Electronic Regulatory Management System (eReg) Assessment

Approval Signatures

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Document Revision History

Rev	Date	By	Revision Summary
1.0	10 NOV 2021	Erica Rocco	Initial Version

1.0 Overview

The Advarra eRegulatory Management System (eReg) is an electronic regulatory binder maintenance system used to collect and manage protocol, staff, and institution regulatory and essential documentation. eReg supports 21 CFR Part 11-compliant document management and approval of documents using electronic signatures.

2.0 eReg System Assessment

2.1. System Access

Authorized sponsors, sponsor representatives, auditors, and site staff access eReg via web-based interface. Authorized individuals complete role-based eReg training prior to being granted access to the system with specified user access roles. Each user has a unique Username and Password. Yale utilizes Single Sign On (SSO) integration with Security Assertion Markup Language (SAML) for internal users. Users with permission to sign documents electronically also configure a Personal Identification Number (PIN). The system does not allow two or more users to have the same combination of Username/Password/PIN.

The eReg system has a password-controlled "timeout" feature to prevent unauthorized access when a session has been inactive for more than 15 minutes.

2.2. Backup and Maintenance

Data backup and restoration is handled by Advarra's hosting vendor, which tests periodic restores. Data are backed-up multiple times a week, and full data backups are retained for 14 days. Advarra updates application servers and databases with security updates and patches, operating system updates, and general maintenance tasks on a regular schedule.

2.3. Data Access

Access to eReg and permissions within the system are limited to authorized individuals and are role driven. See section 2.1 above for information about system access and passwords.

A unique contact/user record is created with the Reviewer role for each monitor and auditor, to allow view-only access to data during an assigned review session. Staff select the protocol, the specific protocol documents and information to be reviewed, and the start and stop dates when configuring each review session.

2.4. Electronic Signatures

Users who will electronically sign documents within eReg set their own PIN for electronic signatures. A user must enter their unique Username and PIN to sign documents. When a record is signed, the system captures the first and last names of the signer, a time stamp, and the meaning of the signature. The signature is securely linked to the signed record. A document cannot be deleted from the system after it has been electronically signed within the system.

2.5. Audit Trail

An audit trail for user activities within eReg is fully automated and is stored in a database which cannot be modified by the users. The audit trail identifies the user who made the change, records a time stamp for when the change was made, notes the action performed, lists old and new values, and the reason for the change when applicable.

2.6. Archival

Data and documents, including audit trails, are stored and retained in the eReg system for an indefinite period of time. Upon IRB Closure (or Abandoning a pending protocol) the protocol record is locked in eReg by a user with the appropriate permission. Locked protocols remain in the eReg system indefinitely and can be selected for a review session if needed.

2.7. Malware and Virus Protection

Advarra operates policies, standards, training, and controls to prevent malware. Advarra servers used for customer applications on managed infrastructure have malware and antivirus detection software installed and enabled, and scan on a regular schedule.

3.0 Additional Resources

- FDA CFR 21 Part 11 Validation Statement: Advarra - Forte eRegulatory Management System

- Advarra eRegulatory Management System 21 CFR Part 11 Compliance Traceability document (available in the eReg Learning Portal, Document Index)

- Advarra eRegulatory Management System User Requirements Specification document (available in the eReg Learning Portal, Document Index)