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Five Steps to Successful Implementation of Clinical Operations Software

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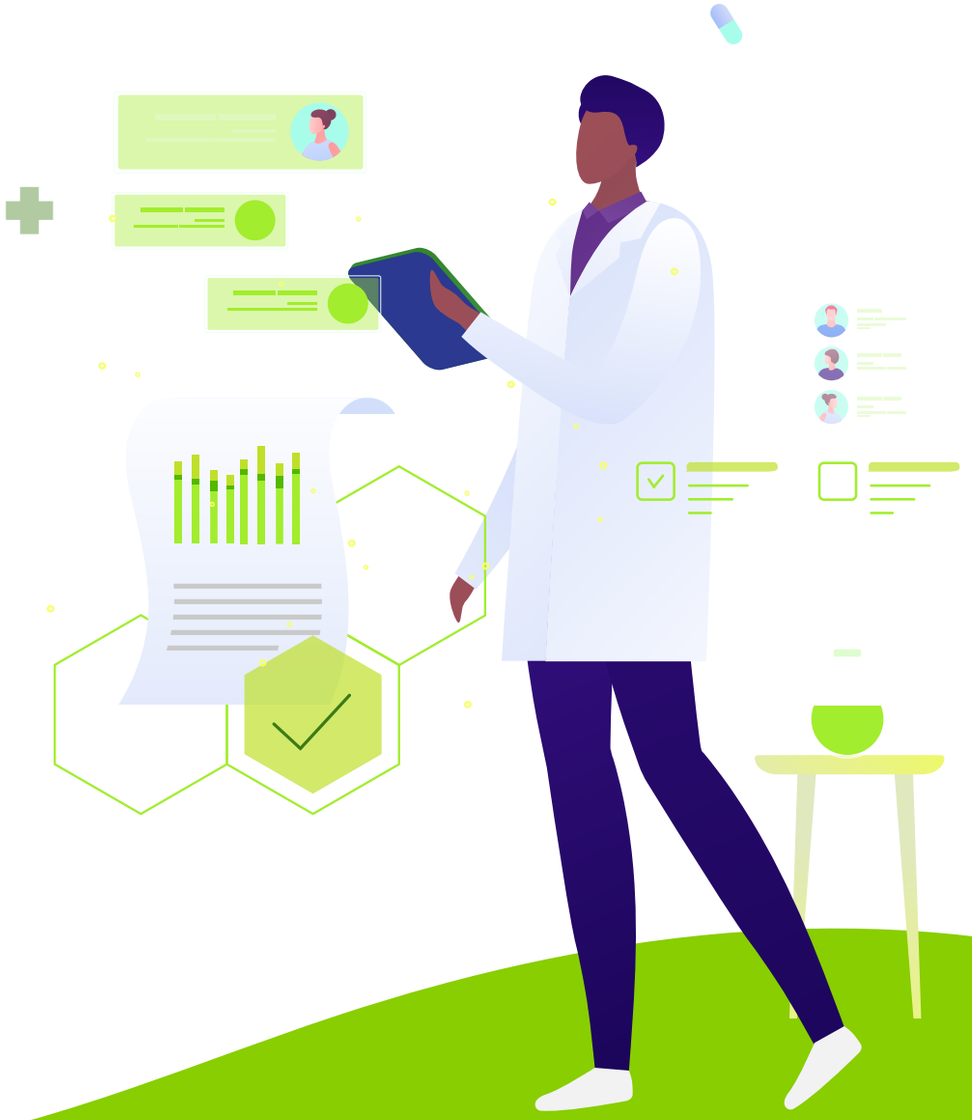
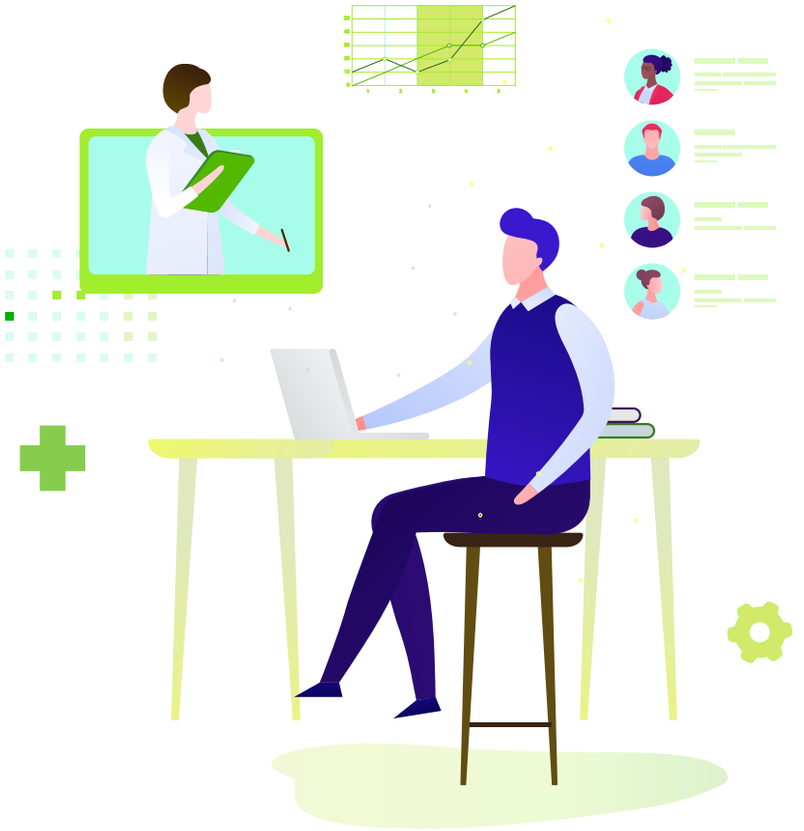


Clinical Site Technology: The Time Has (Finally) Come

For the last thirty years, computer technologies and software systems have been developed and applied to clinical trials, but with an overwhelming focus on meeting the needs of sponsors and CROs. The time has come for clinical sites to implement the same capabilities. These solutions have dramatically lowered in cost and become much easier to implement and use, so the obstacles that prevented use in the clinical site are mostly gone. Sites, your time has come.

Jill and I wrote this ebook for clinical site leaders who plan the transformation of their businesses using technology. It is designed to help you develop your thinking, strategy, and plan for implementing systems.

Use this as a starting point; perhaps best used as something the whole team can read before initial meetings about implementing new systems in the clinic.



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Clinical Site Operations Technology

Clinical research sites, like most businesses, have many moving parts that need to work together to ensure efficiency and quality. Technology, when applied appropriately, can help integrate the parts and streamline research site operations. In this section, let's review some of the key forms of technology and what they accomplish.

Note: For purposes of brevity, we chose to discuss the technology that the site implements rather than the technology that the sponsor dictates, such as Electronic Data Capture (EDC), electronic patient-reported outcomes systems (ePRO/eDiaries), Interactive Web Response Systems (IWRS), and technology used in Central Recruitment Campaigns.

71% of sites use a CTMS

- 2019 whitepaper by SCRS

Clinical Trial Management Software (CTMS)

While there are still some research sites utilizing excel spreadsheets to manage their study schedules, budgets, and financial reports, a CTMS program is the first technology most sites implement. This may be for two reasons:

- First, CTMS software and vendors selling these products have been on the market for at least 20 years and were some of the first eTechnology available at the site level.
- As clinical trials became more complex, so too did the Clinical Trials Agreements and financial invoicing.

CTMS systems help sites ensure the financials are tracked, invoiced, and reconciled. They provide financial reports, budget building assistance, financial forecasting, and many other functions to sites.

eRegulatory

The regulatory documentation necessary for conducting clinical research is defined in the Code of Federal Regulations, including 21CFR11, 21CFR50, 21CFR54, 21CFR56, and ICH E6 R2 Section 8. This documentation is cumbersome and can be quite overwhelming. A typical study is not unlikely to need multiple 2–3-inch binders to contain these documents in paper.

eRegulatory solutions alleviate space constraints and provide instant searchable access to the regulatory documents necessary for research. These solutions house documents on a secure server or in the cloud. They differ from other file storage systems such as Dropbox, SharePoint, or file shares by providing audit trails, version control, role-based access, and even automation requirements for meeting 21CFR11.

eRegulatory systems also provide a means for sites to obtain eSignatures using secure usernames and passwords, alleviating a clinic's need to gather signatures on training documents, FDA Form 1572s, financial disclosures, etc.

While this technology has been around for over ten years, according to a Clinical Research IOs survey in 2013, only 50% of all clinical trial sites currently use or plan to use software to handle their regulatory documents and duties.

eSource

According to the Food and Drug Administration (FDA), source documentation is the initial documentation of data within a clinical study - the “source” is the original element within a clinical trial. And an essential requirement for source documents is that they must contain an audit trail for any changes to ensure the document’s integrity.

Electronic source documents (eSource) technology has been around for a while, but sites have been slow to implement it.

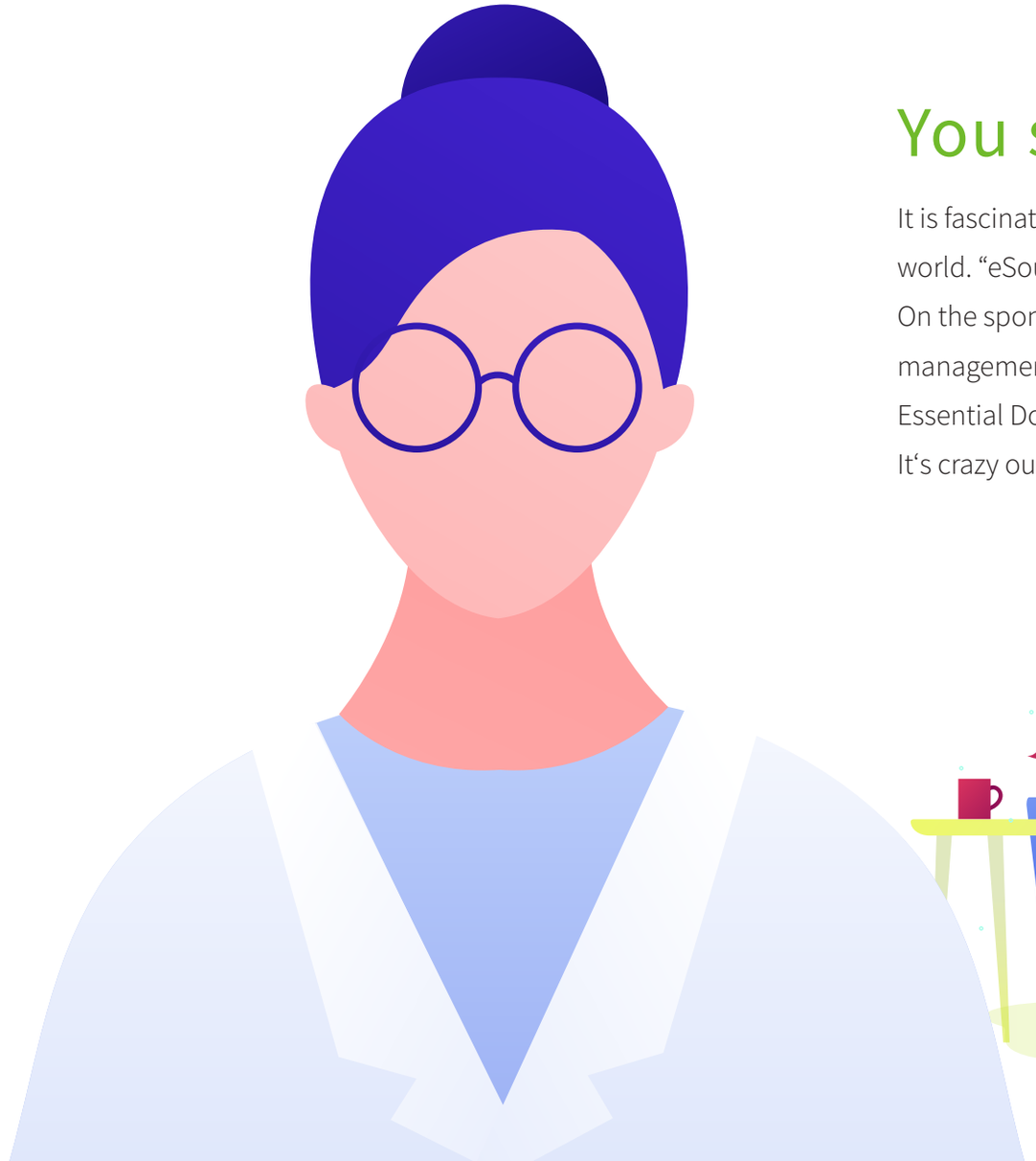
Several reasons include:

- Cost.
- The change management necessary to implement the technology with staff and Principal Investigators.
- The “fear” of having documents lost in the ether of a cloud when paper seems much more tangible.

Additionally, the cautious (read slow) adoption of remote site monitoring never provided a catalyst for sites to initiate this technology.

Historically, sites that adopted eSource solutions were ones with a business model where the site was spread among many locations, and eSource eliminated the transport of paper charts from location to location.

With the global pandemic, we have seen a sprint to implement eSource as remote monitoring has become necessary. Sites still in paper find themselves faxing or uploading reams of patient records to study sponsors after the cumbersome task of redacting all patient information. Even worse, many sites and studies have gone months without any source document review by Sponsors or CROs as all parties scramble to update their SOPs to adapt to the new environment COVID has brought to our industry.



You say eSource; I say ISF.

It is fascinating how many different names there are for systems that do the same thing in the clinical world. “eSource” and “eRegulatory” are names used by clinical sites and the vendors that focus on them. On the sponsor and CRO side, systems with very similar functionality are called ISF (investigator site file) management systems and eTMF systems. Even the content can go by different names: Source Documents, Essential Documents, and even “Binder Files“ all have overlapping meanings depending on the context. It‘s crazy out there!

eConsent

The process of informed consent of study subjects is the one area in research where it is guaranteed that there will be a 100% review of documents by regulatory authorities, study Sponsors, and research sites' internal audit programs. This is the first and arguably the most important step of enrolling a patient in a clinical trial.

Informed consent forms (ICFs) are regularly over 20 pages, and many patients don't read them. Despite research staff reviewing the ICF and answering questions, there is no real standardization or test of comprehension and understanding before a patient provides consent.

The industry has been investigating more efficient ways of conducting informed consent. However, the move towards this technology has been almost non-existent. Before the global pandemic, only 1.5% of sites used this technology in more than 75% of their studies.

We have seen some movement towards eConsent because of the pandemic. However, the changes are primarily in the form of a PDF document emailed to the patient and signed electronically (eSigns) via a secure, 21CFR11 compliant software system. While this allows for a safer environment for obtaining patient consent, it is hard to imagine this has improved readability or patient comprehension of the study, thereby improving the overall consent process.

Stipend Cards

Patients participating in a clinical trial are often paid a stipend to compensate them for their time participating in a trial and their transportation to and from the research site. As a result, many sites turned to stipend cards in the form of reloadable cards (similar to credit cards) to avoid cumbersome payment methods such as keeping cash on site (which is difficult to track) or providing checks.

Using this technology, site personnel can replace a card and transfer any current card funds to a new card if the subject loses it. Stipend cards also provide a convenient way to pay patients immediately after a visit rather than waiting for the approved site personnel to issue a check or provide cash.

Recruitment

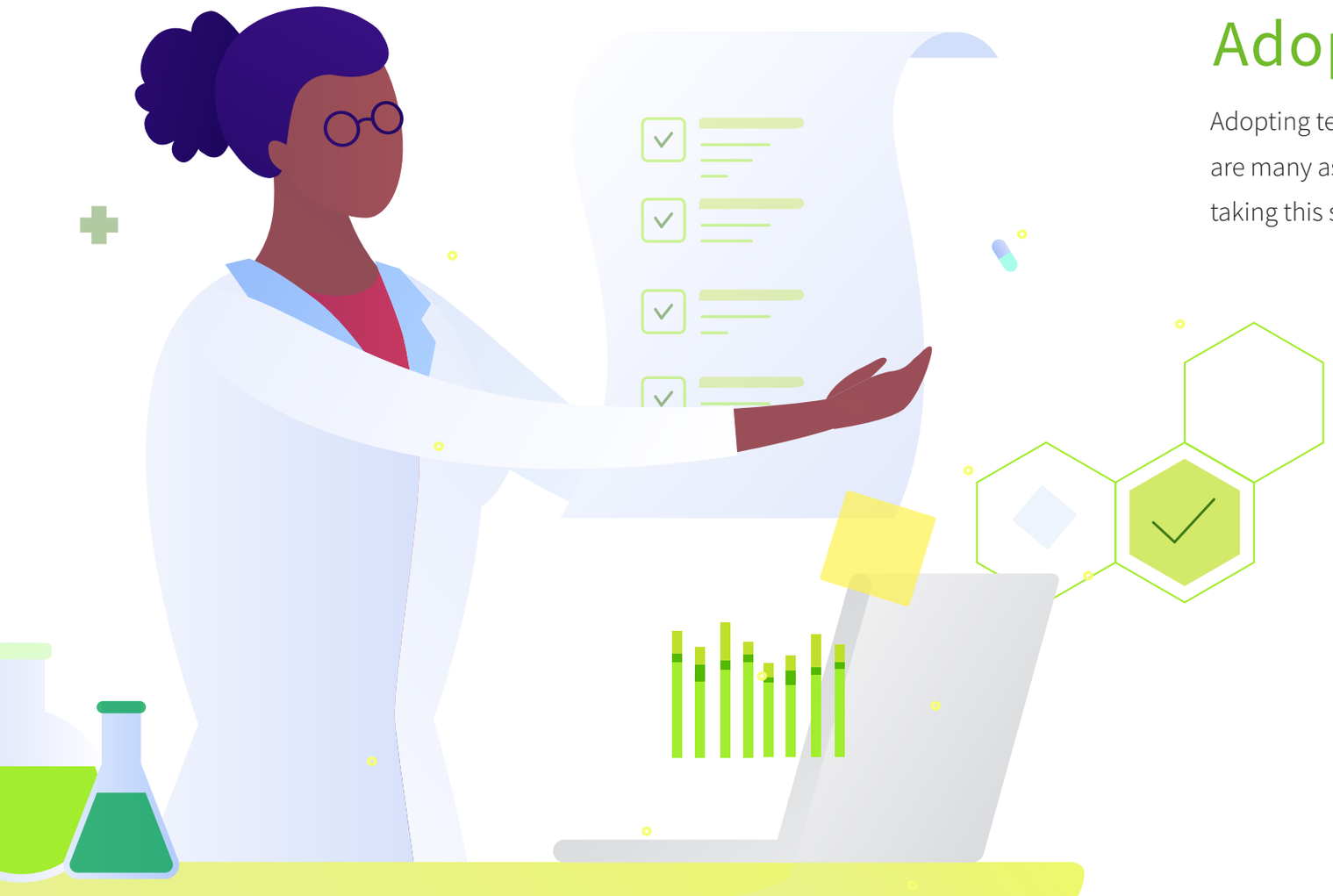
Tracking the referral source of patients enrolled in a clinical trial is essential to sites that want to maximize their return on investment (ROI). Did the patient come from the clinic database, from advertising, or a referral source? For an advertising campaign, how much did the campaign cost, and how many patients were enrolled?

While most sites track these referral sources in some capacity, new software reports on outcomes and provides the breakdown of ROI, simplifying the process. Additionally, this software captures interactions with potential patients, provides reminders to recruitment specialists for further outreach, and can even send a bulk text or email to patients identified as potential study subjects, saving time, and increasing efficiency.

Integrating Technology

Currently, there is much fragmentation among vendors, and sites have often had to piece together the various eTechnology solutions they need. However, over the past few years, we have seen vendors emerge that offer a “total solution” to sites that incorporate most and even all the above capabilities.

There are, of course, pros and cons to choosing multiple vendors for eTechnology at your site or a single vendor that offers a total solution. We’ll discuss how to evaluate some of these issues in the next section.



4 Key Considerations for Adopting Site Technology

Adopting technology can be an enormous undertaking, and there are many aspects that a clinical site will want to address before taking this step.

Do Your Research

Start with defining your requirements. To do this, you need to get key stakeholders together to address some questions. Be sure to include everyone that may need to work in the new system: the secretary may use it for scheduling; the CRC will enter data; the finance department will create invoices and reconcile payments; the recruitment team will review eligible patients; the executive team will make decisions on the reports it generates, etc.

Work with the stakeholders to address questions such as:

- What pain points do you need to solve?
- What capabilities do you want that you don't have now?
- What type of security or storage will the technology have?
- Will the system be compatible with your current systems?

Prioritize the answers to these questions. Keep in mind that you may not get a solution to each problem with a single vendor.

Next, map out your current system and observe the sequencing you currently use. Where are the most errors? Where is the most time spent? Ensure you understand your current situation to understand where technology can help you improve.

When doing your research on vendors, be sure to assess vendor roadmaps. This assessment includes the individual vendor product roadmaps and your site's plan for technology now and in the future.

At the site, this is likely not the first technology you'll add and won't be the last. Taking the time to map out past, current, and future technology will save you time and money as you move towards more technologies.

A few questions you may need to answer:

- Will planned software purchases in the future work with your current technology?
- Will new technology require you to replace old?
- If you have to put in new phone systems, upgrade servers, or purchase all new computers for your staff, you're looking at a heftier price tag.
- Will new technology build on each other as you add it?
- If you purchase an eSource solution, how will it integrate with your current CTMS system to capture all charges?

Additionally, ask the technology vendor these same questions. Ask if they have plans to integrate with any of your current technology in the future. What strategies for their technology are they working on? Are there enhancements in the future that are attractive and may weigh in on your decision?

Years ago, when looking at an eSource solution, I chose to go with a vendor that initially only had eSource but had plans to add CTMS, eRegulatory, a recruitment module, and stipend cards in the future. It worked well for my site as it allowed me to take a phased approach to technology, and I was able to spread my technology purchases out over a few years. I felt the change management that comes with adding new technology was more comfortable to manage with this model.

Also, understand their support and customer service offerings. We've all had experiences where customer service has decreased below our expectations once the sale is complete. You certainly don't want that occurring in your business. Be sure expectations for ongoing support and maintenance are clear for all parties. How do they handle requests for new features by their customers? What is their response rate for IT requests? Who is your point of contact once the salesperson transitions off your account?

Perform a Cost Analysis

Cost is at the top of everyone's list when evaluating new technologies. There are two ways to look at the cost of technology.

Implementing a New Technology Solution

When you implement a new technology solution, you add a new line to your budget worksheet that wasn't there before. To offset this new line item, assess where you are reducing or eliminating other costs.

For example:

- How much will you save on paper and charts?
- How much storage space will you get back?
- Do you increase the convenience and efficiency of multiple staff members working in a patient's chart simultaneously?

By putting a value on these questions, you can determine if the benefits of the technology will offset the cost of the software. The most significant cost savings will likely be in staff time as new technology ideally automates or eliminates steps previously done by your staff.

When doing your cost analysis, try to account for the steps you can eliminate in your current processes, the increased efficiency you will gain, and the access to data you are acquiring to help make decisions down the road.

Upgrading Existing Technology

Suppose you've already implemented a technology but are thinking of upgrading or switching to another vendor. In this case, you need to look at the time it takes to change systems, which can be expensive.

Onboarding fees for the new vendor and the time it will take to train staff on the new system will be the most significant factors in our cost analysis. Assess what you're gaining with this different system compared to your current system and ensure it's worth the cost.

In both cases, you want to ask several questions.

- Will business processes improve with the new technology?
- Will we be able to create source documents faster?
- Will we be more efficient and improve our coordinator error rates?

Determine if the Technology is Worth the Cost

Technology should pay for itself with enhanced workflows, decreased errors through automation, metrics tracking that allows for data-driven decision making and optionality in the workflow. If technology simply provides an electronic version of a paper process with no added search abilities, connection, etc., think twice about adopting it.

Take a PDF form-fill program that allows staff to enter data on laptops, for example. It is inexpensive to implement, saves on binder space, and even allows for some eSignatures. However, when evaluating the solution further, you find that it's not 21CFR11 compliant because it doesn't provide an audit trail, two-factor verification for eSignatures, or secure storage with redundant backups.

You also find that it doesn't allow you to search by the data fields or interface with your CTMS program. It doesn't cut down on protocol deviations because a PDF may not alert you to missing data fields or have auto-alerts built-in for incongruent data.

While it may look more pleasing on your budget worksheet, you'll find it doesn't provide necessary enhancements over a paper solution to make it worth the cost.

On the other hand, good technology will provide edit checks for source document entry. Typos or even entries that may exclude a patient are automatically highlighted, alerting the CRC to address the error immediately rather than at a routine monitoring visit or via a "late entry" note. Source data entered into the system then goes directly into an invoicing interface, so the finance team knows, in real-time, the current accounts receivable, eliminating the time and error-prone need for the CRC to update the information. The technology can also issue a payment to the patient's stipend card when the visit is complete, eliminating the finance team's process to issue a check.

Interview Current Customers

In addition to asking the above questions of your software vendors, be sure to ask them about customers already using the product.

Referrals are helpful in a few ways. First, the salesperson isn't an end-user of the product. While knowledgeable about capabilities, salespeople don't typically have experience using the product. Asking questions of an end-user will enlighten you more than the salesperson who may be following a scripted pitch.

Second, end-users will also bring up topics you didn't even think to ask about. It's a bit of "you don't know what you don't know." Use open-ended questions and be sure to ask about areas where their transition to the software didn't go well (you may learn from their mistakes). Ask for helpful hints and their favorite features of the system. Also, be sure to ask where the system could be more robust. At this point, you have the salesperson's ear so bringing this feedback to them often spurs them to make enhancement requests to their developers if they believe it will land more sales.

Platforms, Suites and Best of Breed: What's the Difference

The point that we want our clinical systems -- CTMS, eSource, eRegulatory -- to work together cannot be overemphasized. But be careful about the different ways vendors claim to address the need for integration.

Traditionally, the answer has been a "platform" approach. The idea is that each application shares the same platform, so it has natural integration capabilities. But beware because platforms also often create complexity and require more customization than anyone wants. Often, the applications have been cobbled together over time through acquisition and do not share a common platform.

The give-away? If it takes months to get into production, you are dealing with a last-generation platform-based system.

"Best of Breed" applications, on the other hand, do not purport to solve more than one problem. As the name implies, they are trying to be the best stand-alone application for a specific need. The challenge with best-of-breed apps is that integration is left to you.

A good compromise is a 'Suite" of applications from the same vendor designed to work together, but each designed for one part of the business. And unlike a platform architecture, each application in the suite can be put into production independently and quickly with minimal configuration.

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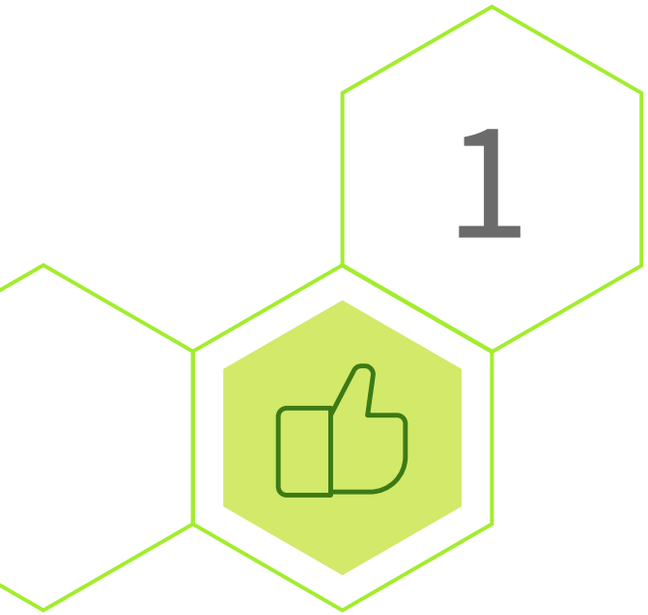
Five Steps to Successful Implementation of Clinical Operations Software

Secure Buy-in.



This step is first for a reason. If you don't have buy-in, it won't matter how good the technology is; it won't succeed. So often in business, we focus on the technical components, the strategy, and implementation that we forget the human aspect. Buy-in needs to occur from the top-line executives to the bottom-line users. The approach to get buy-in from these varying groups differs, so be sure you plan your presentation accordingly.

Top-line Execs:

Topline executives are interested in their return on investment - does this new technology make sense financially? Paint a clear picture of the initial start-up costs and maintenance of the technology. Include any new equipment you need to purchase (tablets, laptops, etc.) as well as time spent training personnel. Ideally, these costs will offset the enhanced efficiency and capabilities this technology brings.

Estimating and emphasizing the personnel time saved is a quick way to put a dollar amount to the ROI. Additionally, the new technology could put your research site at a strategically competitive advantage over competitors.

If that's the case, you may be able to estimate the number of new studies awarded or additional patients you'll have access to with this more efficient system.

For example, suppose the technology you want to implement is patient recruitment tracking software. Find metrics of patients you have lost in the past due to inefficient paper processes and inadequate follow-up. The new technology automates this follow-up and provides reminders and alerts to recruitment specialists, increasing efficiency and translating directly into more patients scheduled.

End-users:

Securing buy-in from the users of the new technology is also imperative. They know their job better than anyone and may resist new technology if they feel it will disrupt their current processes. Bring in a representative early in the evaluation process to help create a feeling of ownership of the new system. You can also secure their support by speaking to the increased efficiency, reduced redundancy, and time savings that this technology will add.

Create a Plan but Don't Get Stuck

Ben Franklin said it best, "If you fail to plan, you are planning to fail." Will you have one "go-live" date, or will you phase in various portions of the technology? For example, you plan to implement a software program with multi-function capabilities such as eSource, eRegulatory, CTMS, and Recruitment. Will you implement these simultaneously or take a phased approach, where you start with CTMS and eSource and then add in eRegulatory and Recruitment Tracking six months later?

A multi-indication site may opt to transition one research indication at a time to ensure staff is trained appropriately and understand the technology fully before it affects each of their studies.

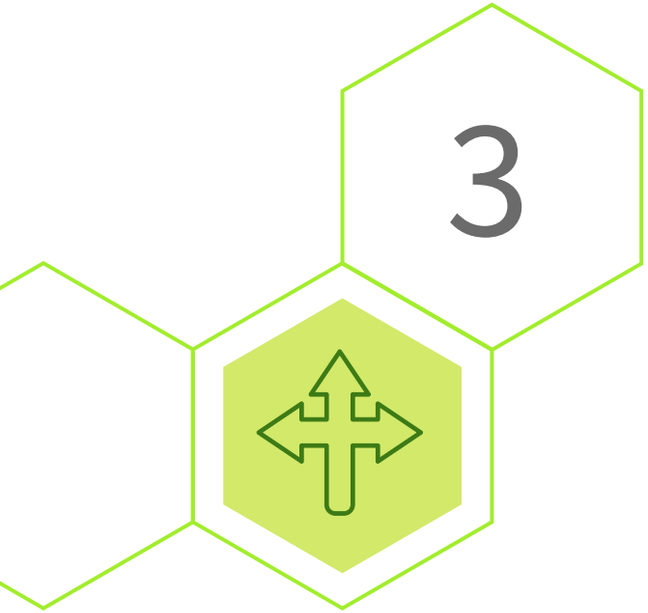
The plan must include as many details as possible, including:

- Who will be in charge of implementing this plan?
- What is the time frame?
- How will training occur?
- Will there be any downtime during software installation that patients and staff may need to schedule around?

The more detailed plan, the fewer surprises you will have during the transition.

"The best-laid plans of mice and men often go awry," however, so flexibility is vital. Don't get so married to your plan that you get stuck. Change is challenging and implementing technology can have some unexpected speed bumps. Be willing to adapt and pivot and be ready to reassess and even slow down the process. Getting it right the first time is easier than having to re-do it. I speak from experience on this one.

Map out the Journey



Along with creating the implementation plan, you need to map out the end-users workflow.

For example, how will a recruitment specialist identify a potential patient and track their calls to this patient, informing them about the study? How will this software track the number of calls or time of day the specialist tried to reach out, and what frequency should reminders be set for the specialist to attempt future calls? If the software allows for email and texting, creating templates or "snippets" that are IRB approved may need to occur before implementation.

Getting down to that level of detail is critical. As proof, consider challenges from our personal experience.

Because we failed to walk through the journey when implementing eRegulatory, we realized too late that, without structuring the naming conventions we wanted to use when uploading documents into our eRegulatory platform, we had inadvertently entered the same documents multiple times but with different names.

This wasn't a failure of the software but, rather, our implementation of the software and our error in not walking through each step.

The software vendor should offer some "best practices" and plenty of advice in this area. To be flexible for as many customers, most vendors provide a lot of site-level customization. This allows you to fit the technology to your needs but can also inadvertently introduce some areas for error when you don't map out the journey. Additionally, asking for input from other users of the software can also be helpful. You can learn from their errors and lessons learned.

Identify Integration Points

Look for ways that the software can integrate with technology that is already utilized at the site.

For example, can the new eRegulatory software integrate with Outlook or Gmail to facilitate the filing of essential correspondence? Can you integrate your CTMS with some functions in QuickBooks for easier bill pay? Are there integrations with your CTMS software and a new Customer Relationship Management (CRM) software program?

Take advantage of these potential integrations to maximize your capabilities with the new technology. Of course, you may choose not to roll out these integrations immediately, but you'll want to plan on when to onboard them, so you get the full efficiency of your technology solution.

Additionally, some software vendors provide a "total solution," which provides an integrated set of features for multiple software solutions. While you may sacrifice some functionality in one area, the ability to have a single sign-on and integration across all platforms may make it worth it.

Software companies make continual enhancements to their platforms, so if the integration isn't there currently, it may be available down the road. Stay up to date on these integration enhancements to take full advantage of the technology and maximize your ROI.

Just Do It

To borrow the famous phrase from Nike, at some point, you'll have to take the leap and "Just Do It." You've done your research, you've called the referrals, and you've written out your plan. Now, it's time to implement. Change is always challenging; expect that the technology will initially seem cumbersome and more complex than anticipated. But, in most cases, this is simply a learning curve. It takes time to produce efficiency in a new system, and it won't happen on the first day.

Ensuring the stakeholders' expectations are managed during this phase is essential. Spending the time to get buy-in from end-users and site executives may have inadvertently created unrealistic expectations of immediate efficiency. Managing these expectations from the beginning is critical, but no matter how much we try, a new shiny toy still comes with high expectations. Reassuring users that a new system or technology takes time to thoroughly learn and get comfortable with before it's at peak efficiency is essential.

Once expectations are managed and the new technology is in place, reassess the usage, capability, integration, etc., at regular intervals. Ask users where there are still bottlenecks. Review the vendor's initial training to ensure you're capitalizing on all the features the software has to offer and that fit your workflow. Don't feel married to the ones that don't work. Some software has features you don't need or don't need at this point. If it's more cumbersome to use a particular feature, feel free to drop it. You can always revisit this capability at future intervals.

Now is an excellent time to reach out to some of those referrals you spoke with when evaluating the software. With the technology in place and used, you understand it better and find your questions changed. Your questions now will be geared towards best practices, workarounds, and lessons learned. As a person that is often on the receiving end of these calls, I welcome them. I've had many conversations that have enhanced my practices and systems with software after calls from users that I initially met when the vendor provided my name to them as a referral.

Jill Heinz

President and COO, Patient Focused Solutions,
President, Injury Care Research & Family Care Research

Jill has worked in the research industry for over 20 years and has been involved with clinical research studies ranging from those funded by the National Cancer Institute, Investigator-Initiated, and Private Industry. She has experience in studies that include oncology, family practice, orthopedics, pain management, glaucoma, and now COVID-19. She owns two successful clinical research companies, is the Chief Operations Officer for Patient Focus Solutions, and is a consultant for other clinical sites that want to enhance the efficiency of their clinical operations.

Connect with Jill

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Ken Lownie

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Ken has over 20 years of experience working with technology companies building solutions that support the demands of enterprise companies. Today, he works with life sciences companies to implement technology solutions that automate and accelerate clinical operations processes. He is a frequent writer and speaker on technology adoption in life sciences.

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About Agatha

Agatha, Inc. is a leading strategic software solutions provider to the healthcare and life sciences industry. With offices in the US, Europe, and Japan, Agatha is dedicated to helping the world's hospitals, biotechnology, pharmaceutical, contract research organizations, and medical device firms optimize the management of their quality, regulatory and clinical documentation and processes.

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