


## Vendor-Supported Integration

### Combining Clinical Trial Management with SharePoint-Based Document Management

#### **What Do You Get...**

...when you combine TranSenda's Office-Smart Clinical Trial Manager and the NextDocs Document Management System?

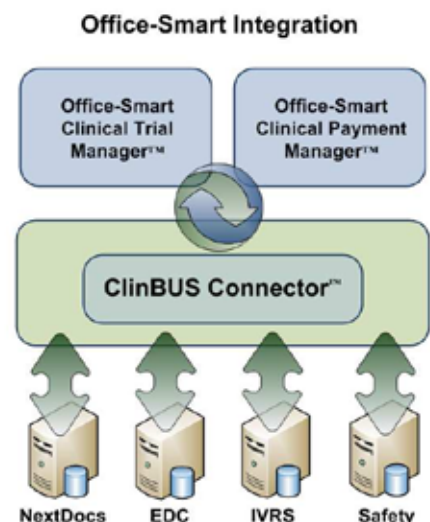
 You get an **integrated clinical trial solution** that works together, works with Microsoft Office, and keeps the whole trial process in sync.

Imagine if your clinical trial management system (CTMS) and your document management system were truly integrated. Each system could update the other as a trial proceeds. For instance, when a document is created, it could reference information in the CTMS about the study. And when a document is approved, it could update the task in the CTMS. The result: A complete clinical trial solution that works together and keeps the whole trial process in sync.

The TranSenda Office-Smart Clinical Trial Manager<sup>™</sup> is a comprehensive clinical trial management system that takes full advantage of Microsoft Office. TranSenda's Office-Smart clinical trial solutions use advanced ClinBUS<sup>®</sup> data interchange technology to make operational data across multiple trials and systems available for use with Microsoft Office SharePoint<sup>®</sup> Server.

The NextDocs Document Management System is built in Microsoft SharePoint; using ClinBUS Connector<sup>™</sup>, it can easily share information with TranSenda's Office-Smart Clinical Trial Manager. The system addresses all FDA 21 CFR Part 11 requirements, and includes off-the-shelf modules for managing trial master file documents, SOPs and regulatory documents.

Together, TranSenda Office-Smart Clinical Trial Manager and the NextDocs Document Management System deliver a unified clinical trial solution deeply integrated with SharePoint and Microsoft Office.



## TranSenda's Office-Smart Clinical Trial Manager: A Next-Generation CTMS

Unlike other clinical trial management systems, which function outside of office software, TranSenda's Office-Smart Clinical Trial Manager is designed to work in concert with the powerful Microsoft® Office System. Office-Smart software delivers productivity gains that can save thousands of hours in the span of a study.

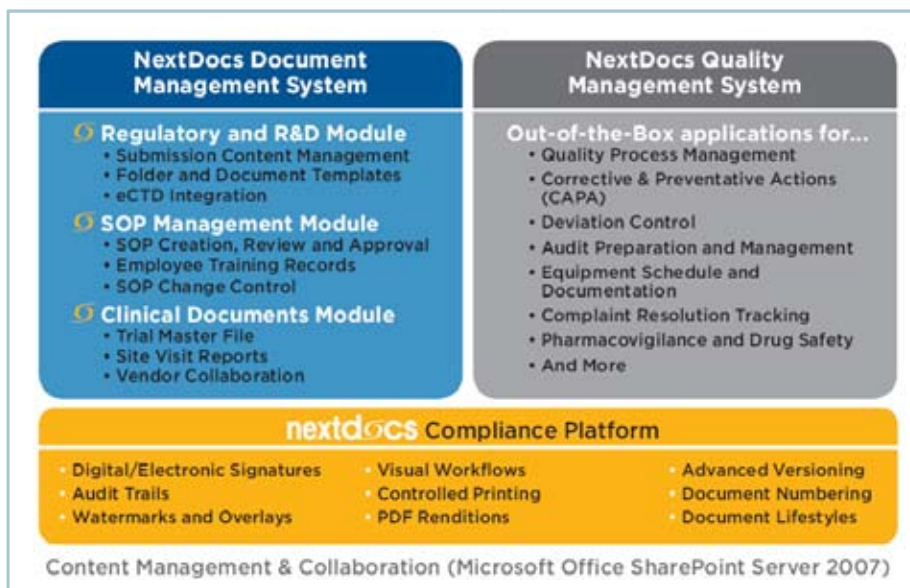
Designed with the versatility to accommodate an organization's unique SOPs, Office-Smart Clinical Trial Manager™ delivers unparalleled flexibility and ease of use. After a few hours of training, organizations can be setting up studies, defining protocols, and managing user permissions —without the aid of IT staff. Study professionals can enjoy a simplified user experience by working within the familiar Microsoft Office environment, actually using Office applications as the front-end interface—online or offline—while interchanging information and tasks with their clinical software

Whether managing multiple trials internally, or outsourcing specific activities, Office-Smart Clinical Trial Manager will transform a disjointed clinical trial software environment into a dynamic information workplace that supports the way study professionals actually perform their day-to-day tasks. As part of the TranSenda Central® system of integrated, modular clinical trial applications, all study data and protocols are extended and supported throughout complementary applications like Office-Smart Clinical Payment Manager™. In addition, the system supports 21 CFR Part 11 compliance.

## NextDocs Document Management: A SharePoint-based Compliance Solution

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 Documents Module is preconfigured 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 provides management of study documents such as:

- Investigator Brochure
- Study Protocol
- Informed Consent Forms
- Monitoring Reports
- Recruitment advertisements
- Study Agreements
- Regulatory Authorization
- Curriculum Vitae
- Enrollment logs
- Case Report Forms

