

# What is Advarra eReg?

## FAQ

The Advarra eRegulatory Management System (Advarra eReg) allows sites to improve efficiency and enhance regulatory compliance across their organization. The platform was developed in collaboration with leading academic medical centers, cancer centers, health systems, sites, and site networks throughout the industry. Focused on site-centric workflows and integrations across the site technology ecosystem, Advarra eReg is the trusted solution to streamline regulatory management.

## Commonly Asked Questions

### Is Advarra eReg 21 CFR Part 11 compliant?

Yes. Advarra eReg is tested and internally validated against 21 CFR Part 11 requirements and is a 21 CFR Part 11-compliant system.

### Does Advarra provide resources for continued compliance with 21 CFR Part 11 requirements?

Yes. Advarra provides a comprehensive packet of validation materials to our customers for each Advarra eReg upgrade.

### What certifications does Advarra eReg have?

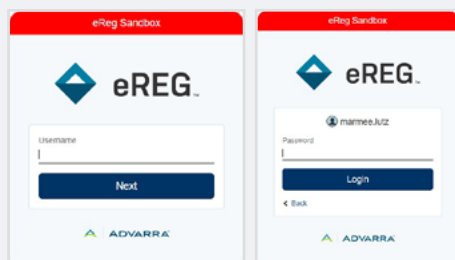
We have received ISO 27001:2013 and SOC 2 Type 2 certification for our technology solutions, ensuring both the Advarra eReg application and processes meet stringent requirements to enhance security and compliance.

### How do you ensure electronic signatures are unique to each individual?

Each Advarra eReg user is given a username to access the system. This username is unique, and cannot be reused for any other user. Below are the steps users follow for electronic signatures within the system.

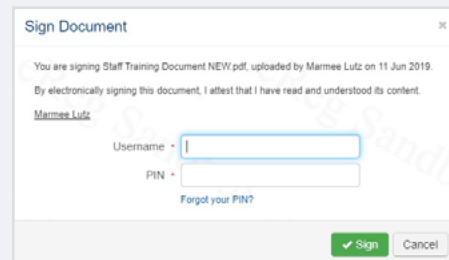
- Users sign in to Advarra eReg using their username and password
- Users set up a unique PIN (first use only)
- Once logged into system, the user enters their username and PIN to sign a document

Logging in:



The first screenshot shows the 'eReg Sandbox' login page with the eREG logo and a 'Next' button. The second screenshot shows the password entry page with the username 'marmee.lutz' and a 'Login' button.

Entering a PIN when signing:

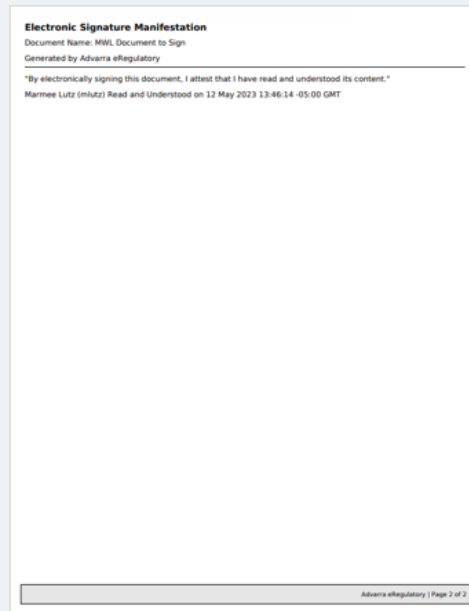


The 'Sign Document' dialog box shows the user is signing 'Staff Training Document NEW.pdf, uploaded by Marmee Lutz on 11 Jun 2019.' It includes a 'Sign' button and a 'Cancel' button.

## What does the electronic signature manifestation look like?

The electronic signature manifestation will include the following information:

- Signer name (first name, last name)
- Username (unique to the signer)
- Signature meaning (selected by signature router at time of routing)
- Signature date/time



## Can documents be edited after they are electronically signed?

No. After a document is electronically signed, it can no longer be updated or edited. If a new version is added or a change is needed to an existing signed document, another version must be added to the system and routed for signature.

## How long are documents held in the system?

Advarra eReg retains all documents indefinitely or until the customer terminates their contract for the software with Advarra.