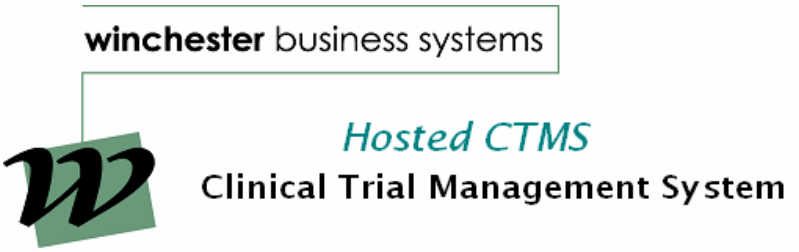

Decision Guide

Learn what a Hosted CTMS system can do for you and understand what issues you should consider during your decision-making process.

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Executive Summary

Today's Clinical Trial Management System (CTMS) solutions aim to help the clinical trials team to manage the myriad documents, files, contracts, contacts, vendors, investigators, patients, and correspondences that are components of today's clinical trials.

By gathering information from multiple data sources and storing it in a centralized location, a hosted CTMS solution provides a holistic view of a clinical trial in real time. Armed with this insight, a company's clinical operations people can better plan and manage clinical trials.

The bottom line with hosted CTMS solutions is that they provide an efficient way for a clinical operation to quickly set up a new clinical trial, manage the trial from start up to close out while reducing operating costs and increasing overall data integrity.

In this ***Decision Guide***, you will find details on what to look for, how to buy, what you can expect to pay, and how to derive the most value from your hosted CTMS investment.

Hosted CTMS Overview

A Clinical Trial Management System (CTMS) is a software application that allows users to access important data, ranging from the status of a clinical trial, budget versus actual spending on a clinical trial, status of site-essential and regulatory documents, author, review, and approve monitoring reports, manage investigator and vendor contracts, manage clinical trial supplies, manage people resources, and track progress of patients on a clinical trial, through a single source in real time. Beneficial to countless departments within a clinical organization, most CTMS solutions include these primary applications:

Relationship Management: Empowers business development and project planning with immediate insight into customer buying patterns; helps managers better forecast future sales; allows companies to adjust production cycles based on real-time sales figures; enables accurate assessment of the sales team's performance.

Investigator Relationship Management: Helps the sponsor and trial teal to manage the complete relationship with investigator sites.

Site-Essential Document Management: Enables the trial team tio generate, track, and approve documents on a trial.

Planning and Budgeting a Clinical Trial: Facilitates the establishment of an up-front project plan and then couples the plan to actual trial performance on a day-to-day basis.

Managing Investigator and Vendor Contracts: Connects accounting, finance, legal, purchasing, and clinical operations helping to establish initial contacts and periodic updates. Assists the trial team in determining when and how much to pay sites based on contracted performance.

Generating and Managing Monitoring Reports: Providing an over-the-web ability for CRAs to enter and edit monitoring reports. Also providing collaboration between the CRA and the trial management team.

Patient and Subject Management: Accepting direct inputs of patient profile and visit information from investigators, CRAs, or EDC systems.

Analytics: Generates real-time, graphical and customized reports so that businesses can better allocate resources, gain strategic insights and optimize enterprise performance.

Hosted vs. On-Premise CTMS

There are two primary types of CTMS solutions for businesses: hosted CTMS and on-premise CTMS. Hosted CTMS (also known as "on-demand CTMS") entails a company outsourcing a portion or all of its CTMS functions to an ASP (application service provider). Lately this outsourcing of software has been labeled "Software as a Service" or SaaS. Some call it "***Cloud Computing***."

Unlike licensed on-premise CTMS software, hosted CTMS tools are payable on a monthly basis without requiring complex implementations or the assistance of an in-house IT team. The result is a cost-effective solution that promises to deliver a quick ROI (return on investment), while freeing a company to focus on its core competencies.

In fact, according to a study from Nucleus Research, more than 80 percent of companies that outsourced CTMS achieved a positive ROI. The study reported that problems with the on-premise CTMS model include high software and consulting costs, ineffective user adoption, and poor management.

But for all its promises of immediate payback, the hosted CTMS model does have its shortcomings. For one thing, whereas on-premise CTMS solutions can be tailored to the particular needs of an organization, on-demand solutions don't allow for the same degree of customization. What's more, on-premise solutions are easier to integrate into a company's existing business processes and applications.

To facilitate the need for the Hosted CTMS to better fit a specific client, Winchester's Hosted CTMS offering is highly "configurable." It can be reconfigured or changed as a company grows or expands. A feature of configurable variables allows Winchester's clients who may be Contract Research Organizations (CROs) to personalize the system such that it completely reflects the CRO's identity and business practices.

For small- to medium-size businesses, however, the price is right when it comes to hosted CTMS tools. By paying per user per trial per month, a company can gain access to a sophisticated application in a mere 30 days without having to burden its IT department or cut off its cash flow. And of particularly good news to growing companies is the fact that Winchester's on-demand CTMS solution is highly scalable and easy to upgrade.

The Benefits of Hosted CTMS

There's good reason the on-demand, Software as a Service (SaaS), and the "Cloud Computing" model has taken the IT world by storm in recent years. With its promises of reduced costs and easy deployment, today's hosted CTMS solutions offer countless benefits to companies ranging from fledgling businesses to international enterprises.

Here are just a few of the biggest benefits:

Rapid Deployment: Hosted CTMS implementations can take as little as a few days and rarely exceed three months. What's more, with an on-demand solution, companies need not invest up-front time in the planning of hardware and software purchases. An on-premise implementation, on the other hand, can easily exceed 12 months – an awfully long time to wait to get into the CTMS market.

Easy Upgrades: On-premise solutions often lay claim to a painstakingly slow product development life cycle, whereas on-demand applications can accommodate the instant deployment of new versions. Furthermore, product enhancements and upgrades can occur instantaneously, and hosted CTMS applications can be configured – and reconfigured – quickly.

Reduced Costs: Forget about purchasing costly hardware and ramping up your IT team with highly paid software experts. With hosted CTMS, there's no hardware to purchase, servers to install or techies to recruit.

Security Safeguards: If today's hosted CTMS vendors want to survive, keeping their datacenter security up to par is paramount. End users, on the other hand, have been known to skip software upgrades and poorly manage their employees' desktop installations – all the more reason to trust global industry leaders with the security of your data.

Basic Features

For some companies, a step-by-step strategy is the most cost-effective and efficient path to a hosted CTMS deployment. Fortunately, Winchester's CTMS solution is modular enough to accommodate such a piecemeal approach.

Relationship management is typically the most popular application of CTMS, followed by the management of individual trials, analytics, and service. The features found in each of these categories include all of the following:

Protocol Manager is comprised of several integrated modules that work together to form a complete **CTMS**. Because of **Protocol Manager**'s *open architecture*, Protocol Manager can interface with Electronic Data Capture (**EDC**) and Electronic Data Management Systems (**EDMS**). Events recorded in each system can apprise the other system(s) of the completion of the event or that an anomaly has occurred. The functions of the modules that comprise Protocol Manager are briefly described below:

- **Protocol Module --** The Protocol Module is used in the overall planning, monitoring, and managing a Clinical Trial. The Protocol Module is the business engine which drives the entire trial process. From within this module a trial is designed to meet the conditions set by the trial Protocol. The Protocol Module also provides reports on the status of the overall trial and activities that are taking place during a trial.

- **Trial Portals --** Protocol Manager utilizes Internet Portals to allow active, on-line interchange with all members of the project team. Portals also facilitate on-line, instant messaging and on-line, web-based team meetings. Discussion "sand boxes" provide vehicles for discussion

interchanges whether the members are on-line or off-line. Portals modules include:

- Sponsors
- Investigators
- Project Managers
- CRAs
- Data Management
- Project Assistants
- Safety
- Clinical Trial Staff

Business Development and Relationship Management – Partners with sponsors of a clinical trial have a unique requirement. That requirement involves offering services to sponsors and coming to agreement on a contract to provide those services to the client. Protocol Manager utilizes a unique model for Business Development that is used by CROs, SMOs, and TMOs alike. Its opportunity management capabilities employ some of today's award-winning approaches to selling.

Sponsors use the Business Development module to manage relationships and contracts with their clinical trial partners as well – CROs, TMOs, SMOs, etc.

Investigator Relationship Management -- The investigator relationship management module begins by providing basic contact management between the sponsor or CRO and the investigative site and its personnel. The module manages relationships with sites, individual investigators [and their staffs]; IRBs, ECs, Labs, and other clinical trials partners who actually conduct parts of the trial for the CRO or sponsor.

The module tracks the complete profile of the Investigator including current activities, trials that the Investigator has participated in and Investigator-related documents. By utilizing the Secure Login capabilities of ComPac GxP, an Investigators can enter into the system through the Investigator portal and update his own information.

Specific functions of the Investigator Relationship Management module include:

- Investigator recruiting & management
- Investigator payments -- payment events and invoicing
- Monitoring and trip reports
- Appointments and calendar management
- Regulatory document management

Investigator Payments -- Complete Investigator contracts and payment triggers may also be enabled for this system. Specific functions of the Investigator Payment Management module include:

- Investigator Contracts

- Investigator Payments and Invoices
- Payment Events based on contracts and other
- Payment events based on Patient Events

Monitoring -- Trial monitoring is an "embedded" component of several of the modules that comprise Protocol Manager. Monitoring begins with appointment scheduling and follows the monitoring work-flow through to the approval of the monitoring and trip report. Trial and site metrics are automatically available to the Monitor such that information is entered only once in the system.

Trial Documents -- Enabling electronic document management on a trial can provide a significant advantage in time and cost savings as well as producing higher quality information. The document module in Protocol Manager stores all of the documents associated with a trial (1572, CV, ICF, etc...).

Documents can be specific to countries, regions, and clinical trials. When an investigator is "initiated", the correct regulatory documents are automatically created from a trial document library. The specific country document is selected for creation.

Documents managed under this module have full version control and check in/ check out control. Documents may be scanned directly into the system or attached if they already exist in electronic format. Once added to the module they are enabled with workflow and review capabilities as well as expiration and notification attributes.

Specific functions of the Trial Documents Management module include:

- Forms letter library
- Regulatory (site-essential) document library
- Monitoring and trip reports

Patient Relationship Management -- The Patient Relationship Management Module tracks all activities and information around a subject enrolled in a clinical trial. The patient record is tracked along with Visit and Schedule information. CRF pages Queries and Protocol Deviations are also tracked. Ad-hoc visits, Ad-hoc CRF's and multi-leg trials are all easily handled by this powerful and flexible module.

Specific functions of the Patient Relationship Management module include:

- Patient recruiting
- Patient scheduling
- Patient tracking
- Electronic Data Clarification(s) – EDCFs
- Protocol Deviations & Exceptions

Patient Recruitment and Registry -- The recruitment module is a call center application for the evaluation of prospective patients on a clinical trial. The module contains a list of qualifying questions as defined by the protocol. Additionally, marketing and follow up questions may be recorded. By utilizing this module a list knowledge base may be formed and maintained and a reservoir of potential trial subjects for future studies is developed.

Inventory -- The Inventory control module tracks the shipment of drugs and the inventory of drugs on site at a trial center, including the lot and batch numbers of the drugs as well as expiration and recall dates. In addition to drug shipments Kits, medical supplies and other site essentials can also be tracked within this system.

Specific functions of the Inventory Management module include:

- Clinical Supplies
- Test kits
- Documentation bundles
- Kits
- Components
- Serial number and randomization numbers

Human Resources Management -- The Human Resources module contains a personnel directory of the company's personnel who are or could be involved in a clinical trial. Contact information is maintained as well as up-to-date CVs and training schedules.

Person content recorded in Human Resources contains information including department, job title, resource type, etc. "Contract Personnel" are also placed in the Human Resources module such that they may obtain protocol assignments from the trial project manager within the Protocols Module. The Protocols Module tracks assignments of personnel to specific trials based upon their availability.

Activity and Expense Reporting -- Trial personnel may enter time and expenses in this module. Once entered this information provides an accurate and up to date costing on the clinical trial. Through this module it is possible to review the budget information, compare actual versus forecast budgets and more accurately plan the expense of future projects.

Report Manager -- The Report Manager produces Ad-hoc reports or stored reports across databases and across studies. By utilizing the Report Manager a project manager, sponsor or any authorized individual can generate a custom report of information on the trial.

Cost

While the price of an on-premise CTMS solution can easily run upwards of $250,000, companies can subscribe to an on-demand tool for as little as $50 per user, per month. But a modest up-front fee isn't the only factor helping companies save their hard-earned dollars on a CTMS deployment. A study by Gartner Inc., which looked at the total cost of ownership of enterprise applications, found that 80 percent of the cost of deploying and maintaining on-premise applications is not due to licensing, but to additional costs related to hardware and administration of the software.

But that's not all. According to Gartner Inc., through 2010, on-demand CTMS will provide as much as 10 to 13 percent lower five-year total cost of ownership than on-premise software for moderately complex CTMS deployments.

Whether your view is to the long- or short-term, there are a number of areas where an on-demand CTMS solution can cut costs. These include:

Front-end Expenses: Thanks to the CTMS solution's on-demand model, there's simply no need to purchase hardware, software or added IT infrastructure to accommodate the introduction of CTMS technology.

Manpower: Implementing and maintaining a CTMS solution requires the ongoing expertise of highly qualified IT professionals. By turning to an ASP, however, a company can save thousands of dollars in IT manpower and help desk support.

Customization Mania: Although criticized for its one-size-fits all approach to CTMS, a standard on-demand CTMS tool can spare a company the price tag – and hassles – that often accompany application customization.

Security: A CTMS solution doesn't have to reside within a company's walls to be safe. Rather, today's hosted CTMS solution providers go to great lengths to safeguard their clients' data. And that's good news to businesses unwilling to invest in costly security controls and experts.

Eighty percent of the cost of deploying and maintaining on-premise applications is not due to licensing, but to additional costs related to hardware and administration of the software.

Hosted CTMS Checklist

What to ask before you buy. Before talking to a CTMS vendor, you will need to know the following information about your current situation:

- ❑ How many employees are in your clinical organization?
    - o Project Managers?
    - o Coordinators and Project Assistants?
    - o Monitors and CRAs?
    - o Casual Use Executives?
- ❑ Will your company be in growth mode over the next five years?
- ❑ Are you expanding the number of phases, trials, sites, and subjects?
- ❑ Is managing site-essential and regulatory documents a problem>
- ❑ Is managing monitoring reports and the corresponding issues a problem?
- ❑ How quickly are you looking to deploy a CTMS solution?
- ❑ What are your total CTMS project cost limits?
- ❑ Do you have the in-house IT resources to support an on-premise solution?
- ❑ What degree of customization are you expecting from a CTMS application?
- ❑ Do you have the safeguards in place to securely manage in-house datacenters?
- ❑ How could you benefit from an in-depth view of your active clinical trials?
- ❑ How could your project managers and CRAs be better managing investigator relations?
- ❑ How can you improve your investigator-support services and activities?
- ❑ How easily can you generate milestone and progress reports?
- ❑ If you are a CRO, how effectively are you targeting top customers?
- ❑ How effectively are you allocating your people, budgets and resources on clinical trials?
- ❑ How quickly are you responding to investigator and CRA inquiries?

Conclusion

Purchasing, implementing and maintaining a hosted CTMS solution may be a relatively hassle-free endeavor, but it's not the end of the road. Making a technology available is one thing; driving adoption of the solution among employees and creating processes to support its capabilities is a whole other ball game.

Said Tim Hickernell, an Info-Tech Research Group senior analyst: "In the end, it's about process. If you don't have your processes in place, I don't care if the software is on-demand or if the software is on-premise, it's not going to be utilized fully."

Certainly, failing to get the most from your CTMS investment is wasted money. But the real bottom line is that, in today's highly competitive marketplace, companies simply can't afford to alienate their investigative sites. While American businesses experience between 20 and 50 percent investigative site turnover annually, it costs about five times as much to attract a new site as it costs to keep an old one. Maintaining investigative site loyalty through a hosted CTMS solution can mean the difference between success and failure.