

# How Florence Protects Your Clinical Research Workflows

**Discover how Florence’s Site Enablement Platform addresses security and compliance concerns with its robust features, industry certifications, and seamless integration for clinical trial management.**

Florence prioritizes security and compliance in our Site Enablement Platform for clinical trial management. Designed for data integrity, system validation, and access control, our platform adheres to top industry standards and regulatory requirements. Florence eases research site concerns with a comprehensive suite of features, ensuring seamless integration and a secure environment for critical data.



### Comprehensive Data Management & Security

- ALCOA++ principles for data integrity
- HIPAA-compliant data-level security
- Advanced encryption and network security



### System Validation & Compliance

- User Acceptance Testing for performance
- FDA 21 CFR Part 11 compliant eSignatures
- GDPR guidance adherence



### Access Control & Document Management

- Role-based access and two-factor security
- Built-in automated audit trails
- Long-term archiving of critical data



### Robust Infrastructure & Cloud-Based Hosting

- AWS hosting for security
- Scheduled data backups and export options
- Extensive technical and SOP controls



### Support Capabilities & Training Comprehensive Training

- Comprehensive training and global support
- Dedicated GDPR Taskforce
- Incident and response management



### Global Certifications & Guidance Adherence

- Third party certification of compliance with FDA 21 CFR Part 11, ICH GHP E6(R2), Eu Annex 11 and MHRA Data Integrity Guidance.
- Data Privacy Framework self-certification (EU-US, U Extension and Swiss-US)

*Trust Florence’s Site Enablement Platform for secure, compliant clinical trial management and seamless integration.*

**20K**

Trusted by 20,000 research sites around the globe as their eISF infrastructure.

**7.2M**

Facilitating more than 7.2 million clinical trial activities monthly.

**70+**

Trusted by research sites, and CROs in 70 countries.

**Learn More**  
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# Key System Features That Support Security and Compliance

## **ALCOA-C and ALCOA++ Principles**

Florence has technical controls to ensure records are Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available and Traceable.

## **System Validation:**

Florence supports User Acceptance Testing (UAT) to ensure accuracy, reliability, and consistent performance.

## **Audit Trails:**

Florence's audit trails capture all changes, including deletions, ensuring data integrity and traceability.

## **Security and Access Control:**

Florence restricts login to authorized users and allows for role-based access and permissions.

## **Data Backups:**

Florence conducts scheduled backups and enables customers to download/export data during the active contract.

## **Essential Document Management:**

Florence facilitates separate and/or combined sponsor and site filing, ensuring individual elements are readily identifiable and retrievable.

## **Part-11 Compliant eSignatures:**

Florence supports secure and legally binding electronic signatures that meet FDA 21 CFR Part 11 requirements, streamlining the document approval process.

## **Amazon Web Services (AWS):**

Florence uses AWS as our hosting provider to ensure robust security and alignment with ISO, HIPAA, and HITECH compliance requirements, providing a secure and reliable platform for your data.

## **Long-Term Archiving:**

Florence ensures the preservation and accessibility of essential documents and data through reliable long-term archiving solutions, safeguarding your research site's critical information for future reference and regulatory compliance.

## **Data Encryption and Network Security:**

Florence employs state-of-the-art encryption methods and robust network security standards to protect your data from unauthorized access and ensure data integrity.

## **Data-Level Security:**

By adhering to the HIPAA security rule, we ensure that your data is safeguarded at all levels, including storage, transmission, and processing, maintaining the highest security standards.

## **Data Processing Agreements and EU Standard Contractual Clauses:**

Our Data Processing Agreements/Addenda (DPA) include the EU Standard Contractual Clauses (SCC) and applicable supplementary measures to ensure compliance with GDPR during data transfers and processing.

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# Florence Site Enablement Support Capabilities

## **Comprehensive Training Opportunities:**

Florence provides product updates, Help Desk articles and videos, onboarding and implementation training, and support resources.

## **SOPs and Consultation:**

Florence provides SOP templates and consultation services to assist customers

## **Incident and Response Management:**

Our team proactively handles potential security threats by following strict incident response protocols, ensuring timely resolution and minimal impact on your data.

## **Ongoing Policies and Procedures:**

Florence continuously evaluates and updates our policies and procedures to maintain the highest quality standards, including regular testing of our infrastructure and monitoring for potential vulnerabilities.

## **Dedicated GDPR Taskforce:**

Florence has established a dedicated GDPR Taskforce to ensure compliance with the EU's General Data Protection Regulation (GDPR) 2016/679 and maintain a strong commitment to data protection.

## **Technical and Procedural Controls:**

We have implemented robust technical and procedural controls to safeguard the personal data of EU individuals in accordance with GDPR requirements.

## **Company-wide Training:**

Florence conducts regular company-wide training sessions to ensure all employees are knowledgeable about GDPR and understand their responsibilities in maintaining compliance.

## **Ongoing Monitoring:**

We continuously monitor the evolving data protection landscape and adapt our practices accordingly, ensuring the highest level of data security and compliance with GDPR.

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# Additional Information

## Certifications and Standards

*ICH E6(R2): Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice*

*EC – EudraLex: Volume 4 - Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 11 – Computerized Systems*

*MHRA – “GxP” Data Integrity Guidance and Definitions*

*FDA Guidance for Industry Electronic Records; Electronic Signatures - Scope and Application (21 CFR Part 11)*

*GDPR: Florence is fully compliant with the General Data Protection Regulation (GDPR), ensuring the highest standards of data privacy and security.*

*Data Privacy Framework (DPF): Florence is active under the EU-U.S. Data Privacy DPF, the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF to provide adequate data protection.*

*California Consumer Privacy Act (CCPA): Florence is compliant with CCPA requirements to protect the data privacy rights of California residents.*

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