

Clinical Document Management



The Collaborative Platform for Simplifying, Streamlining, and Automating Clinical Trial Processes

NextDocs' collaborative solution for clinical trials, built on Microsoft SharePoint provides an integrated platform that streamlines processes, automates information exchange, and dramatically reduces administrative overhead associated with running clinical trials. Our clinical portal allows clinical teams to work together in an effective and efficient manner by keeping trial personnel connected, informed and on task – providing access to everyone at any time, from anywhere. NextDocs Clinical Document Management solution is based on the NextDocs compliance platform, which includes a comprehensive set of features that address all ICH, FDA, EMEA, and MHLW regulatory requirements.

CLINICAL PORTAL

Internet portals that allow stakeholders to access trial information and monitor overall trial progress are often viewed as the “silver bullet” to the collaboration challenge – and just as often are accompanied by claims of increased productivity and decreased trial costs. Unfortunately, most portal solutions available on the market today do not live up to these promises. They fall short because they simply present information from diverse sources in a unified way and are not well integrated with the underlying processes that create, manage and disseminate that information.

At NextDocs we embrace the concept of an integrated collaboration platform which is a unified collection of components that, in combination, provide an environment where diverse constituents can participate in the creation and management of clinical trial artifacts in real time. Our clinical portal supports:

- Investigator self-registration
- Automated user account provisioning
- Trial personnel and facility management
- Role specific landing pages and navigation
- Standard work item inventories
- Clinical trial data integration

ELECTRONIC TRIAL MASTER FILE (eTMF)

All companies in the pharmaceutical industry must maintain a trial master file (TMF) for each clinical trial they sponsor. Even though regulatory guidance (such as ICH E6) exists, there is no comprehensive common model for managing those documents. Typically, a company is left to interpret the guidance and develop a unique TMF management strategy – one based on institutional knowledge, past experience and opinion.

In 2009, the Drug Information Association (DIA) embarked upon an effort to define a standard clinical trial master file taxonomy or “reference model” for

Key Features and Benefits

All the benefits of traditional document management system plus more:

- » Collaborative platform for managing all clinical trial documentation
- » Workflow-driven processes ensure consistency and increase efficiency
- » Advanced metadata dictionaries manage trial site and personnel information
- » Data-driven creation of key site-level documents such as the FDA 1572
- » Electronic alerts and notifications communicate key information to trial personnel
- » Real-time visibility into each trial site file to assess completeness and compliance
- » Automated distribution of critical product safety information saves time and money while meeting regulatory obligations
- » Comprehensive eTMF document inventory that is based on the DIA Reference Model

use by industry. This collaborative effort involved over 120 representatives from 87 biopharmaceutical companies, contract research organizations, consultancies, technical vendors (including NextDocs), and regulatory agencies.

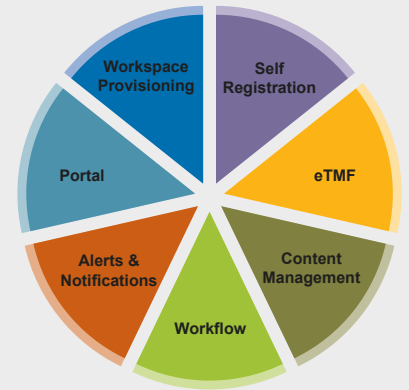
At NextDocs, we aligned our eTMF solution with the DIA TMF Reference Model from the start – providing our clients with a comprehensive document inventory out-of-the-box. Our clinical collaboration platform simplifies the management of essential trial documentation by effectively integrating document management processes with the way people work on a daily basis. Workflows, not people, drive the creation of many documents.

SAFETY REPORT DISTRIBUTION

Delivering safety documentation to clinical investigators is an important regulatory obligation. Investigators must be notified of suspected serious adverse events associated with products under study. A single safety document can generate hundreds of notifications to investigators and the timely and accurate delivery of these documents is important for compliance with country specific regulations.

NextDocs Safety Report Distribution feature not only ensures that these critical documents are delivered, but also eliminates physical handling and courier costs associated with manual distribution methods. NextDocs provides on-demand distribution of a single approved report, batch distribution of all approved reports and a comprehensive report distribution history.

The Seven Elements of a Clinical Collaboration Platform



Clinical Solution Components

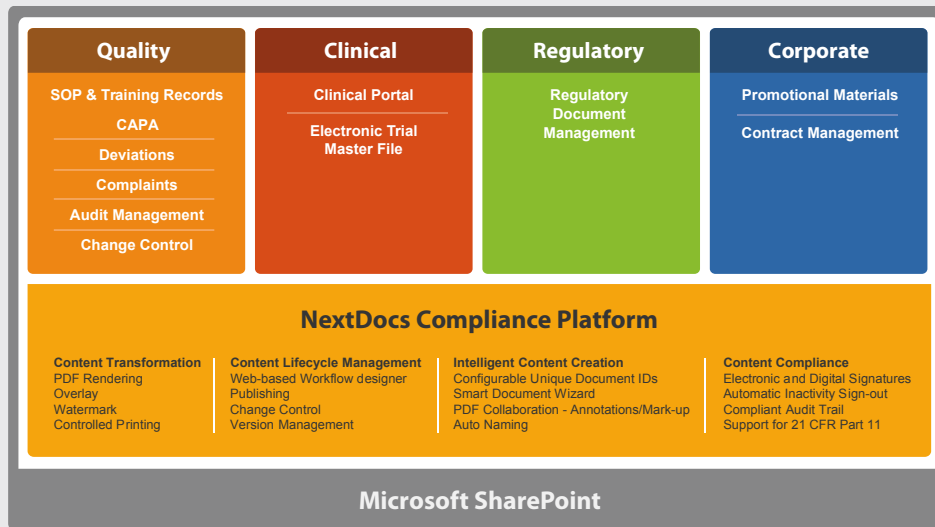
When you purchase the NextDocs Clinical Document Management solution, you start with a product that is fully configured for use in managing clinical trial documents, and which could be validated and deployed by doing nothing more than adding specific information about your products, studies, etc. to pre-existing lists, importing your templates, and adding your users to appropriate roles.

STANDARD SOLUTION COMPONENTS

- » Complete inventory built on EDM Reference Model specifications
- » Predefined lists that limit valid values for document properties to values that you supply
- » Best practice lifecycle for review and approval
- » Smart Document Wizard that minimizes user metadata entry by auto-populating document properties and filing in a standard folder structure
- » Comprehensive lifecycle including review and approval workflows
- » Role-based security
- » Optional digital signature
- » Audit trail
- » 21 CFR Part 11 Compliance

NEXTDOCS COMPLIANCE PLATFORM

The NextDocs Compliance Platform includes a comprehensive set of features that addresses all ICH, FDA, EMEA, and MHLW regulatory requirements. It is built in and fully integrated with the Microsoft SharePoint Server framework.



- Real-time Adobe PDF conversion triggered by document state change or workflow step
- Controlled document management including configurable application of watermarks & overlays
- Full lifecycle management of the document from inception to obsolescence
- Flexible and powerful process automation tools for change requests, document review, and approval
- Check in/Check out controls to prevent documents from being overwritten
- Version tracking with major and minor versioning, version history and previous version restoration
- Configurable document numbering
- Auto population of document properties
- Electronic/digital signatures that address all regulatory requirements
- Audit trails that provide a detailed log of every activity performed in the system



NextDocs is the global leader in providing Microsoft SharePoint-based compliance solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA and other agencies while automating processes, improving efficiency and dramatically reducing costs. NextDocs provides solutions for managing regulatory documents, SOPs, clinical documents as well as a full set of quality processes from CAPA to complaints. NextDocs customers include pharmaceutical companies, biotech firms, device manufacturers and contract research organizations.

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