

Understanding & Managing Financial & Compliance Risks Through Clinical Trials Management Systems

Clinical Research Today

The current environment in which organizations conduct clinical research is fraught with complex regulations, ever-changing compliance challenges, and mounting financial pressures. Organizations face a growing need to expand translational and clinical research capacity while dealing with flat NIH funding for biomedical research. Meanwhile, industry sponsors continually demand quality results and clean clinical data with ever tighter budgets. These pressures have led research organizations to review their clinical trials operations in search of ways to better manage the clinical research enterprise through:

- Better access to information,
- More efficient processes,
- Tighter financial management,
- Lower compliance risk, and
- Delivery of high-quality data to sponsors.

The clinical trials enterprise at many organizations is decentralized and highly dependent on the variable experience of individual principal investigators and research coordinators. In many hospitals, clinical research is often invisible throughout the organization and typically is managed opportunistically rather than strategically. Research organizations, from large academic centers to small research units within community healthcare providers, often manage in a reactive way, missing opportunities to optimize the use of resources.

Central administration generally has little control over funds flow related to clinical research, minimal information about the volume of research taking place, and limited ability to ensure that the actual costs involved with each project are recovered from the sponsors. This can

lead to significant financial losses, poor research outcomes, and exposure to higher compliance risks. Examples of these problems can include:

- Financial losses due to under-estimation of costs or over-estimation of enrollment,
- Dedication of scarce institutional resources to research projects that are poorly designed or are not aligned with institutional mission and strategy, and
- Increased compliance risk related to billing patients and insurers inappropriately.

Effectively managing a clinical trials program can mitigate both compliance and financial risks associated with research operations.

Leveraging Available Information and Providing Structure

One of the most useful tools available to clinical research organizations is a clinical trials management system (CTMS). These systems were developed to improve overall management of clinical trials from an operational, regulatory compliance, and financial perspective. A CTMS can have a direct impact on many challenges of managing clinical trials by providing:

- Visibility into trial- and subject-specific information across the entire enterprise,
- Financial management tools: from pre-study budgeting to in-study expenditures & invoicing,
- Coordinated management of all phases of a research project, and
- Support for research billing compliance.

The CTMS serves as a central repository of administrative, operational, and financial data, significantly reducing redundant data entry, and reducing error.

The Benefits of Implementation

One notable benefit from implementing a CTMS is the improvement in communication, processes, policies, and accountability that can be obtained through the implementation process. Successfully implementing a CTMS requires a thorough review and redesign of processes and expectations. The process of implementation brings together individuals spanning the clinical, compliance, and financial departments to fully understand (often for the first time) existing processes and to design effective new processes. As a result of this collaborative effort the organization will have:

- Clear and commonly understood processes,
- Clearly documented roles and responsibilities,
- Enhanced channels of communication across participants in research processes, and
- Clear policies and expectations.

Where Clinical Trials Management Systems Matter Most

The primary benefit of a CTMS for an organization is the impact it has across all aspects of the clinical research cycle: from the pre-planning stages (including feasibility review, budget development, coverage analysis, and contracting) through the actual management of recruited and enrolled research subjects, patient procedure tracking, milestone capture, and study close-out. CTMS facilitates centralization of all types of research information in a web-based environment, giving key stakeholders access to information and enabling streamlined processes.

Key Clinical Trial Processes Affected by CTMS

Pre-Planning and Feasibility

The pre-planning start-up phase of the clinical research process is a critical point in the research cycle and strongly influences the success of the project. During this phase, the initial feasibility of the clinical trial is assessed, a budget is developed, and the stage is set for effective implementation of the study. A CTMS can provide an effective and efficient framework to structure the processes around pre-planning.

Budget Development

Effective budget development using a CTMS can also assist in reducing the risk of financial loss. The key to a financially sound project is understanding the financial model before the first patient enrolls. An accurate budget encompasses many types of cost. Budget development requires the collaboration of study team members and experienced administrators. CTMS functionality provides:

- Immediate access to the latest charge master procedure costs,
- Standardized, applicable research rates & real cost information,
- Tools to support a uniform and complete budgeting approach, and
- Break-even analysis.

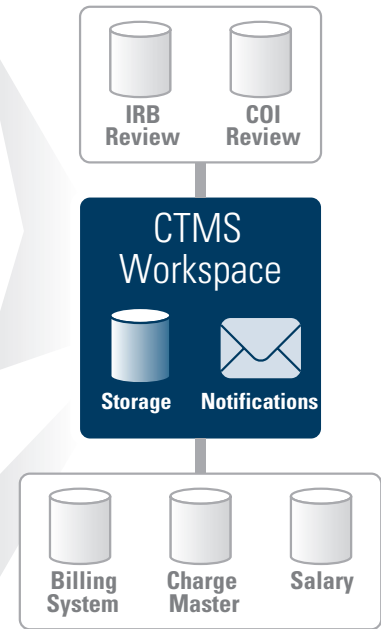
The development of the budget in a CTMS can also establish baseline information that will be used throughout the course of the trial to analyze the financial status of the project.

Conducting Coverage Analyses

Coverage analyses is a recommended process for managing compliance risks related to billing clinical trial subjects and their insurers. A CTMS:

- Allows organizations to standardize the approach for defining coverage based on the Clinical Trials Policy (formally the Clinical Trials National Coverage Determination),
- Supports documentation of decisions, including references to National and Local Coverage Determinations and clinical guidelines, and
- Provides a tool to support collaboration between coverage analysts and researchers.

| COLLABORATORS | DELIVERABLES |
|---|--|
| PI Legal | <input checked="" type="checkbox"/> Contracts <input checked="" type="checkbox"/> Nondisclosure |
| PI Budget Analyst | <input checked="" type="checkbox"/> Transmittal/ Cover Sheet <input checked="" type="checkbox"/> High Level Budget |
| Dept Chair Division Chief PI | <input checked="" type="checkbox"/> Resource Review Approval <input checked="" type="checkbox"/> COI Review |
| PI Budget Analyst | <input checked="" type="checkbox"/> Detailed Budget <input checked="" type="checkbox"/> Procedure List |
| Coverage Analyst PI | <input checked="" type="checkbox"/> Coverage Analysis <input checked="" type="checkbox"/> Procedure Payor Tagging |
| Contract Admin PI Sponsor Contact | <input checked="" type="checkbox"/> Contract Payment Terms <input checked="" type="checkbox"/> Milestones |
| Coverage Analyst PI | <input checked="" type="checkbox"/> Final Coverage Review |
| IRB Analyst PI | <input checked="" type="checkbox"/> IRB Approval |
| Contract Admin | <input checked="" type="checkbox"/> Activation |



Being able to ear-mark each procedure with the specific coverage determination supports segregation of charges to study accounts or 3rd party payers and helps reduce the risk of potentially billing incorrectly.

Research Trial and Subject Tracking Capabilities

The project and subject tracking ability of many CTMS supports both management of individual clinical trials and the roll-up of clinical trials information into departmental/institutional tracking reports. Many research organizations struggle with tracking and monitoring open clinical trials and the participation of patients in those trials. CTMS provides accurate subject tracking and management reporting without additional work from study teams. Having access to this information can be a significant leap forward for organizations.

Complete Study Financial Management

CTMS impacts financial management in several ways:

- Expenditure tracking,
- Accounts receivable monitoring & reporting, and
- Invoicing & payment distribution.

The ability of these systems to perform financial tracking and management tasks benefits organizations by providing more accurate and timely financial data, giving them the ability to intervene in a timely manner. Actions triggered by access to timely information may include taking steps to increase enrollment, renegotiating trial budgets, contacting sponsors for payments owed, and sometimes closing a study. CTMS also aggregates financial data to provide an ability to monitor and manage the finances of the clinical research enterprise.

Easy and Ready Access to Research Information

One of the strongest benefits of CTMS is its ability to gather, organize, store, and provide a large number of key stakeholders with access to study information. Management of clinical trials is a complex and dynamic operation that relies on effective communication and access to information. CTMS provides an environment that integrates trial information across financial, regulatory, and operational functions. Access to this information enables active management of trials and effective trial processes, and reduces the time and effort required by manual processes.

Conclusion

A CTMS can benefit a research organization in multiple ways. First, a CTMS can provide the ability to collect and track financial, regulatory, and operational information simply and without the need for duplicate data entry. Second, a CTMS can provide such information readily to multiple stakeholders, from study teams, to patient financial services to senior leadership. Finally, a CTMS can support process standardization, which is important to organizations with research conducted across a wide range of clinical areas. Given these capabilities, a successfully implemented CTMS can positively affect the compliance, financial, regulatory, and resource management of the research enterprise.

About Huron Consulting Group

Huron Consulting Group helps clients effectively address complex challenges that arise in litigation, disputes, investigations, regulatory compliance, procurement, financial distress, and other sources of significant conflict or change. The Company also helps clients deliver superior customer and capital market performance through integrated strategic, operational, and organizational change. Huron provides services to a wide variety of both leading academic institutions, healthcare organizations, including Fortune 500 companies, medium-sized businesses, leading academic institutions, healthcare organizations, and the law firms that represent these various organizations. Learn more at www.huronconsultinggroup.com.

Huron's Healthcare and Education Consulting practice has assisted many clients with the development and management of the clinical and translational research enterprise. Projects have included: development of clinical research strategy, selection and implementation of clinical trial management systems, development and implementation of policies and procedures, and interim management. Clients have included medical schools, independent academic medical centers, community hospitals, and healthcare systems.

About Click Commerce

Click Commerce Research and Healthcare is a leading provider of automated research administration and compliance systems to some of the premier academic medical centers and research institutions in North America, including the University of Michigan, University of Southern California, The Mayo Clinic, Children's Hospital Boston and Children's Hospital of Philadelphia. More information can be found at <http://research.clickcommerce.com>.

For more information, please contact:

Matthew Staman

Huron Consulting Group
312-583-8742
mstaman@huronconsultinggroup.com

Nick Stier

Click Commerce
503-601-4523
nick.stier@clickcommerce.com



Huron Consulting Group helps clients effectively address complex challenges that arise in litigation, disputes, investigations, regulatory compliance, procurement, financial distress, and other sources of significant conflict or change. The Company also helps clients deliver superior customer and capital market performance through integrated strategic, operational, and organizational change. Huron provides services to a wide variety of both financially sound and distressed organizations, including Fortune 500 companies, medium-sized businesses, leading academic institutions, healthcare organizations, and the law firms that represent these various organizations.

1-866-229-8700
www.huronconsultinggroup.com

Experience. **Redefined.**[™]