

Office-Smart Clinical Trial Manager™

TranSenda is now a part of BioClinica

BIOCLINICA™
Global clinical trial solutions. Real-world results.

Leverage the Microsoft Office System to save thousands of hours per study

For clinical trial professionals who want their study software to work *with* their Office software, TranSenda's Clinical Trial Manager is also available in an Office-based version. Unlike other clinical trial management systems, which function outside of office software, TranSenda's Office-Smart Clinical Trial Manager is designed to take full advantage of 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 each 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. 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™.

Key Benefits

- ◆ Installation takes a few weeks instead of many months with a flexible study configuration wizard and embedded features that facilitate validation
- ◆ Training is streamlined and adoption is assured when staff can do all their work within Office, e.g., site visit reports can be completed through Outlook with no need to use, much less learn, other software
- ◆ Fundamentally improve productivity by fully leveraging Microsoft's Office System, including Access, Excel, InfoPath, Outlook and Word in concert with a proven, next-generation CTMS
- ◆ 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
- ◆ Fastest possible Return on Investment (ROI) by getting more value from existing investments in Microsoft tools
- ◆ Office-Smart Clinical Trial Manager creates a natural next step to bring your current favorite Office tools and spreadsheets into the regulated world of clinical trials
- ◆ A single Office-centric source for critical study data and documents can improve quality & reduce errors by eliminating mismatched data from workaround spreadsheets created outside of the system or from re-entering data
- ◆ Achieve the ultimate in study team collaboration and global multi-site connectivity using Microsoft's versatile portal technology, integrated contact management and messaging
- ◆ Remote user access portals for all study team members provide a single, secure source for maintaining critical study data & documents, reducing the need for staff to input data
- ◆ Connecting Office-Smart Clinical Trial Manager to Microsoft Office SharePoint Services makes insightful metadata available for configurable dashboards, reports, workflow and more
- ◆ Advanced ClinBUS® data interchange technology supports unprecedented connectivity between 3rd party applications, making operational data across multiple trials and systems available for use with Microsoft's Office System

Office-Smart Technology

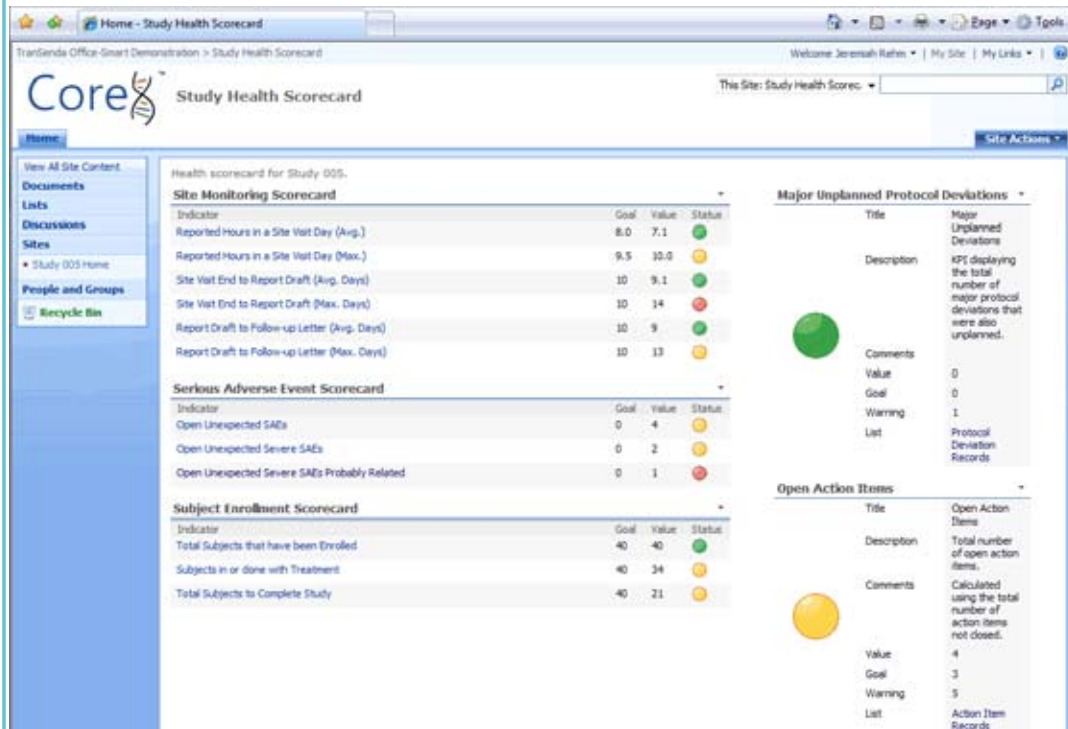
- ◆ Takes advantage of the Microsoft Office System
- ◆ Simplifies processes to increase productivity
- ◆ Reduces training and speeds adoption
- ◆ Saves time and money
- ◆ Reduces errors
- ◆ Delivers faster ROI
- ◆ Encourages teamwork and collaboration



Office-Smart Clinical Trial Manager™

TranSenda is now a part of BioClinica

BIOCLINICA™
Global clinical trial solutions. Real-world results.



Reduce spending by choosing the Software-as-a Service (SaaS) option

Streamline your overall study and achieve a lower Total Cost of Ownership (TCO) by integrating Office processes into clinical operations

Decrease training, speed adoption and increase productivity by taking advantage of the familiar Microsoft Office environment

Key Features

- ◆ Study configuration wizard enables dynamic site initiation for either single or multi-sponsor users
- ◆ Versatile set up accommodates SOPs, allows custom alert notification, protocol deviation tracking and more
- ◆ Context-intelligent navigation across standardized screens
- ◆ Seamless use of all Microsoft Office SharePoint Server features—such as Single Sign-On, which enables users to access multiple systems from one point
- ◆ SharePoint portal capabilities include document management, workflow collaboration, team sites and wiki sites
- ◆ Users can securely perform study-specific roles based on flexible operational permissions
- ◆ Robust scheduling functionality tracks and monitors patient visits and CRF receipts; also sets multi-mode alert schedules and triggers
- ◆ Extensive reporting includes nearly 100 standard reports, ad hoc reporting and configurable SharePoint dashboards
- ◆ Advanced record lookup capability enables search through document titles and metadata; includes record hyper linking
- ◆ Basic document management via SharePoint Services 2007
- ◆ Office 2007 users can access documents via Outlook and update document metadata through Word
- ◆ Extensive tracking includes subject screening & enrollment; study visits; site monitoring; CRF page status; test article & supply shipments; SAE disposition, action items & reconciliation; documents; correspondence and more
- ◆ Patent-pending ClinBUS® data interchange technology ensures connectivity to 3rd party applications
- ◆ Supports ClinicalTrials.gov Protocol Registration System
- ◆ System validation is facilitated through embedded features, test scripts and documentation

TRANSENDA TECHNOLOGY OVERVIEW

Web-Based Technology

Built with Microsoft's .NET technology, TranSenda's Office-Smart clinical trial solutions are web-enabled by design. Office-Smart clinical trial solutions are based upon Microsoft SharePoint Services and can also leverage the advanced features offered in Microsoft Office SharePoint Server 2007 (MOSS), an integrated suite of server capabilities that supports all intranet, extranet, and Web applications.

Connectivity

TranSenda's patent-pending ClinBUS data interchange technology enables the exchange and presentation of operational data from multiple systems to internal and external users in real-time. The unique ClinBUS approach to clinical system integration facilitates a family of data connectors for legacy and enterprise applications. Maximum interoperability is further enhanced by TranSenda's open standards architecture which supports XML-based conventions and industry standards, such as CDISC.

The System

Most TranSenda solutions are powered by TranSenda Central—a system of integrated modules that share a process-based platform of common functionality. Integrated modular solutions form a flexible and expandable clinical trial system that can be readily modified with changing needs and regulations. In addition, the system supports 21 CFR Part 11 compliance.

Hosting Services

For organizations with limited IT resources or desire to minimize infrastructure investment in order to simplify system management, TranSenda offers hosting services, including via Software-as-a-Service (SaaS).

This document is for informational purposes only. TranSenda MAKES NO WARRANTIES, EXPRESS OR IMPLIED, IN THIS SUMMARY.

