. The servers are hosted in MetroHA.

The components below support the functionality of the Web Tool

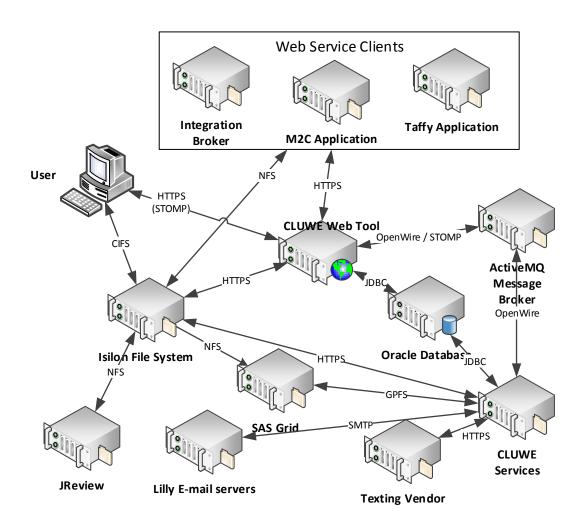
- EMC Isilon Network Attached Storage: This device is managed by the Lilly Storage Team and acts as a file repository for the SAS datasets, SAS programs and other artifacts generated by the business processes. It is available to both Windows and Linux systems and presents a single permission model regardless of the operating system it is accessed from. A backup cluster is hosted off-site for disaster recovery and file restoration purposes. The Isilon does not provide versioning or user accessible metadata services.
- SAS Grid: The grid is a SAS program execution engine managed by the Enterprise Analytics team. The grid
 is hosted in MetroHA.
- Oracle Database: The database stores the Web Tool's transactional data as well as the audit data generated by the user's activities within the Web Tool. The database is hosted in MetroHA.
- CLUWE Services: System functionality has been distributed among several java Spring Boot applications
 called Services. These services monitor message queues for commands, execute those commands and
 return their completion status to the user. Multiple instances of a service can run at the same time
 increasing the performance of the system.
- Apache ActiveMQ Message Broker: The message broker orchestrates message delivery between the CLUWE Services and the CLUWE Web Application executing on the jBoss servers. The message broker is managed by the Web Hosting Organization (WHO).

Users interact with the system primarily through the Web Tool which allows users to select files from the Isilon file system and perform actions on those files such as version, sign or submit SAS programs to the grid for execution. The Isilon folders and files for which the user has access are displayed in the navigation area of the site. User actions are represented by tabs labelled with the action name such as Version and Schedule. When a tab is selected, the navigation area of the site updates to only display files for which the action can be applied. For instance, only SAS programs are executable on the grid so selection of the Schedule tab by the user results in the navigation area only displaying SAS programs.

Once the user initiates an action on one or more files, the user can continue using the site while the custom java code on the web servers orchestrates the steps required to fulfill the action. All the actions available to the user require the integration of the Isilon and the database. File permission changes, moves and rename operations are performed through the Isilon Platform Application Programming Interface (PAPI) web services. The site does not open files nor does it modify the contents of any files. All actions, except for Info, store who initiated the action, when it was initiated, the status and additional action specific data in the database. This data cannot be modified by users.

Scheduler functionality requires two additional integrations; the Quartz scheduler and the SAS command-line utility named "sasgsub". The sasgsub submits SAS programs to the grid and returns the grid job id, log location and work directory which are stored in the database. The sasgsub utility only submits jobs to run immediately so the Web Tool site uses the Quartz scheduler libraries to execute sasgsub at the scheduled times. The Linux sudo functionality allows Quartz to execute sasgsub as the user who submitted the program(s) so all user permissions will be honored by the grid during execution. SAS jobs are monitored using the the "bjobs" command-line tool provided by SAS.

Users can also access the Isilon file system directly as a Windows or NFS file share to view or modify programs or datasets if their permissions allow. User permissions are controlled through Windows file permissions and Active Directory groups. When a user is added to a CLUWE AD group, they inherit the permissions assigned to the group. The Isilon ensures that the permissions are the same regardless of whether the user is accessing the files through Windows or Linux. For instance, when a user is given read access to a file from Windows the user will also be given read access in Linux. This merging of permissions requires that all CLUWE users have both an AD account and a Linux account.



5. INTERFACE DIAGRAM

In addition to the interfaces described above, the Isilon file system is mounted on other systems such as Integration Broker to allow those applications to read or write data files.

6. ELECTRONIC RECORDS/ELECTRONIC SIGNATURES

LQP-302-24, Electronic Records; Electronic Signature defines the requirement that computer system meet to consider electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper

Any file that has not been versioned and resides in the "Prd" branch of the Isilon file system can be electronically signed using the Web Tool. The user selects the signature meaning at the time of signing.

7. OPEN SOURCE

The following OSS Java Libraries are used by the system but are supported through the RedHat JBoss Enterprise Application Platform. Because of the RedHat support and the industry wide adoption of the libraries there is no risk in using them.

Package	Spring Framework	
Intended Use	Java application development framework	
Functionality within the System	Performs the following functions within the system: Dependency Injection LDAP Integration LDAP Group to Role modeling Security Property Injection Web Service Client and Server Model View Controller (MVC) implementation	
Complexity	High	

Package	Hibernate
Intended Use	Object Relational Modeling (ORM) persistence framework for simplifying database access.
Functionality within the System	Handles all database transactions.
Complexity	High

Package	Apache Commons	
Intended Use	Reusable modules for common system activities	
Functionality within the System	Commons libraries are used for the following purposes: • Parsing and creating file system paths • Base64 encoding	
Complexity	Medium	

Package	Quartz
Intended Use	Java job scheduling library
Functionality within the System	Responsible for scheduling the execution of SAS programs for the Job Scheduler functionality.
Complexity	Medium

Package	Jackson JSON Parser
Intended Use	Java library for processing JSON data formats
Functionality within the System	Serialize and de-serialize messages to and from the Isilon NAS.
Complexity	Medium

Package	Jasypt Encryption Library
Intended Use	Java library for encrypting and decrypting data
Functionality within the System	Handles the encryption and decryption of application properties.
Complexity	Medium

The following OSS packages are approved for Lilly use through the OSS Governance process (http://lillynet.global.lilly.com/sites/ditse/OSSGovernance/default.aspx). Their use within the system is to provide consistent web site UI controls which respond directly to the user actions instead of requiring a response from the servers. The risk associated with using these libraries is low as they do not modify any data and their use is reviewed.

Package	Bootstrap
Intended Use	Front-End Framework for creating web applications
Functionality within the System	Handles all user input and data display.
Complexity	High

Package	jQuery
Intended Use	For adding advanced UI interactivity on web applications.
Functionality within the System	First stage of user input validation before server side validation. Passes data to the servers and displays server response.
Complexity	High

Package	FancyTree jQuery Tree Control
Intended Use	Represent the Isilon file system allowing the user to select files for system actions.
Functionality within the System	First stage of user input validation before server side validation. Passes data to the servers and displays server response.
Complexity	Medium

8. REFERENCES

A current list of system-specific documents stored in Regulus can be generated using Regulus. The documents are stored in the IT Library Regulus repository at IT_Library > LRL IT > Systems C to D > CLUWE and IT_Library > LRL IT Secure > Systems C to D > CLUWE.