

## The Florence CloudBinder® Suite is compliant

Clinical study sites are responsible for receiving, storing and managing critical regulatory documents. Managing this enormous amount of documentation while remaining compliant can be stressful, so Florence Healthcare created the CloudBinder Suite to help. The following is a summary of how this suite is compliant with key regulations for patient care overall, and within clinical research specifically.

## Florence CloudBinder complies with the following

### HIPAA : Privacy

Florence CloudBinder is HIPAA compliant.

### 21 CFR Part 11: Electronic Records

Cloudbinder repeatedly and reliability follows Part 11 guidance.

### 21 CFR 11.3: Document Connectors

Uploading trial documentation is easy and safe with Florence.

### 21 CFR Part 11.10 and 11.30: Permissions

Florence CloudBinder contains closed system and open system controls to manage access to crucial documentation.

### 21 CFR Part 11.10 (e): Audit Trail

Florence 's comprehensive audit trail is simple and secure.

### 45 CFR Part 160 and 45 CFR Part 164 (The Privacy Rule): Redaction

CloudBinder empowers trial sites to follow the law in protecting trial patient's identification information while improving the trial site's workflow.

### 21 CFR 312 and 812: Florence Stamps

Investigator sites are responsible for the unique identifiers which track trial documentation. Florence makes unique identifiers in a simple click.

### 21 CFR Part 312.62(b) and Part 812.140(a)(3): Document Sharing and Retention

Florence makes it possible to easily prepare documents for sharing and subsequently storage for long term retention.