



8 Steps to Picking the Right CTMS

SELECTING A CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS) FOR YOUR SITE is not a trivial process and can cost academic medical institutions upwards of \$3 million to implement¹, but thinking of it in a step-wise manner could be helpful in your journey. The process can be compared to shopping for a car, or other large purchasing decisions most people have had to make.

People who buy a car likely follow certain steps, such as:

1. Conduct an online search for the type of vehicle they are looking for. They may already be familiar with a brand name or type of vehicle.
2. Determine necessary features (all-wheel drive, manual transmission, etc.).
3. Determine how to purchase or finance the vehicle.
4. Plan the future of a current vehicle, if you have one.
5. Shop for the car and test drive it.
6. Obtain pricing information.
7. Negotiate, make a decision and buy.
8. Take delivery.

Following the above steps, shopping for a CTMS may look like this:

- 1. Conduct an online search for the type of CTMS you are looking for.**

Are you looking for a CTMS that is primarily for research sites, sponsors, CROs (contract research organizations), SMOs (site management organizations), or do you want one that can support all of the above? If you conduct investigator-initiated studies and/or have studies in which you function as a coordinating center, then you want a CTMS that has capability to support both kinds of activities. Maybe you conduct an online search for "Top 5 Site CTMS", "CTMS for site", "ROI of a CTMS", "Best Clinical Trials Management Systems", etc. depending on what you are looking for.

Speak with influencers or subject matter experts in the industry. If you conduct coverage analysis for studies that involve routine/standard of care procedure, then ask leaders at a conference that focuses on billing compliance. If you know colleagues that provide services to sites (study entry services, budget development and negotiation, coverage analysis, etc.), ask them which systems they like using the most and why. Just as the car your best friend drives might not be the best fit for you, the same is true for a CTMS. Part of the process for first-timers is to figure out what is important to you.

- 2. Determine features you want to have and what you are trying to achieve**

Are you trying to go from A to B with as little waste, burden or effort as possible? Or are you aiming to address a bigger challenge such as ensuring all systems are integrated to address research participant safety, decrease protocol violations, and/or increase research billing compliance?

What is a need versus a want? Will you build or buy? Will you need to perform extensive requirement engineering² or will addressing existing or near-term challenges suffice? Do you have the organizational commitment and other supporting infrastructure necessary for successful implementation?³

I will share an experience I had when I was overseeing the central clinical research office and clinical research operations for a large healthcare system in New York. I had the task of overseeing the CTMS selection process from the operational and business perspective. We needed to have a single CTMS that would address needs across the health system. With thousands of studies, dozens of hospitals, and hundreds of ambulatory sites, you can imagine how extensive the list of “requirements” was. I recommend honing in on those most critical capabilities necessary to help focus your stakeholders on achieving the desired business goals.

While my CTMS selection process resulted in an unequivocal selection of one CTMS, financial approval was not immediately granted despite having the right stakeholders involved. The next step, budget, is important.

3. Determine your potential budget to purchase the CTMS

This might be a tough question to answer, but it’s an answer you need early in the evaluation unless you have a blank check to move forward. The shopping process is often begun by directors of research, managers and research leadership at institutions that see the value in having a CTMS. Oftentimes the financial approval for large institutions comes from a different team or person, so sharing the potential return on investment and value of a CTMS will be important to determine the financial investment your leadership is willing to make based on that perceived value.

The return on investment for a CTMS could include cost avoidance, risk reduction, margin protection and more. What problems are you trying to address? What business goals are you trying to achieve? As these questions are addressed, financially quantify the potential cost reduction, margin protection, etc. you aim to realize with a CTMS.

An example of risk reduction could be circumventing a pitfall called “double-billing” or “double-dipping” that occurs when two parties pay for the same procedure (i.e., sponsor and patient’s insurance). This may constitute fraud and can be costly: in 2005 an academic organization voluntarily disclosed inadvertent research billing issues that carried a fine of approximately one million dollars.⁴ Another example of risk reduction is the ability to share subject participation information between the CTMS and your electronic medical record (EMR) to avoid contraindications and non-compliance. If safety and compliance are primary

drivers, determine how much you are willing to spend to support them.

4. Plan what you will do with your current research data/CTMS

If you have existing data (such as CTMS, spreadsheets, or other system), that should give you a head start when implementing a new CTMS. You will need to make a determination of what you want to do with your existing studies and data. Some CTMS vendors charge for data migration, data hosting, data integration, etc., so factor this into your purchase process. Will the new CTMS provider have integration services, consultants, and offer the solutions necessary to address your needs? Oftentimes, discussing the existing data well in advance of implementation can avoid surprises down the road.

Some data can be easy to import into the system; some data may be less feasible. Costs will vary. Some data is easiest to import while the system is brand new (i.e., a blank slate), and more difficult after data entry and implementation has begun. You will need to weigh the burden of manual data entry versus the value of data import. Consider how you plan to implement the new system and how you’ll set up the data. Do you want to import foundational data like patient demographics, study definitions, charge masters or all studies, their statuses, patient calendars, etc.? Your CTMS vendor could help guide you in these choices.

5. Test drive the CTMS

This is likely one of the most under-utilized freebies in this process! When buying a vehicle, I absolutely need to test drive it. You should accept and actually use this offer – if you are too busy to complete this step, delegate this to key users. You should know ahead of time which system your teams would prefer to use on a day-to-day basis as this will increase user adoption once you do select your CTMS.

6. Obtain pricing information

If being cost-conscious is a critical part of your decision, you should move this step up and combine it with #3.

CTMS vendors price differently; you will find that pricing could be based on year or monthly licensing, number of users, studies, sites or visits completed. Depending on your needs, you may also have costs for integrations, features, services, consulting and training. When you receive the pricing information, ensure you understand how it is priced so that you can know if your specific “package” is priced correctly.

For example, in order to give pricing information, a vendor may ask, “How many studies does your organization conduct a year?” You say one thousand and the vendor gives you a quote based on that number. However, perhaps not all one thousand studies will be tracked in the CTMS because 10% will occur in the medical school and another 20% are unfunded.

The return on investment for a CTMS could include cost avoidance, risk reduction, margin protection and more. What problems are you trying to address? What business goals are you trying to achieve? As these questions are addressed, financially quantify the potential cost reduction, margin protection, etc. you aim to realize with a CTMS.

So the quote might be priced higher than necessary for your designed use. That said, perhaps you aim to centralize all clinical research (whether or not it is funded) across your entire organization to understand volume, time, effort, and expenses across your portfolio. In this case, the pricing would be accurate.

A question that might help plan for the expense is to ask, "What functionality carries additional cost?" For example, sometimes vendors charge for custom reports while others are provided at no additional cost to the site. By the end of this step, you should have a clear understanding of costs beyond the license fee, implementation and/or training.

7. Negotiate, make a decision and buy

With a CTMS, there might not be as much space for negotiating as with buying a car. Buying the best-in-class or all the bells and whistles will come with a certain price tag, no?

Speak with your sales representative and ask for scenarios in which you can expect a lower cost. Could you perhaps have a staged implementation process in which you roll out by department/site, and steadily expand across your network? Or if your top priority is to change your study start-up process and conduct coverage analysis to increase billing compliance, and your EMR implementation has yet to be completed, perhaps the vendor can accommodate the addition of the EMR integration at year two versus year one. Could you do without the EMR integration for another 6-12 months and conduct the preparatory work in the interim? Depending on your goals, these scenarios may or may not be feasible, but this gives you an idea of how to approach this step. While charges will be set for each line item, you could perhaps negotiate when you will receive each item.

For me, buying a car has been a very personal decision and one in which I also consider my family. I tend to be selfish in buying sportier or smaller cars rather than the SUVs I'm 'supposed to' purchase. The same can happen in institutions where you may have leadership making decisions for an entire institution without input from its members. This brings me to a final point- when you buy a CTMS, think of the users and how you want to effectively enhance their experience.⁵ While my children have no choice for having to ride in the back of a tiny two-door car and also don't care that I have made that choice for them, users of technology do care. They care about the additional burden it could add, whether they need to enter data in multiple places, if they can export or print, if they can lock certain fields to prevent compliance issues, if they can audit records after an employee is let go, etc. Even the simple look and feel of the product can elicit a positive or negative response.

The selection process itself might warrant the help of consultants, depending on your organization size, goals, and resources available (or lack thereof). You might need to involve a multidisciplinary team to vet the decision, such as personnel in research compliance, corporate compliance, security, research information technology, revenue cycle, billing compliance, financial analysis, research services, or outpatient registration, a medical officer, a chief information officer, and the list can go on. But what is crucial is senior leadership involvement and/or organizational commitment^{3,6,7}- these individuals can clear obstacles and communicate the necessary value across the organization.⁷

Remember that change adoption is increased when you address ability and motivation⁸ – even as you include those that need to be at the table, kindly be open to the opinion of your key users and subject matter experts. By the end of this step, you should also feel confident that you negotiated the best deal for your organization and that you involved the right people to make the best decision.

8. Take delivery

For some, this final step will be as easy as receiving access to your CTMS within a day, and for others, this could be the beginning of a transformation. Unlike other purchases, where you take delivery and have no relationship with your sales representative or vendor, you will likely see the vendor at your site, trade shows, and conferences, and have the ability to call and email them. So if you are happy or unhappy, your CTMS vendor is going to hear from you. This relationship is of great value to the vendor, as it gives them more opportunities to know what you need to streamline your research operations. More importantly, it is (hopefully) a partnership that results in continuous improvement for the product itself, which helps you in the long run.

Your CTMS implementation project need not be part of the 50% of information technology projects that fail.⁷ While each CTMS shopping experience will be unique, thinking through the process in the steps outlined above can help make the process less daunting - and ideally more successful. ☺

¹ Eberhart C, Stevens E, Moran J. Academic medical centers can tackle CTMS successfully. *Applied Clinical Trials*. August 30, 2013.

² Schöbel M, Stäubert S, Löbe M, Meinel K, Winter A. Requirements on clinical trial management systems for academic site management organizations. *Stud Health Technol Inform*. 2016;228:292-6.

³ Campion TR Jr, Blau VL, et al. Implementing a clinical research management system: One institution's successful approach following previous failures. *AMIA Jt Summits Transl Sci Proc*. 2014;2014:12-17.

⁴ Barnes M, Bruns EM, O'Connor BT. Rush University Medical Center settlement: Improper Medicare billing in clinical trials under September 2000 NCD. *Ropes & Gray*. (December 22, 2005.) Accessed August 2017 from: <https://www.ropesgray.com/newsroom/alerts/2005/12/december-2005-rush-university-medical-center-settlement-improper-medicare-billing-in-clinical-trials-under-september-2000-ncd.aspx>

⁵ Handa A, Vashisht K. How IBM is embracing the future through design. *UX Matters*. (February 6, 2017.) Accessed August 2017 from: <https://www.uxmatters.com/mt/archives/2017/02/how-ibm-is-embracing-the-future-through-design.php>

⁶ Burger R. 20 Surprising project management statistics. *Capterra Project Management Blog*. (September 26th, 2016.) Accessed August 2017 from: <http://blog.capterra.com/surprising-project-management-statistics/>

⁷ Florentine S. IT project success rates finally improving: After years of stagnating IT project success rates, a new survey from PMI shows that rates are finally on the rise. *CIO*. (Feb 27, 2017.) Accessed August 2017 from: <https://www.cio.com/article/3174516/project-management/it-project-success-rates-finally-improving.html>

⁸ Grenny J et al. *Influencer: The New Science of Leading Change*. 2nd ed. New York, NY: McGraw-Hill Education; 2013.

Cerdi Beltré
Director of Data Strategy and Business Development
[IBM Watson Health](#)



Wes Fishburne
Offering Manager, Life Sciences, eClinical Division
[IBM Watson Health](#)

