Title:	CLUWE Web Tool Business Continuity Plan

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TITLE: CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL BUSINESS CONTINUITY PLAN (BCP)

REVIEWERS

Your electronic signature indicates that you have reviewed this document and that for your area of expertise, agree it is accurate and complete.

Business Subject Matter Expert

Quality Consultant

APPROVERS

System Custodian

Your electronic signature attests that this plan was written and reviewed by the appropriate subject matter experts, is feasible from a technical perspective, and is appropriate based on the DRP and considering the likelihood of the computer system being unavailable to support critical business processes.

System Owner

Your electronic signature attests that this plan was written and reviewed by the appropriate subject matter experts, addresses all requirements for a BCP, accurately describes the process required to run the business while the system is unavailable, and is appropriate considering the likelihood of the computer system being unavailable to support critical business processes.

Business Quality Assurance (BQA) Representative

Your electronic signature attests that applicable regulatory and business requirements have been met.

TITLE: CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL BUSINESS CONTINUITY PLAN (BCP)

PURPOSE

The continuity plan defined in this document ensures essential business operations can continue during an outage of the CLUWE Web Tool. It will refer to the processes that the business will follow until the CLUWE Web Tool is restored.

SCOPE

The following areas are in scope for this BCP:

Process	Purpose
CLUWE Tools – Scheduling Jobs	Allows end users the ability to submit and schedule SAS programs to run in a background process on the SAS Grid
CLUWE Tools – Electronic Signature (eSign)	Allows end users the ability to eSign production files with specified signature meanings.
CLUWE Tools – Versioning	Allows end users the ability to version production files within Lillyce file repository
CLUWE Tools – Information	Allows end users the ability to see if production files have been esigned within the Lillyce file repository

The following areas are out of scope for this BCP:

- The BCPs for systems (Lilly or third party) that have been directly or indirectly integrated with or depend upon the CLUWE Web Tool. Examples include but not limited to Integration Broker, Isilon File Storage, SAS Grid, Enterprise Guide, Display Manager, M2C application, C2C application, etc.
- Processes to address natural or other disasters impacting personnel, work areas, networks, or data centers.

ASSUMPTIONS

The following assumptions apply to this BCP:

- If the event causing the CLUWE Web Tool service interruption impacts more than the CLUWE Web Tool, key resources may not be available
- Work may not resume at typical productivity levels during implementation of this plan, nor immediately after restoration of the system.
- Technologies needed to support BCP procedures are not affected by the same service interruption affecting the CLUWE Web Tool.
- Throughout this document, the term “data” includes all object types stored in CLUWE (for example, SAS data sets, Excel spreadsheets, SAS programs and macros, Word documents, etc.).

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
0	17-Feb-2016	New document	Mark Hemauer – Consultant – Modernization Implementation

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1. RISK EVALUATION

The following represents the risk related to the computer system along with the business processes that could be impacted if the risk was to occur. Criticalities of the risk as it relates to the business process supported by the system are defined as:

High: Business relies solely on the capability for which no acceptable manual process exists and/or failure of the capability could put meeting associated regulatory requirements at risk.

Med: Business portfolio time lines could be negatively affected but no risk of meeting associated regulatory requirements would occur and/or a manual process can be quickly be adopted minimizing impact to business productivity.

Low: Business user productivity could be negatively affected but no risk of meeting associated regulatory requirements would occur and/or a manual process can be quickly be adopted minimizing impact to business productivity.

Risk	Process Impacted	Criticality	Mitigation
The CLUWE Web Tool Scheduling capability is unavailable for less than 24 hours	The end user will not have the ability to submit nor schedule SAS job(s) to run without the need of the user being connected to the SAS Grid.	Low	Users can login to the SAS grid and run the programs interactively. Where this is not practical, users will be directed to alternative ways to submit offline execution as outlined in the document named Alternate Method for Submitting Programs to the Grid to be maintained outside this BCP.
The CLUWE Web Tool eSign capability is unavailable for less than 24 hours	The end user will not have the ability to electronically approve artifacts as required by MQO procedures.	Low	A template will be maintained in the User Reference Materials section of the CLUWE Support site listing all valid system eSign meanings. Users will be directed to a process by which to sign artifacts using a paper-based process as outlined in the document named Alternate Method for Signing Files to be maintained outside this BCP.
The CLUWE Web Tool Version capability is unavailable for less than 24 hours	The end user will not be able to prepare the production area in support of a post-production change.	Low	The CLUWE Business support team will retain the ability to interact directly with the production file system. Users will be directed to a process by which to request assistance of the business support team. The business support team will follow the process to manually version files as outlined in the document named Alternate Method for Versioning Files to be maintained outside this

Risk	Process Impacted	Criticality	Mitigation
			BCP.
The CLUWE Web Tool Info capability is unavailable for less than 24 hours	The user will not be able to view electronic signature information on any files.	Low	The CLUWE IT support team will retain the ability to directly access the database to retrieve signature information. Users will be directed to a process by which to request assistance of the business support team as outlined in the document named Alternate Method for Obtaining eSignature Information to be maintained outside this BCP. The business support team will engage IT to retrieve the needed information.
Any single capability or entire system is unavailable for more than 24hrs	Business and IT support teams ability to continue to meet portfolio timelines by executing manual processes	Med	Prioritization of clinical work will occur: Regulatory requests will be given top priority followed by critical portfolio work followed by all other activities. The same manual processes will continue to be used. Extended system outage will result in impacted portfolio timelines but all work will be able to continue, just not within expected timeframes. Manual processes are seen as being able to meet all regulatory needs until the system can be restored regardless of the length of the outage.

2. BUSINESS IMPACT

Extended unavailability of the CLUWE Web Tool capabilities could have profound effect on Lilly being able to meet critical portfolio timelines which could translate into a large financial impact due to missed revenues. Short term impacts would be felt as a decrease in end user productivity due to alternative processes being available.

Therefore, it has been determined that the system can be unavailable for less than 24 hours without significant pain on the business but durations lasting more than a day will require system owner to assess if manual procedures outlined in this BCP should be enacted.

3. CRISIS PLAN

The crisis plan describes the instructions for continuity of the critical business functions from the time the computer system is unavailable until it is returned to production.

3.1 Executing the Crisis Plan

The System Owner declares when it is necessary to implement this plan and contacts the individuals listed on the Key Contacts List to begin the alternative methods.

Execution of the Crisis Plan is dependent upon management judgment and discretion based on business timing, criticality, and the estimated downtime for the CLUWE Web Tool. The System Owner with considered input from the System Custodian, Business Support Team, IT Support team and business leaders as necessary and determine if conditions exist to trigger execution of the Crisis Plan.

The following steps, their need to occur and order, may vary depending on the situation.

1. System Owner (SO) and System Custodian (SC) are in near-constant communication
2. CLUWE SMEs (IT and Business) convene to gather information around impact
   2.1. Scope affected
   2.2. Timing/duration of expected impact
   2.3. Technologies impacted
3. SO triggers communication of crisis to users and those on the Key Contacts List impacted by the crisis.
4. IT to provide SO updates hourly or as needed to facilitate communication out to Key Contacts and users
5. SO or their delegates communicate alternate procedure(s) to users and those on the Key Contacts List
6. Users utilize alternate method(s)
7. SO or their delegates communicate status updates on daily basis or as deemed necessary
8. SO or their delegates communicate system restoration

3.2 Key Contact List

The list of key contacts is maintained in the list named Key Contacts located on the CLUWE Support Site Changes to the Key Contact List do not require approval.

3.3 Alternate Methods

The manual processes to be used in the event the BCP is activated are to be maintained outside the BCP. They are maintained by the CLUWE Business support team and are listed here for reference only:

- Alternate Method for Submitting Programs to the Grid
- Alternate Method for Signing Files
- Alternate Method for Versioning Files
- Alternate Method for Obtaining eSignature Information

3.4 After the Crisis

The CLUWE Web Tool only provides users with the ability to interact with the SAS Grid and File repository. The manual processes that are executed while the system is down does not require for any information be updated or re-entered into the CLUWE Web Tool. Once restored all that is necessary is to stop execution of the manual processes and communication the users the system is restored.

4. BCP TESTING

At the same frequency as the post-implementation period review, the System Owner, based on input from the System Custodian and Business SMEs, will determine if it is necessary to conduct a review of this BCP as part of the post-implementation periodic review to ensure the plan's accuracy. At the time of periodic review, the business team will decide which type, if any, of BCP testing needs to occur, either a tabletop exercise or an actual testing of the manual processes. The team will document the decision and BCP testing results in the periodic review report. The periodic review report will reference any additional documentation created to support the testing and any issue resolution.

5. BCP STORAGE

The official copy of this BCP will be kept electronically in Regulus along with the rest of the system validation documentation. Approvals of this document will be done electronically in Regulus so a paper copy with signatures is not required.

6. 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 (Clinical User Working Environment).