



# Is Anything Really New in Clinical Trial Software?

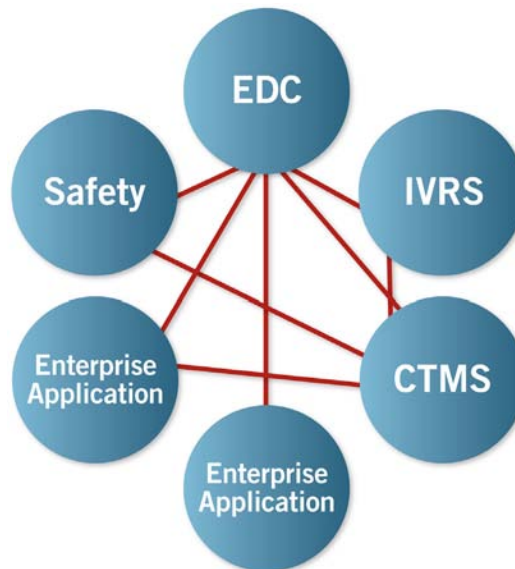
## The Next Generation Clinical Trial Management Platform

### Executive Summary

As eClinical vendors have matured, their commercial applications have replaced most homegrown systems and are now the de facto choice for most clinical organizations. With this success comes a responsibility — to relentlessly innovate and evolve — and to help drive new efficiencies and processes that improve drug development in every area they touch.

### The Evolution of Clinical Trial Software

Clinical trial software applications were first developed within large pharma enterprises. A sponsor could justify the cost and effort of proprietary development and point-to-point integration because the infrastructure could be used to conduct many studies over years.



*Figure 1 Traditional Closed Clinical Trial Software Environment*

This original closed environment of the sponsor (above) has evolved into a far more complex configuration involving CROs and clinical applications from a multitude of software vendors. For example, a sponsor's study may involve several different EDC and IVRS systems, and several specialized CROs.

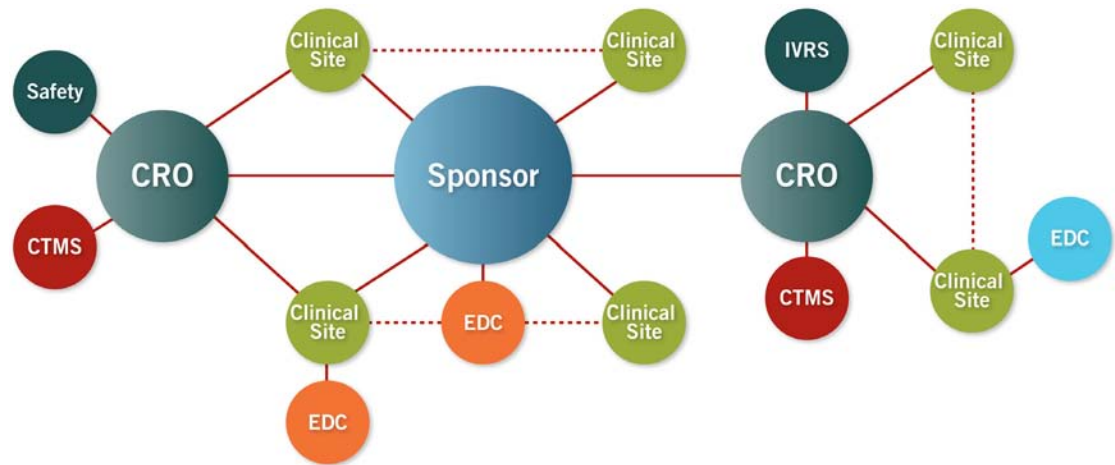


Figure 2 Today's Clinical Trial Environment

This poses substantial challenges for a trial sponsor:

1. How can I report on data distributed across all these different clinical systems?
2. How can my clinical operations people deal with multiple complex user interfaces?
3. How can I effectively use CROs without losing oversight and control of my studies?
4. How do I implement an IT infrastructure that provides the adaptability to meet my unique and evolving business needs?
5. How do I manage my IT costs, especially if I have to integrate all these different systems for each study?

### Today's Alternatives

Before we look at a next generation Clinical Trial Management Platform that could address these challenges, let's review the state of the industry today.

#### Clinical Trial Reporting

- Data locked within clinical applications
- Hard-coded inflexible reporting

#### The User Experience

- Multiple systems per user
- Complex proprietary user interfaces

#### **Working with Business Partners**

- Sponsors train CROs at their expense to use sponsor systems, or build out fixed infrastructure
- No solution for interoperating with acquisition systems

#### **Business Agility**

- Dependent on long vendor upgrade cycles
- Limited customization to address unique business needs

#### **Managing Clinical Trial Software Costs**

- Companies locked into vendor suites that limit competition
- Legacy systems tied to old and less efficient software technologies
- Clinical trial software vendors replicating and maintaining unique integration platforms better-served by state-of-the-art cross-industry solutions

### **The Next Generation Clinical Trial Management Platform**

The challenges described above demand a new approach to clinical trial software infrastructure – an alternative to the conventional clinical trial suite. What are the key attributes of a next generation Clinical Trial Management Platform?

#### **Open Architecture**

“Open” in this context means allowing other organizations to build functionality based on a common operational data model – as opposed to forced integration when mandated by a customer. This provides competitive alternatives with greater functionality at a lower cost.

#### **Separation of Clinical and Operational Data**

Web services alone do not enable an open architecture. Exchanging data using web services requires agreement on the meaning of each piece of data, which is the bulk of the effort of an integration project. This is particularly challenging in clinical trials because the data types are different for each study. A next generation platform must provide an operational data model based on a core set of data definitions for all the data that can be common.

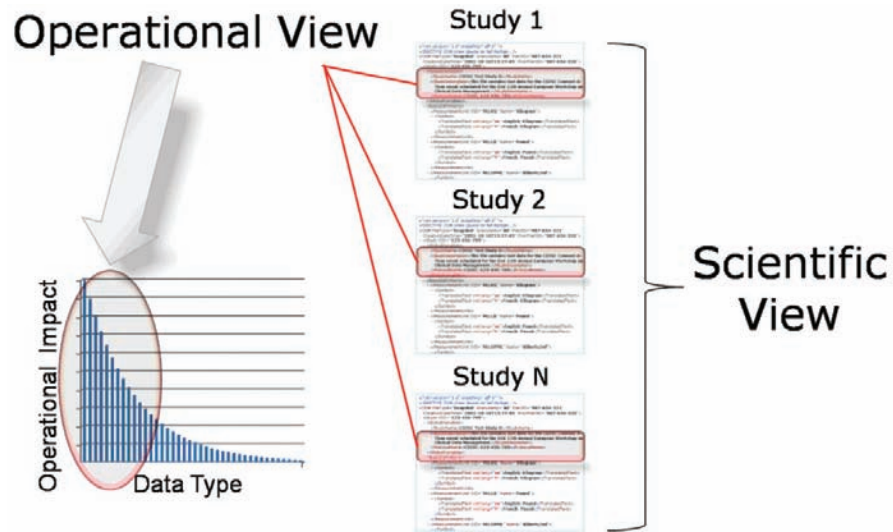


Figure 3 Focusing on Clinical Trial Operational Data

### Integration and Interoperability

Tools should be based on the latest integration technologies used across multiple industries, and not limited to integration tools developed and evolved by a single clinical trial software vendor.

Interoperability is the next level beyond integration. Integrated systems just share data. Interoperable systems allow users to perform similar functions from within their own applications. The next generation Clinical Trial Management Platform should address how users work within the most prevalent software user environment – Microsoft Office.

### Collaboration

Collaboration means more than just being able to access the same data. It requires the translation of that data into targeted information based on user roles. It also involves the ability to distribute work throughout the team, with appropriate approvals and audit trails along the way, through configurable workflow.

What should a next generation Clinical Trial Management Platform look like?

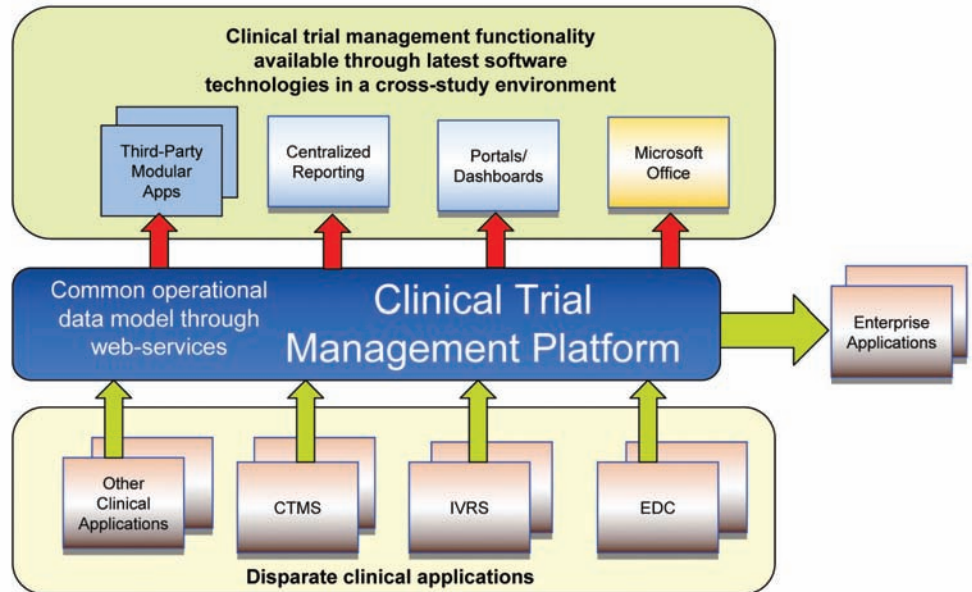


Figure 4 Next Generation Clinical Trial Management Platform

### Next Generation Architecture

Microsoft and BioClinica have partnered to define a next generation Clinical Trial Management Platform that meets the needs of today's clinical trial environment of clinical applications distributed among clinical business partners. The diagram below shows the architecture of the BioClinica Integrated Operations Platform (BIOP).

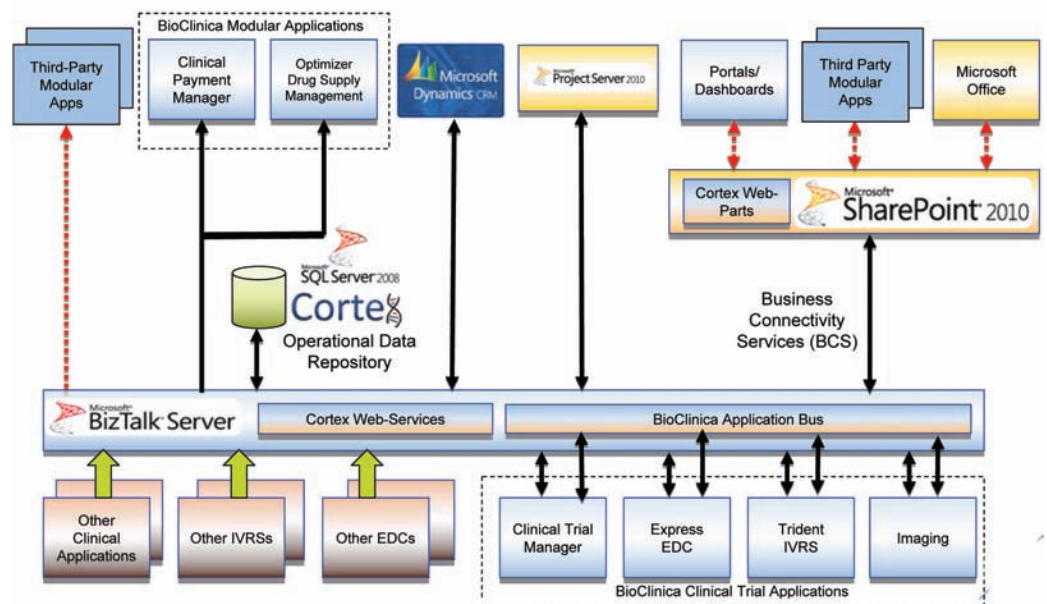


Figure 5 BioClinica Integrated Operations Platform (BIOP)

BioClinica's integration repository and set of operational data web services, "Cortex" (based on patent-pending technology), serve as the foundation for operational data interchange among software applications. The red arrows signify the access points open to third-party clinical trial software vendors and IT departments to configure and develop software based on a study-neutral operational data model populated from any of the connected clinical trial applications, regardless of vendor. Methods for getting data from the clinical trial applications can range from regular import of exported files to web services. Microsoft BizTalk Server provides a powerful solution to map and configure integration, and it supports transition to the cloud model discussed later. And, Cortex's data model is aligned with CDISC SDTM and the Metrics Champion Consortium (MCC) Clinical Trial Performance Metrics.

Modular applications at the upper left can access the consolidated operational data via the Cortex web services and provide cross-study functionality. For example, BioClinica's Clinical Payment Manager has access to site visit and CRF completion information to generate site payments. The Optimizer clinical trial shipment planning and tracking application pictured here has access to actual subject enrollment information to update drug shipment plans. These are the first of a family of modular applications that can be built out by third-party software vendors and IT departments using the cross-study operational data model. For example, consider a study planning modular application that can access up-to-date subject enrollment information. Modular applications can be written once to work on any combination of studies and clinical trial applications, providing functionality at lower cost.

The power of the Clinical Trial Management Platform and consolidated operational data is truly unleashed through the Microsoft SharePoint and Microsoft Dynamics platforms. SharePoint has ushered in a new level of collaboration and productivity across many industries. The challenge in clinical trials is to obtain and organize the data from legacy clinical trial applications. The BioClinica Integrated Operations Management Platform solves that problem by synchronizing the cross-study operational data with SharePoint in a form that SharePoint understands – Sharepoint lists. This opens up the operational data to easily-configured, role-based portals, workflow and Microsoft Office applications (for further information, see "Five Things Clinical Professionals Should Know About SharePoint" on BioClinica's website).

Microsoft Dynamics XRM is widely-recognized as a Customer Relationship Management application. It certainly serves that purpose well within life sciences companies, but it also a powerful platform for configuring web-based user interfaces and workflow.

Microsoft Project Server replaces much of the custom functionality built out in proprietary systems, and takes advantage of its tight interoperability with SharePoint. Project Managers can leverage the powerful resource planning and project management capabilities currently used across industries, while simplifying the user experience through SharePoint and Microsoft Office.

### Summary

The Clinical Trial Management Platform represents a new and unique approach to help solve the industry’s challenges discussed at the beginning of this paper. It is something new in the realm of clinical trial software, and provides an alternative to having to be locked into a single suite vendor to have your applications work together.

Industry Challenge	Current Solutions	Next Generation Operations Platform
Clinical Trial Reporting	<ul style="list-style-type: none"> <li>• Data locked within clinical applications</li> <li>• Hard-coded reporting</li> </ul>	<ul style="list-style-type: none"> <li>• Cross-study operational data reporting through role-based configurable portals and third-party reporting tools</li> </ul>
User Experience	<ul style="list-style-type: none"> <li>• Multiple systems per user</li> <li>• Complex proprietary user interfaces</li> </ul>	<ul style="list-style-type: none"> <li>• Targeted information through portals</li> <li>• Interoperability with Microsoft Office applications</li> </ul>
Working with Business Partners	<ul style="list-style-type: none"> <li>• Sponsors train CROs at their expense to use sponsor systems, or build out fixed infrastructure</li> <li>• No solution for acquisitions</li> </ul>	<ul style="list-style-type: none"> <li>• Interoperate with business partner systems through a common operational data model</li> <li>• Leverage Microsoft Office as the user “common denominator”</li> </ul>
Business Agility	<ul style="list-style-type: none"> <li>• Dependent on long vendor upgrade cycles</li> <li>• Limited customization for unique business needs</li> </ul>	<ul style="list-style-type: none"> <li>• Configurable portals, user interface and graphical workflow</li> <li>• Extensibility through open-architecture</li> </ul>
Managing Clinical Trial Software Costs	<ul style="list-style-type: none"> <li>• Companies locked into vendor suites with few competitive choices</li> <li>• Software vendors tied to old software technologies</li> <li>• Software vendors replicating better and less costly industry-wide integration solutions</li> </ul>	<ul style="list-style-type: none"> <li>• Best-in-class solutions and service providers</li> <li>• Modular applications and portal components that are developed once and sold many times</li> <li>• Leverage modern software technologies for development</li> </ul>

## The Potential of Cloud Computing

New cloud-computing technologies like Microsoft Azure can provide an integration fabric to interchange clinical operational data through the Cortex data model. The ability to interchange clinical operational data through the cloud takes business partner collaboration to the next level. The BioClinica Integrated Operations Platform has been architected to support transition to Microsoft Azure to allow life sciences companies to take advantage of the trend towards cloud-computing.

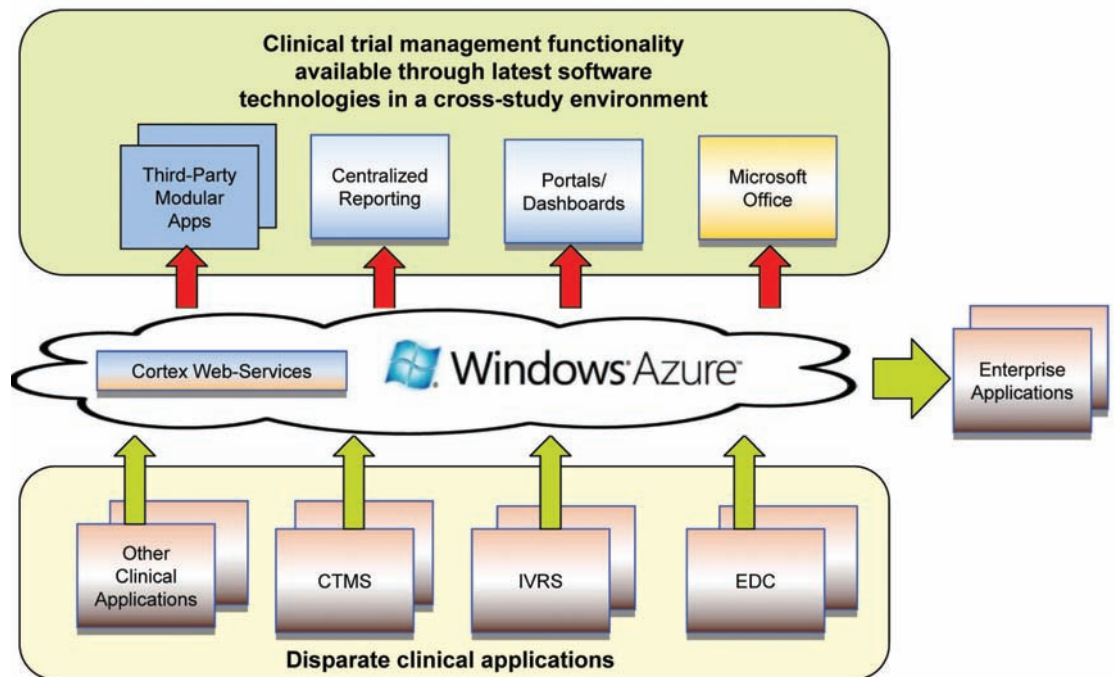


Figure 7 Clinical Trial Operations Platform Cloud Transition