



Clinical Documents Module

The NextDocs Clinical Documents Module Provides:

- 🔗 Complete eTMF
- 🔗 Secure extranet collaboration
- 🔗 Investigator portal
- 🔗 **Scheduling and tracking...** of site monitor visits
- 🔗 **Complete document lifecycles...** from creation through review and approval
- 🔗 **Fully configurable...** visual workflow creation
- 🔗 **Compliant...** Support for all 21 CFR Part 11 and related regulatory requirements, including digital signatures

Improve Communication and Collaboration Between Sites, Monitors and Sponsors

The **NextDocs Clinical Documents Module**, built on Microsoft SharePoint, provides an out-of-the-box solution for collaboration and document sharing between sponsors, investigators, site monitors and other parties.

Unlike traditional software systems that add layers of complexity to clinical processes, the NextDocs Clinical Documents Module is pre-configured for managing the entire set of typical clinical study documents and processes. That makes setting up each study both easier and faster. And with SharePoint's familiar user interface and seamless integration with Microsoft Office, users readily adapt to the system.

The NextDocs Clinical Documents Module is part of the NextDocs Document Management System, which extends Microsoft SharePoint with a set of integrated features that

fully address all the requirements of regulations such as 21 CFR Part 11. The result is a clinical document management solution that delivers better collaboration, more efficient collection of study data and lower costs.

The NextDocs clinical study portal provides a single point of communication and collaboration for investigators, vendors, monitors and sponsors.



ISV/Software Solutions



The NextDocs Difference: Compliance without Complexity

The **NextDocs Document Management Systems** are off-the-shelf applications that address all FDA 21 CFR Part 11 requirements. Built on the **NextDocs Compliance Platform**, they are 100% browser-based and completely integrated into the SharePoint framework.

SharePoint's familiar user interface and seamless integration with Microsoft Office applications provide a familiar environment for users. IT professionals enjoy the fact that NextDocs modular solutions install directly into their SharePoint environment, extending rather than replacing familiar system administration processes. The result is faster deployment, higher adoption rates and far lower costs than alternatives based on legacy platforms.

The NextDocs Compliance Platform

The NextDocs Document and Quality Management systems are built on the NextDocs Compliance Platform which addresses the entire range of 21 CFR Part 11 requirements.

- 🔗 **Lifecycle management** allows management of the document from inception to obsolescence
- 🔗 **Version tracking** with major and minor versioning, version history and previous version restoration
- 🔗 **Audit trails** provide a detailed log including every activity performed in the system
- 🔗 **Check In/Check Out** controls to prevent documents from being overwritten
- 🔗 Configurable **document numbering** allows flexible numbering schemes
- 🔗 Real time **Adobe PDF conversion** triggered by document state or workflow step
- 🔗 **Electronic/Digital signatures** that address all regulatory requirements
- 🔗 **Metadata tagging** that can drive folder placement and/or lifecycle decisions automatically
- 🔗 **Folder templates** that allow all or part of a folder structure to be saved as a template
- 🔗 Controlled document management including configurable application of **watermarks & overlays**

