White Paper: Using Collaborative CTMS to Save Clinical Research

Research's Collaboration Crisis

Athletes win games, but coaches provide the structure and foundation that make winning possible. Without a coach, athletes often flounder and are out-of-alignment, meaning they have the skill to win, but are not properly communicating to get the job done. Today's clinical research industry operates in a very similar fashion. There are thousands of highly skilled research organizations who are performing at their peak, but lack a "coach" who will help to bring everybody together to succeed in the common goal, performing high quality research.

Today's research organizations face several challenges, many of which are rooted in communication and collaboration issues. In order for a trial to be completed successfully, dozens of moving parts need to come together; and communication and collaboration are the keys to success. Without effective collaboration and communication between research organizations and the partners they work with, research organizations see higher costs, longer timelines, increases in errors and greater levels of confusion.

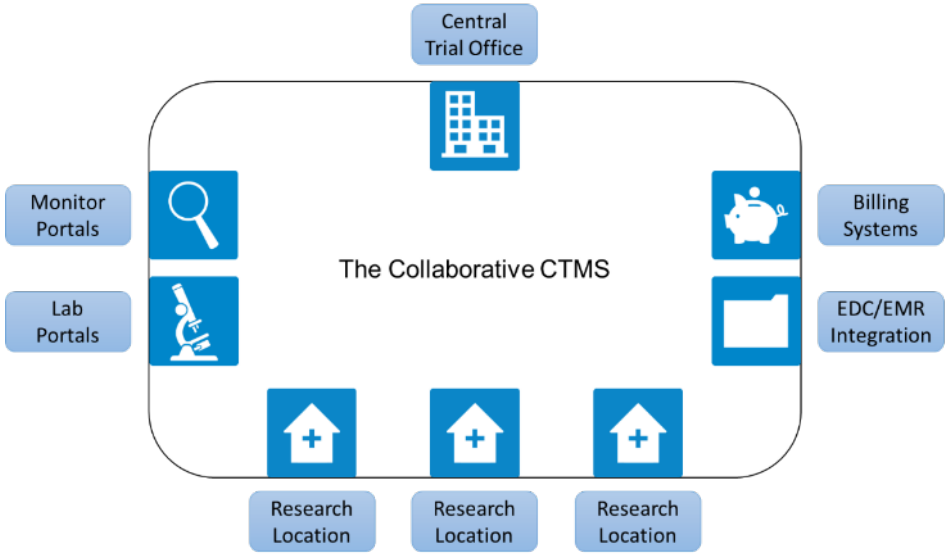
Additionally, each year the cost of conducting trials goes up, so it is important to consider what options are available to help mitigate these risks and help to keep costs under control.

Sounds Serious! What Can I Do?

There are a few different options when it comes to improving communication and collaboration between research organizations working together. Organizations can strengthen partnerships, hold regular meetings and work to ensure a steady flow of information from one point to another, but this is time consuming and leaves organizations exposed to human errors and unforeseen circumstances. To best address this concern, research organizations need a collaborative CTMS.

What is a Collaborative CTMS?

Traditionally, clinical trial management systems (CTMS) have been designed as stand-alone software applications for either single research locations or for organizations managing multi-location research, including CROs, site networks, healthcare networks and others. However, as clinical research became more complex, it became apparent to the research community that something needed to



change in order to optimize trials at all levels of the research process. That change has come in the form of the collaborative CTMS. With the increase in cost and complexity of trials it has become more critical than ever to ensure that every organization participating in a clinical trial is able to actively communicate and collaborate with the others.

A collaborative CTMS is the ultimate tool for ensuring that each trial is a complete success. The more collaboration seen in a study, the greater chance of success. With collaboration, delays can be prevented, information won't be lost, confusion will be averted and questions can be answered, all from one central location. A collaborative CTMS can be as simple as sending study protocols from one system to another, all the way through a fully-integrated platform with complete bi-directional exchange of information from dozens of different data points. The greater the level of collaboration, the more researchers benefit.

Why is it Important?

As the cost of clinical research increases from both a financial and time perspective, research organizations will seek out ways to increase the likelihood of a trial succeeding. The most impactful way research organizations can mitigate this risk is by optimizing their research operations by utilizing a collaborative CTMS. Without adequate communication and collaboration, provided by a CTMS, between research partners or locations, research costs go up, timelines get extended and profits go down.

Improving communication between sites and sponsor organizations with collaborative CTMS applications is important because it benefits everybody involved in the research process, and helps to ensure the success of a research trial.

How Can a Collaborative CTMS Save Clinical Research?

A Collaborative CTMS gives research organizations the ability to perform like never before. Through a collaborative CTMS research organizations have real-time information right at their fingertips, giving them the ability to make decisions, see trends and be up-to-date with every facet of all of their clinical trials.

Streamlining the interaction between all of the parties involved in a clinical trial leads to faster turnarounds, more complete data and a better picture of what is taking place in any particular study at any particular location. With the cost of bringing new drugs to the market constantly increasing, it is critical to reduce costs wherever possible. Effective collaboration can help organizations save money while conducting research by eliminating wasted time, preventing costly errors and ensuring accurate billing and financial tracking.

Along with conducting the best possible clinical research, research organizations are also motivated to grow their business in many ways, including the number of studies, personnel and profitability. While effectively and accurately managing the clinical actions related to each trial is critical, many trial management systems do not effectively address the need for business growth. Collaborative CTMS systems can also take this into account.

The ability to make timely and educated decisions is critical to the success of a trial. Waiting too long to make a decision, or making an uneducated decision, can have disastrous financial and time related consequences. A collaborative CTMS provides the necessary hierarchy and

aggregation of study data to provide researchers with actionable, real-time information from all research partners and locations. Being able to make decisions quickly and accurately helps reduce timelines and keep costs to a minimum. Additionally, this information helps to ensure that studies are on track and on budget.

Things to Keep in Mind Before Selecting a CTMS

When the time comes to select a CTMS, it is critical to consider several very important factors that can greatly impact the final outcome. Below is a list of twelve key factors to keep in mind while researching and selecting a clinical trial management system.

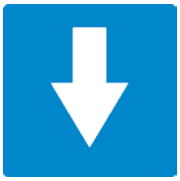
Breadth - Great CTMS software will integrate a wide variety of features that better help organizations report, track and analyze trial data. Features such as patient databases, recruitment, patient scheduling, financial management, document management and reporting all go into a CTMS that can effectively manage trials. Along with these features, some of the greatest CTMS software will be capable of providing web-recruitment services as well as regulatory modules. CTMS software companies that ignore these features are only capable of providing the basic services to their customers, and research organizations using these CTMS products typically see lower ROI and decreased profitability.

Scalability - As an organization conducting or managing clinical trials, expanding to generate more business is always a possibility. This expansion may be through the addition of trials at existing locations, or through the addition of multiple trial locations both globally and domestically. Taking into account potential business expansion in the future is a necessary step before selecting a CTMS. There are many CTMS companies that have software that is capable of scaling along with trial growth. Some CTMS companies embrace this and even offer multiple CTMS software options that fit various types of growth.

Updates - Software changes frequently. It is important that CTMS developers continue to release updates to make their CTMS software run more efficiently, and integrate new features that allow for optimized trial management. A CTMS company that understands its users are always evolving will consistently have software updates every few months.

Compliance - It is important that your CTMS software is capable of recording and storing data in ways that comply with all facets of HIPAA, Safe Harbor and 21 CFR Part 11. Moreover, the applications should provide a full audit trail so all activities can be recorded.

Integration - Most research organizations are also using services from other technology providers. It is important that CTMS software has the capabilities to integrate with other clinical tools; doing this further enhances the CTMS benefits for research organizations by giving them even more control. Great CTMS products are capable of integrating with EDC and EMR software, regulatory applications and other types of research tools.



Data Import - Whether switching from another CTMS, from a proprietary CTMS or Microsoft Excel, the new CTMS company should be able to take existing data and import it into the new CTMS. This way, companies are not burdened with the task of reentering data.

Secure Data Storage - Many CTMS companies host their products and host the CTMS database for each client. Ensuring that these companies can effectively store and protect confidential data, while also ensuring the CTMS product remains accessible at all times is essential. If a CTMS company is partnering with a company who does not value security, then avoid using that CTMS.

Changing Needs - As an organization evolves, its needs are almost guaranteed to change. It is important to be partnered with a CTMS company that understands this and is open to working with its customers to ensure the CTMS allows users to effectively conduct clinical trials. A great CTMS company is always analyzing the industry and knows what is coming before it is requested by customers.

User Accounts - Having separate user accounts allows for better tracking of trial data and employee accountability. Some CTMS companies limit the number of users allowed on the CTMS and charge additional fees if more users are required. If this charge is too high, research organizations may have multiple people logging into one account, which raises concerns with HIPAA regulations. Having a CTMS that allows for unlimited users helps research organizations become more productive and remain compliant.

Ease-of-Use - Researchers need to be able to enter data in a way that is intuitive and consistent. This means the CTMS software being used should be easily navigable, well organized and designed to minimize the number of required clicks to accomplish a task. A great CTMS should also have easily generated reports that take the raw data, analyze it and present it in a way that researchers and administrators can benefit from it.

Training - Adopting a CTMS is a major change for any research organization. If a CTMS software company does not offer comprehensive training on its products, organizations may be underutilizing the software or using it inefficiently, which could diminish the likelihood of success. Moreover, a lack of training could prevent research organizations from fully adopting the CTMS they purchased, wasting the money and time that was spent investing in the system. A leading CTMS software company should offer training and tutorials so research organizations can better themselves through the use of this new software.

Support - Even with proper training, questions and requests will arise from any organization using a CTMS. Looking for a CTMS company that provides high quality, ongoing support is essential. Given that questions can arise at any time, research organizations should be able to contact the CTMS company support staff and receive assistance immediately.