

The True Cost of a Clinical Trial Management System (CTMS)

Whether you're in the market for a Clinical Trial Management System (CTMS) for the first time or a seasoned veteran with CTMS experience, there are some key issues to consider when evaluating the complete cost of a CTMS.

Summary of Cost Considerations:

- **Up Front Costs** – Are there charges to initiate? Will you be invoiced before the system is available to you?
- **Term Commitment** – Does the vendor require a multi-year commitment? Are there penalties if you need to terminate early?
- **Recurring Costs** – What factors impact recurring charges? Number of users and/or studies? Do you have control over the recurring costs?
- **Add-In/Optional Fees** – Are there additional charges for training, integration, customization, validation, etc?

Common Delivery Models:

- **On Demand Software as a Service (SaaS)** – Typically the least expensive option, these web/cloud based systems allow you to subscribe and start using the system quickly. These systems are multi-tenant, because multiple customers are using the same system, although each has an isolated environment for their data.
- **Dedicated Software as a Service** – The mid-priced option, these web/cloud based systems provide a dedicated (single-tenant) environment that is managed by the vendor. This model allows a good balance of customer control and a streamlined deployment and maintenance model that is managed by the vendor.
- **On Premise / Enterprise** – As the most expensive option, these systems may or may not be web based. Although they afford the client the most control over the system, the customer must provide the hosting facilities and there are typically hardware costs and labor-intensive setup and maintenance efforts.

Other Considerations:

- **Fiscal and Resource Commitment** - Know and understand your company's fiscal and resource commitments. Enterprise CTMS products often require expensive initial investments and dedicated resources. Software as a Service (SaaS) web-hosted products are built to be easily implemented without extensive resource commitments.
- **Flexibility** - Do you need a system that is flexible and scalable to meet the ever changing needs of your studies and programs? If so, a SaaS-based system may be better suited to adapt to your needs.
- **Accessibility** - Are critical portions of the study oversight outsourced or managed through different offices or external vendors? If so, having a system accessible to these team members will help ensure you get the information you need in the format that you need it!

More Detail on the Key Considerations:

1. Up Front - Setup/Initiation Fees

Both On-Premise and Dedicated SaaS-based systems typically include a one-time initiation or installation fee. Be sure that the vendor clearly defines what they are providing in this area, as fees vary widely and may be significant. For Dedicated SaaS-based systems, this may include the complete deployment and basic setup of the system, which can be a significant value for firms that want to minimize internal IT and server costs. On-Demand SaaS based systems typically have low to no (zero) setup/initiation fees, because the system is already deployed and available (although you may have fewer custom setup options in that model).

Installation and Implementation Costs

Consider the complexity of the CTMS deployment. Do you have to hire a systems integration specialist? Do you have to hire or reserve internal IT resources? Do you have to appoint a CTMS system lead, who may spend more time managing the system than managing your clinical trial? Do you have to buy hardware? In addition to the financial outlay, there can also be productivity costs while you wait several months for the system to come on-line. From a cost perspective, most SaaS-based products score well in this category, with minimal implementation costs and quick deployment timeframe.

Consider Your Customization Needs

Most clients need some level of customization, to ensure the CTMS fits the unique study and organizational needs. Products that are designed for flexibility will allow the client to directly customize the system based on per-study and per-user needs. However, some systems may require “programming” to customize the system, which can carry a significant price tag. Ask the CTMS vendor how they handle system customizations.

2. Contractual Term Commitment

Does the vendor require a multi-year commitment? If so, consider the total cost of your commitment over the contract period. Are there penalties if you wish or need to terminate the agreement during the contractual term? While an extended contract agreement may be required by some vendors, you will find other vendors who work to keep your business through an effective product and great service, while offering flexible subscription pricing. For maximum flexibility and minimal commitment and risk, look for an On-Demand or Dedicated SaaS vendor that does not require a contractual term.

3. Per-User Fees

SaaS-based solutions typically include a monthly Hosting/Subscription fee based on the number of users. On-Premise systems commonly have an up-front license fee, also based on the size of your user base. Although the SaaS-based fees are recurring, you will find these fees to be smaller from many SaaS vendors in comparison to the on-premise model. Many SaaS-based products (on-demand and dedicated) offer a “pay per use” model, allowing per-user costs to be flexible from month-to-month as the size of your user base grows or shrinks. The smaller up-front and/or per-user costs from some SaaS systems allow you to minimize your commitment and risk.

4. Per Module Fees

Do you need optional “modules” (feature bundles) from your vendor in order to meet your requirements? If so, some vendors could charge extra for modules such as monitoring, payment, supply tracking and regulatory tracking. You may find better options with vendors that include all modules at no additional cost... giving you full flexibility if your requirements change down the road. On-Demand systems typically have multiple plans, offering “premium” features at a higher cost. Find out what plans are available and what features are included.

5. Training Costs

How will you get your team (and users from other sites/vendors/teams) up to speed and productive on the CTMS? What training model works best for your organization? Do you want all-hands in a training room for a day, or the flexibility of “real-time” training (shorter, focused sessions as you progress into different functionality, and bring more users onto the system).

Does the vendor provide direct training and/or training resources, like videos or documentation? Is training included in base license/setup fees, or is it an additional cost?

In any case, training is an important consideration as it may carry significant cost (which is not always included in the basic “sticker price”). Consider the benefits of a system based around standard web interfaces, as it will minimize your training costs and the expense of having your team tied up in the training room.

6. Support and Maintenance Fees

Product support can be critical to ensuring the productivity of your team. While 24x7 phone and online support are common, the cost varies widely from product to product. SaaS-based systems may have support and maintenance fees built into the monthly, per-user subscription fees. Find out what is included, and consider what your company needs. As an example, Trial By Fire includes phone, email and web-based support, but the vast majority of users choose to submit requests via email (which can be most efficient for providing screen shots and other issue details).

Additionally, you want a vendor that is continually improving the system using a change-control process, but you must consider whether the

vendor will charge you when updates and/or new versions are available. You will likely find SaaS-based products to be less expensive and more streamlined in this area. Since SaaS vendors typically manage the servers, they have the capability to update the software with minimal impact to your organization.

7. Validation / 21 Part 11 Compliance

Validation and compliance is a complex subject matter and we recommend consultation with a compliance expert to help determine your specific needs. The CTMS may not require validation if the system has a study planning/tracking focus and is not the primary source for regulated electronic records or documents. If you do require a validated CTMS, beware of vendors promoting a compliant “out of the box” solution. Compliance experts advise that a properly validated system requires a collaborative effort between customer and vendor (yes, both sides have responsibilities for compliance). System validation can be a resource intensive and expensive process, and must be factored into your budget.

8. System Integration Fees

The CTMS is typically one of many eClinical systems in use, and therefore must integrate and share data with your other systems. Be sure to consider the integration costs, which may include API and Data Connector fees. Some systems include APIs and common connectors at no additional charge, but others charge a significant up-front or monthly fee. If you have custom integration needs, you may need to factor in the cost of a specialized systems integrator. Will that vendor manage and maintain the integration, or will that require your IT resources? On the other hand, some CTMS vendors offer a streamlined and cost-effective approach to integration.

“Looking at the total cost of ownership, we’ve found that 80% of the cost of deploying and maintaining an on-premise CTMS is not due to software licensing, but to additional costs related to hardware and administration of the software.” – Gartner, Inc.

Cost Comparison Estimates of the CTMS Delivery Models*

Type of Cost	On-Demand SaaS <i>1st year estimate \$500 - \$20k</i>	Dedicated SaaS <i>1st year cost estimate: \$20k - \$100k</i>	Enterprise On-Site <i>1st year cost estimate: \$100k-\$500k</i>
Setup Fees (e.g. initiation, installation, implementation) Consider whether customizations are needed, and whether the customizations require billable work from your vendor or integrator.	Typically, None. On-Demand systems are already initiated and available. Setup of the new customer workspace is typically automated or user driven (e.g. setup wizard).	One time cost of \$10k - \$20k is typical, but some larger vendors charge upwards of \$100k. Because SaaS-based systems are hosted by the vendor, all costs needed to go live (e.g. installation and implementation) are typically included in the setup fee above.	Upwards of \$100k is typical. Because enterprise systems are hosted and maintained internally by the customer, implementation costs typically include: <ul style="list-style-type: none"> • \$20k - \$60k for base software installation • Hardware, servers, hosting fees, network infrastructure • Internal IT services • 3rd party system integrator costs • External/remote access (e.g. Citrix)
Recurring Fees: Per-User (e.g. license, subscription) Note that some systems may charge per-study rather than per-user.	Typical user fees: \$10 - \$50 per user per month.	Hosting and subscription fees typically run \$50 - \$400 per user per month.	Two common scenarios for user license fees: <ul style="list-style-type: none"> • \$300-400 per user per month • \$150k fixed, plus a per-study fee
Per Module Fees (e.g. add-ons for monitoring, payments, etc.)	On-Demand systems typically have multiple subscription plans which offer more functionality at a higher cost.	Some vendors include all supported modules with the base license/subscription fees. Other may charge \$20-\$100 per module per user per month.	Some vendors include all supported modules with the base license/subscription fees. Other may charge \$50-\$300 per module per user per month.
Training Costs	Self-service video training is common. Live (online) training may be available at additional cost.	Many vendors include online (live) training at no additional cost. However, some vendors charge upwards of \$50k.	A base training package may be included (no additional costs). However, some vendors charge upwards of \$100k.
Support and Maintenance Fees (e.g. 24/7 phone support)	Email/web support included. Phone and/or dedicated support typically available through premium plans or additional cost.	Two common scenarios: <ul style="list-style-type: none"> • Some vendors charge recurring fee of \$25-50 per user per month • No additional cost (included in license/subscription fees) 	Two common scenarios: <ul style="list-style-type: none"> • \$3k/month • 20-30% of annual license fees
Validation / 21 Part 11 Compliance	General validation package may be available at additional cost.	Given the dedicated system, typically \$15k and up	Given the on-premise system, typically \$100k and up.
APIs and Data Connector Fees	Integration may be a premium feature, or add-on integration services may be needed to support your specific systems.	Three common scenarios: <ul style="list-style-type: none"> • \$30k fixed • \$1000 per month • Setup costs only (recurring cost is included in license/subscription fees) 	Two common scenarios: <ul style="list-style-type: none"> • \$25k fixed • \$5-25k per area
Contract/Commitment Terms	Typically, no contractual term commitment. Most on-demand systems use a monthly subscription model, which can be cancelled at any time. Discounts may be available via an annual prepay.	Subscription plans are typically monthly. Some vendors may require a multi-year term. Others may offer no contract term ("pay per use" on a monthly basis).	Contract terms vary, but given the high initial investment, you should plan for 5-10 years of use. Note that user support and system maintenance may carry a contract term as well.
* NOTE: Vendor-specific CTMS pricing is typically not public information, and prices are often tailored to specific customer needs. Therefore, it is very difficult to generalize pricing, as we have done above. Please use this grid as a guideline only, to assist you in determining the "true cost" for your specific needs. This data is based on a vendor-blinded survey performed by a clinical consultancy.			

Don't be overwhelmed by the cost factors of a CTMS-- simple solutions with simple pricing do exist. The complexity of your requirements and size of your team may necessitate a large and detailed cost analysis. However, you will find a number of SaaS-based CTMS vendors who understand that the CTMS should be a productivity tool from end to end, including a simple pricing model and an easy path to adoption.