CASE STUDY

Harvard Clinical Research Institute (HCRI) Realizes Efficiencies and Savings on Clinical Trials with Bioclinica® OnPoint CTMS

Situation

Having grown to a premier research organization with 400 clinical trials to its credit, HCRI's clinical trial management needs had surpassed the conventional processes it had been using to manage and monitor information and documents related to its clinical studies. The Institute's 140 users relied on Excel spreadsheets and other manual processes that proved labor-intensive, inefficient, and a barrier to team communication.

To remedy the situation, HCRI sought a clinical trial management system (CTMS) – one that would establish a consistent process across all studies, while improving efficiencies, team communication, and collaboration. The Institute preferred a CTMS with real-time data collection and reporting capability and hoped to accomplish its goals without increasing overhead costs, and without burdening users to learn and adopt new technology.

About HCRI HCRI is an academic research organization established by Harvard Medical School, Beth Israel Deaconess Medical Center and Partners HealthCare System. The Institute provides efficient integration of industry and academic resources for clinical research and development. It collaborates with academic researchers to offer expertise in a range of therapeutic areas including interventional cardiology in which it is a recognized leader.

HCRI provides industry and academic researchers with a center for data collection, management and analysis that is fully compliant with regulatory standards. HCRI also offers sponsors expert trial design, safety management and independent centralized clinical endpoint event adjudication.

The Challenge

How could the Institute enable its many users to access and manage study information without increasing clinical operations overhead? How could this be achieved simply and efficiently?

Two conventional options existed, each posing a challenge:

- Give users access to the application.
  - This carried significant training, investment, and recurring administrative costs
- Give users the data in a familiar format, such as Excel files.
  - Non-dynamic files require significant time and effort to generate, manage, and update.

Solution

HCRI selected Bioclinica's OnPoint – the Microsoft® Office-smart CTMS that employs Office productivity tools familiar to its user base. This creates a centralized environment and provides a highly efficient way to manage clinical trials and streamline clinical operations. OnPoint uses innovative ClinBUS® data interchange technology to make data available through Microsoft SharePoint Server. ClinBUS enables the use of SharePoint data grids to connect Microsoft Excel spreadsheets and databases, including Microsoft Access, to Office-Smart solutions for data import or integration. With this new level of connectivity, HCRI can now use previously hard-to-get-to data for the creation of SharePoint websites and dashboards—and leverage its existing Microsoft Office tools, including Excel, Access, Outlook, and Word.

OnPoint created a central repository housing all of HCRI's clinical information using real-time data and provides uniform tracking of trial processes. Assembling clinical operations across multiple studies within a central environment was a major leap forward. The Institute made additional progress toward

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enhanced team performance and productivity by broadening user access with role-based viewing. Role-based access to SharePoint portals and OnPoint includes:

- An executive portal with study summaries;
- A project management portal with reports, dashboards, contacts, and links to native CTMS pages;
- A site management portal with links to site documents, contacts, reports and native CTMS pages;
- IT, clinical review and safety; and
- Other portals round out HCRI's new CTMS.

All of HCRI's clinical studies are now viewable in single list on a SharePoint homepage with links to the individual studies. Users are able to create custom reports suited to their needs. Office-Smart list views provide data-grid views similar to Excel files, but with real-time data. Any data contained in expired documents is presented in a meaningful way to the user. Subject, monitoring visits, and document records may be quickly and easily added and edited. Links take users directly to the OnPoint application where new sites can be easily managed and new studies quickly set up.

Results

Since 2009, HCRI has used OnPoint for most of its new clinical trials and all of its trials since 2013. Of these, 48 OnPoint CTMS studies are now closed – impressive performance considering one study alone enrolled 20,000 subjects. Additionally, more than 300 closed studies were entered in OnPoint for historical data. Bioclinica's OnPoint CTMS creates an efficient and consistent clinical trials process with real-time reporting capability, improved team communication, and collaboration. Collectively, these benefits have enabled the clinical trials leader to achieve an even higher level of service. HCRI attributes Bioclinica's OnPoint CTMS for dramatic enhancement in the services it provides to study sponsors.

Benefits

Streamlined Management Using a CTMS that is interoperable with Microsoft Office SharePoint, HCRI:

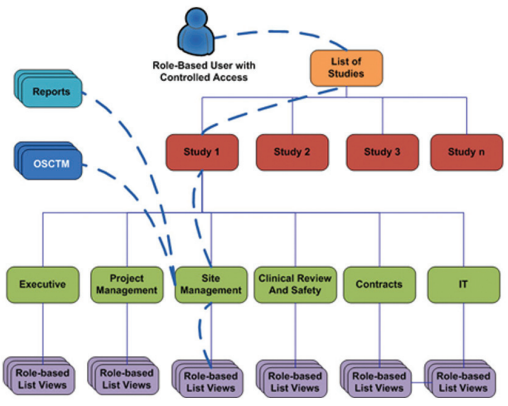
- Significantly reduced time and effort on each study
- Improved stakeholder access to data
- Streamlined operational data management processing

Cost Savings

- Data collection and retrieval
- Personnel efficiencies:
  - Payment processing improved 35%
  - Site monitoring improved 25%
  - Regulatory document review improved 20%

Flexibility

- Adapts to changing needs
- Leverages data interchange technology for enhanced integration with third-party EDC and other eClinical software systems



Bioclinica is a global provider of integrated, technology-enhanced clinical trial management solutions. Whether you are a sponsor or CRO, a virtual company or a global enterprise, Bioclinica offers value and dependability.