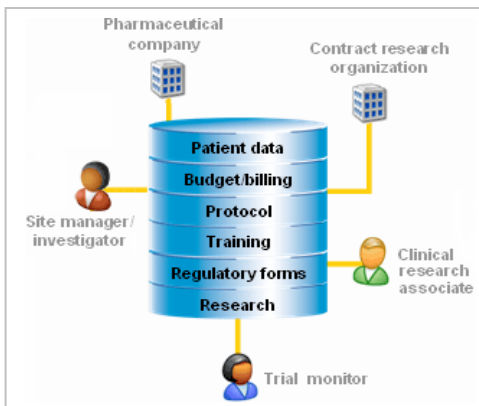




Simplifying Clinical Trial Management Using the Microsoft Office System

One of the largest barriers pharmaceutical companies face in bringing new drugs to market is the clinical trial process. Often paper-based and always subject to intense regulatory pressure, clinical trials involve managing massive amounts of documentation between multiple parties and systems. A clinical trial solution based on the Microsoft® Office System can help make it easier to plan effective trials, capture patient data, and manage administrative tasks more efficiently.



A clinical trial management solution gathers and centralizes data for easier access, greater visibility and more efficient processing

The Clinical Trial Challenge

Pharmaceutical companies can spend 12 to 15 years and up to \$900 million to bring a drug to market. About 45 percent of this cost is accrued during the clinical trial phase. What's more, a recent study indicated that more than half of all trials conducted in the United States are behind schedule by one to six months.

Because improving time-to-market for new drugs is critical for pharmaceutical companies, managing the clinical trial process is one of the most significant areas of opportunity for improvement.

Today, pharmaceutical companies struggle with the following challenges:

- **Lengthy and complex trial design and planning process.** Clinical trials can often involve thousands of patients and hundreds of support staff.
- **Inefficiencies and delays capturing patient data.** Consistent, streamlined capture of patient data is critical for success.
- **Inability to connect to a wide variety of systems.** Clinical trials often involve interaction with numerous trial sites using disparate systems and processes.
- **Difficulty remaining compliant with FDA guidelines.** Stringent FDA regulations are placing more pressure on how clinical trials are managed.
- **Lack of archived materials to build best practices.** Each clinical trial is often started "from scratch," and doesn't utilize historical best practices and feedback.

Overall, these challenges can be overcome. Pharmaceutical companies will benefit from streamlining the

clinical trial management process through a clinical trial management solution.

Clinical Trial Management Solution

The goal of a clinical trial management solution is to facilitate the planning, execution, and tracking of relevant clinical trial activities.

Improved Process Planning

- Design and prototype trials faster and easier
- Model visit schedules, data schema, edit checks and form design using a drag-and-drop interface
- Build powerful form libraries and collaboration processes to facilitate even faster design cycles

Standardized Data Collection Processes

- Increase the speed and accuracy of data entry and exchange through Web-based data collection
- Generate more consistent reports through an FDA-compliant library of templates
- Provide single sign-on access to multiple clinical processes including electronic data capture (EDC), data management, adverse events reporting

More Effective Data Management and Analysis

- Provide one centralized place to track progress by study, site, staff member
- Exchange protocol synopsis, confidentiality agreements and other critical documents electronically and securely
- Integrate with different site systems for faster data exchange, query resolution and data reconciliation

- Provide the pharmaceutical sponsor of the trial with greater visibility of clinical data

Improved Trial Administration

- Streamline administrative processes through one central location for tasks, issues, and schedules
- Integrate with budgeting and finance applications
- Get team members up and running faster with both real time and archived online training modules
- Provide sites with online access to sponsor and CRO information, archived documents and FAQs

Next Steps

To learn more about clinical trial management solutions built using the Microsoft Office System visit:

www.microsoft.com/office/showcase/ctm

Solution Showcase for the Microsoft Office System

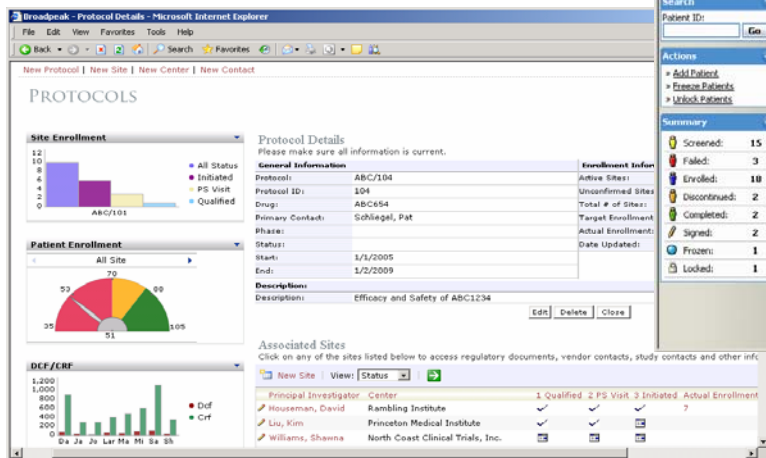
The clinical trial management solution is one of the many business scenarios available in the Solution Showcase for the Microsoft Office System.

The Solution Showcase highlights examples of how leading organizations can solve business problems using the Microsoft Office System. The Solution Showcase provides guidance so Microsoft customers can obtain more value from their investments in the Microsoft Office System, and provides a featured listing of Microsoft technology partners who can help customers design, build, and implement Microsoft Office-based solutions.

For more information about the Solution Showcase, please visit:

www.microsoft.com/office/showcase

Administrative portals can be customized with trial status dashboards, document libraries, task lists, study statistics and more



The screenshot shows a patient tracking table in a Microsoft Internet Explorer browser. The table lists patient IDs, their status, last event, and various review and action flags.

Patient ID	Status	Last Event	DCFs	SD-Verify	M-Review	D-Review	Signed	Frozen	Locked
000000-ABC	Completed	Day 30	✓	✓	✓	✓	✓	✗	✗
100-0000-AB8	Screened	Screening	✓	✗	✗	✗	✗	✗	✗
111-1111-4KWA	Screened	Screening	✓	✗	✗	✗	✗	✗	✗
111-1111-E6EA	Screened	Screening	✓	✗	✗	✗	✗	✗	✗
1111-ASD	Enrolled	Screening	✗	✗	✗	✗	✗	✗	✗
1113-BET	Enrolled	Day 8	✗	✗	✗	✗	✗	✗	✗
222-2223-GEF	Screened	Screening	✓	✗	✗	✗	✗	✗	✗
222-2227-QVY	Failed	Screening	✗	✗	✗	✗	✗	✗	✗
222-2229-H9E	Screened	Screening	✓	✗	✗	✗	✗	✗	✗
2222-221C	Enrolled	Day -2	✗	✗	✗	✗	✗	✗	✗
2224-FBY	Enrolled	Day -1	✗	✗	✗	✗	✗	✗	✗
2225-H9E	Enrolled	Day 1	✗	✗	✗	✗	✗	✗	✗
2226-H9E	Enrolled	Day 2	✗	✗	✗	✗	✗	✗	✗
2229-SGJ	Enrolled	Day 3	✓	✗	✗	✗	✗	✗	✗
3330-43D	Enrolled	Day 4	✗	✗	✗	✗	✗	✗	✗

Patient data can be tracked instantly across sites and studies in real time