

Managing the Multi-Disciplinary Clinical Research Enterprise

Clinical Research Management

The Problem

Academic clinical and translational research centers confront challenges that are distinct from those of pharmaceutical companies and contract research organizations. Academic centers contend with hundreds of trials at once in an environment where there are many other, often competing, concerns ranging from limited resources to meeting ever-changing regulatory requirements. Organizationally, some activities are conducted by a centralized clinical trials office while others are performed within the many diverse groups or departments of the center or enterprise.

Because there is rarely any cross-communication between these islands of information, it is difficult, if not impossible, to maintain information about the institution's entire research portfolio. Simple questions about the number of ongoing trials, the current status of these trials, and the expected and actual accruals are not easy to answer. Maintaining a grasp of the financial status of individual studies is equally challenging. Even when critical data is available, there are significant latencies. The consequences include sponsors not being properly invoiced, data being entered multiple times into multiple systems which can result in billing inaccuracies, loss of revenue, and potential issues with the Centers for Medicare and Medicaid Services (CMS) guideline compliance.

The Solution

OnCore® has a long history of successfully addressing the broad spectrum of challenges faced by research centers by providing an effective and sustainable informatics infrastructure for managing clinical and translational research operations. Because it is a true enterprise system, this applies not only to integrating information systems (e.g., laboratory, clinical trials management, and billing systems) but also to the integration of common operational components (e.g., regulatory, administrative, and finance) with an appropriate balance of centralization and decentralization within the organization.

The Enterprise View

Although various research-related activities may be performed either by a centralized office or distributed among individual operational units, they can be monitored with OnCore at the enterprise level in support of an institution-wide focal point of responsibility and coordination. Examples include contract, budget, and financial management for industry sponsored studies; aggregated statistical reports on active studies, subjects on studies, adverse events, accrual rates by operational unit, etc. across all departments as well as other participating organizational entities; standardized tracking of clinical research staff credentials; shared services that support investigator initiated research such as trial design, biostatistics, laboratory, and data collection and management; community outreach programs including an inter-departmental, publicly accessible listing of all currently accruing studies with eligibility and treatment information for referring physicians.

Virtual Repositories

Departmental, group, or other organizational units within the organization may require their own, specialized infrastructure even though they must be integrated into the larger, institutional environment to be effective. Rather than requiring the creation of separate infrastructural components, OnCore provides virtual research repositories to give the appearance of wholly separate, specialized components.



Key Capabilities

- Easily adapted to unique needs and operating procedures of an organization
- Birdseye view of research activities
- Budgeting and financials management
- Customizable electronic Case Report Forms (eCRFs)
- Study setup and activation workflows
- Subject safety monitoring
- Aggregated statistical reports across organizational units
- Automated notifications
- Electronic Data Capture and Data Management (EDC + CDM)
- Paperless Committee Management with ePRMS
- Study Information Portal
- Custom Reporting Technology

Study Financials Management

This component is fully integrated with the study administration and clinical data management components of OnCore® and includes budget estimating, tracking subject clinical event completion, automatic invoice creation, reconciliation of payments with invoices, affiliate payments, and managing billing accurately between standard of care and research related events. An enterprise charge master allows for tracking costs as well as recommended research charges for all clinical or administrative procedures. Multiple rate bases may be used if the recommended charges are based on specific factors such as industry sponsored vs. federally funded.

Internal Integration

The OnCore Integration Framework provides a flexible mechanism for integrating data from a variety of data sources like lab and hospital information systems. This allows OnCore to leverage relevant data, e.g., patient demographic information needed for subject registrations and specific lab results called for in electronic case report forms in investigator initiated trials.

Study Administration

OnCore provides capabilities to set-up and activate studies, manage committees, collect subject information, monitor accrual, deviations and toxicities, and report on study progress, safety, and other key management information.

Affiliate Management and Support

The OnCore affiliate management capabilities can help extend the scope of outreach activities to increase community participation across the state or region. More specifically, the affiliate management functions provide an overall enterprise view of the research-related activity at all the affiliate sites while ensuring that affiliate staff can efficiently participate in clinical and translational research programs.

Outreach

Because all clinical trials are tracked in a single database, outreach coordinators can easily direct referring physicians and the general public to the most appropriate studies. In addition, when studies are made available using the Study Information Portal, the general public and outside referring physicians can search and view protocol information via a website link.

Custom Reporting

The custom reporting feature offers the ability to add institution-specific or department-specific reports to the system that have been created using the third-party report engine technology, JasperReports. Custom reports can include rich features such as charting and cross-tabs and may be produced in a variety of file formats such as PDF, Excel, CSV, and RTE.



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