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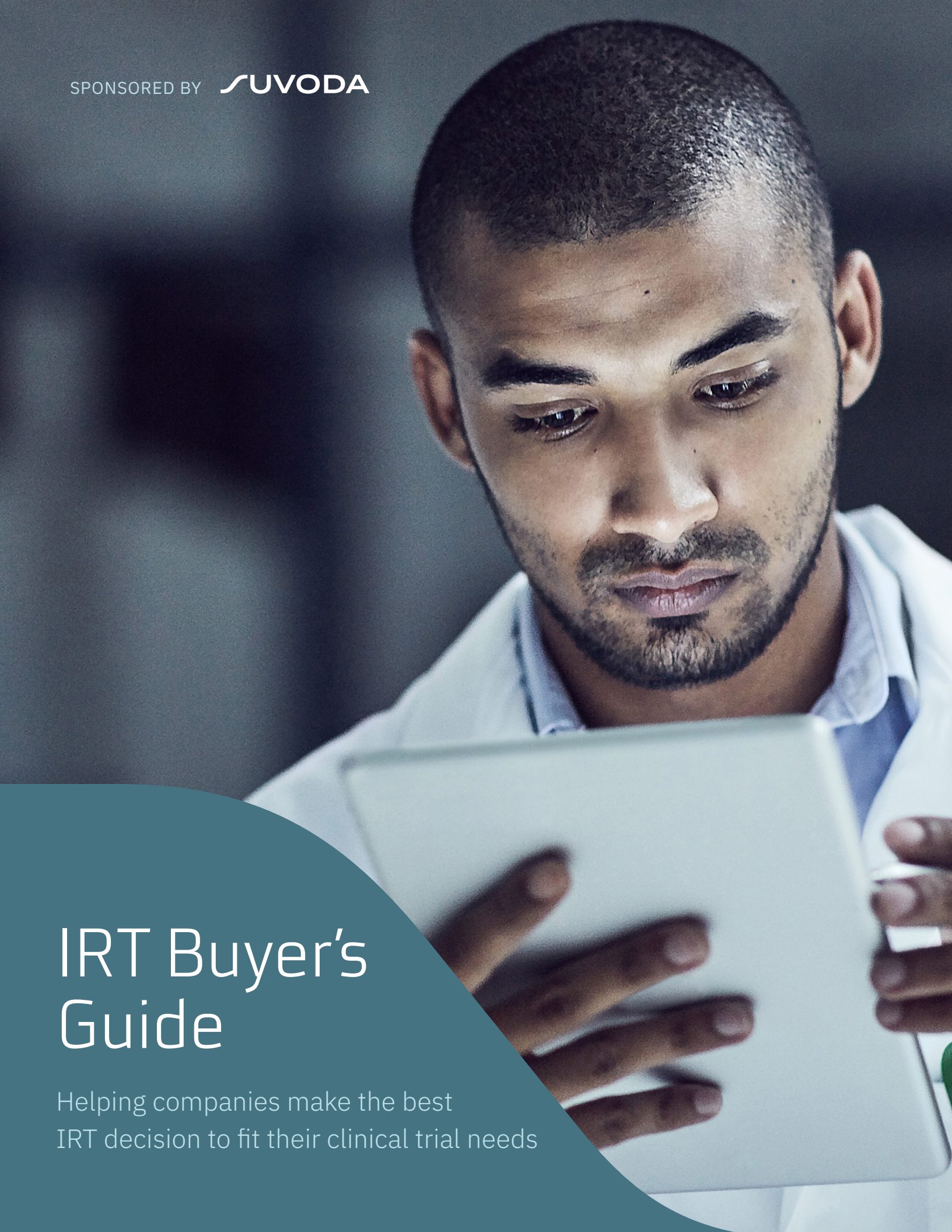

IRT Buyer's Guide

Helping companies make the best IRT decision to fit their clinical trial needs

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Introduction

There are many decisions to be made in designing and running a clinical trial. From protocol design to country and site selection, staffing, and budget, the going can be difficult. Fortunately, technology can come to the rescue. By choosing the right tools, your staff can feel more in control. But how do you decide what the right choice is?

This guide is intended to help you think through one particular aspect of technology selection — how to pick an IRT (Interactive Response Technology) vendor that best suits your needs. While this guide will not go deep into the details of IRT, it will provide you with a framework and an understanding of the questions to ask as you undertake vendor selection.

This eBook has been sponsored by Suvoda, but it remains agnostic. No particular vendor is positioned as the best. While not a comprehensive outline of all that goes into vendor selection, the book is designed to help you think about your company's particular needs so you can perform a thorough evaluation. The goal is to assist you in making a decision your team can feel confident about.

Interactive Response Technology (IRT) Defined

A good place to start is by learning what exactly IRT is and how it will serve you.

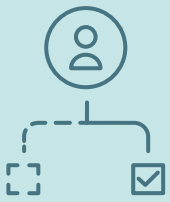
IRT systems, sometimes referred to as RTSM (Randomization and Trial Supply Management), serve clinical trials by managing patient randomization, ensuring the patient receives the right drug(s) or placebo, and managing patient scheduling for all visits — from initial screening to the end of treatment. The benefits are improved efficiencies and better tracking, data integration, automation of select activities, and reporting. What used to be shared by phone (IVRS) and tracked manually is now done on the web. As such, the information is updated in real-time with more accuracy.

You might believe your situation is too small or simple to warrant the use of IRT. However, it's important to consider that the essential function of an IRT system is to get the right drug to the right patient at the right time. IRT gives trials oversight and management of the multitude of variables that go into patient and drug supply logistics. Not only is it appropriate for larger Phase II and III trials, but it can be beneficial for Phase I trials as well.

> the essential function of an IRT system is to get the right drug to the right patient at the right time

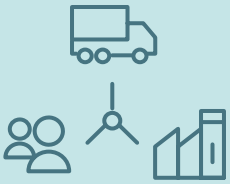
The data yielded by the IRT system further helps to support the management of your drug supply. This function is important so you can see the disposition of your medication at every level, which enables you to make informed decisions for additional supply needs.

IRT has two primary functions



Managing patient logistics

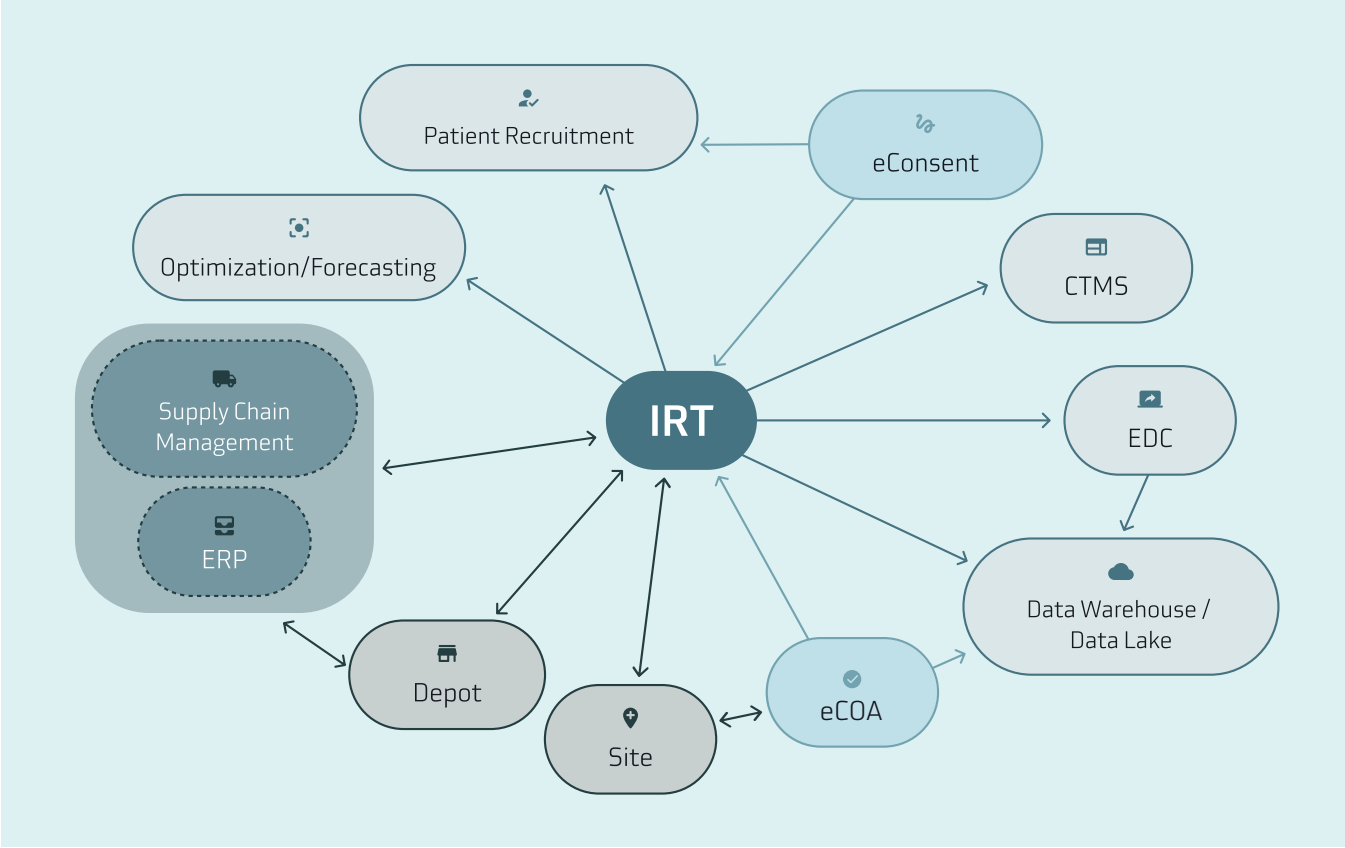
Patient screening, randomization, and visit management



Managing drug logistics

Ordering, stocking, shipping, tracking, inventory levels, and more.

One other aspect of IRT that needs to be understood is the frequent need to integrate with other systems. IRT integrations cuts down on the amount of manual data entry done by staff, which reduces the risk of data inconsistency. The types of systems that IRT is often integrated with include CTMS (clinical trial management software), eCOA (electronic clinical outcome assessment), eConsent, and EDC (electronic data capture), as well as depots and site systems. Chances are, if the IRT vendor has a significant market presence, then the interfaces have already been developed to enable one-way or two-way system integration.



BOTTOM LINE

IRT offers an easier and more efficient way to manage patient logistics and drug dispensing, along with reporting tools and possible integration across the platform. Customers benefit from a more holistic view and real-time information. This is true for companies of all sizes and stages of development.

The Vendor Selection Process

Choosing the right vendor benefits trials by helping to meet trial timelines and budgets.

When beginning the evaluation of IRT vendors, you must first determine which vendors to consider.

- **Clinical research organizations (CROs)** that will run the trial for a sponsor
- **IRT specialized companies** that focus on advanced IRT functionality
- **Clinical technology companies** that offer several technology products, of which IRT is one

Choosing which type of vendor to consider may depend upon your outsourcing strategy, expertise, and familiarity with IRT. Regardless of the route you choose, you will still want to perform a comprehensive investigation that considers the multiple facets and complexities that make up patient and drug logistics.

Assuming you've selected the companies you want to evaluate, the next step is to ask yourself what factors you should consider. Here are four fundamental areas to think about in the vendor selection process.

There are four fundamental areas to think about in the vendor selection process

1 The Evaluation Team

CONSIDERATIONS

While every company is different, IRT vendor evaluation teams typically range in size from three to six people representing the following mix of positions

- Clinical Operations
- Drug Supply Operations
- Data Manager / I.T.
- IxRS Manager
- Logistics
- QA Manager
- Vendor management/ purchasing

QUESTIONS TO ASK YOURSELF

Who should be on our vendor evaluation team?

Will each individual create a balance in the makeup of voices?

2 Key Factors

CONSIDERATIONS

These are some typical top-of-mind factors.

Product functionality: Can the IRT system be customized to effectively manage the level of complexity and unique needs in the trial protocol? What reporting does it have to help you make informed decisions through the course of the trial? How well does it integrate with other systems? How easy is it to make changes mid-trial and are there self-service capabilities?

Compliance and quality: Can they support your standard operating procedures (SOPs)? Will they commit to working with you to ensure you're fully compliant?

Customer support: Are they responsive with site support and helpdesk? Do they have clear processes that enable effective troubleshooting? Are they able to provide global support with multilingual staff operating 24 hours a day? Does their staff understand clinical trials and your therapeutic area? Will there be support staff with an understanding of your specific protocol?

Easy to use: What will the product look and feel like? Is it easy to understand and navigate? Do process steps flow naturally? Can you find answers and get help within the system? What does training look like for the study team?

QUESTIONS TO ASK YOURSELF

What selection criteria will we use to judge vendors?

Is it a mix of quantitative and qualitative?

Are the factors weighted equally?

Timelines: Can they meet your trial's timeline?

Pricing: Does the pricing reflect the quality of the offering? While pricing is important, it is often a lower priority when considering other factors that can make a significant impact on the trial. IRT typically represents 2% to 3% of the total study budget for Phase II and III trials.

Vendor team makeup: Does the team have strong communication skills? Do they have the technical expertise and problem-solving perspective needed? Are they responsive, professional, and committed to trial success?

3 Overall Fit

CONSIDERATIONS

Vendors can vary in many ways, just as your company does when compared to your competitors. If a vendor has the right product but feels like the wrong fit in terms of how they do business or would work with you, you need to take this observation seriously. What can a "wrong fit" look like? It can be all kinds of things — from the nature of their project team to their ability to anticipate and articulate challenges ahead, to the granular details of how they support customers, to whether "collaboration" is a word or a practice. These all matter when assessing the fit.

QUESTIONS TO ASK YOURSELF

Does the vendor have the same business fundamentals and approach as we and/or others do?

Will we and/or others work well with the vendor?

you can rely upon them to set up your IRT system on time, on budget, and to fully support you throughout the life of the trial.

4 Reasons to Believe

CONSIDERATIONS

At the end of performing due diligence, you need to have reasons to believe that the vendor can and will deliver what they say. You need to know that you can rely upon them to set up your IRT system on time, on budget, and to fully support you throughout the life of the trial.

QUESTIONS TO ASK YOURSELF

After all the analysis, is there sufficient proof that the vendor is as advertised?

What do colleagues say? Does anyone on the team have prior experience with the vendor(s) being considered?

Will they provide consistent support?

BOTTOM LINE

It is best to take the time to set up a process that reflects your company's needs. By identifying the key factors — both qualitative and quantitative — and assessing the vendors' capabilities, you will give yourself the best chance at picking the right vendor for your trial. This is not a stage where taking a shortcut or rushing through your team's thinking is a good idea. *Note: See the Appendix for sample RFP questions for additional factors that may be evaluated during a vendor assessment.*

Different Trials Need Different IRT Technology: Questions to Consider

We can’t know what the future holds, but evaluating your situation and needs early in the process helps you face changes as they happen.

One of the biggest challenges in selecting a vendor is trying to anticipate what your team will need down the road because trials are often fluid, with many changes expected. To a certain extent, the type of trial is a reasonable predictor of the likely challenges, and this should inform your decision-making. Here are some examples:

1

Oncology trials

Oncology trials are among the most complex trials and changes are often needed throughout the life of an oncology trial. For example, there can be new treatment arms or dosing changes. Randomization and the blinding (or double-blind) requirements can add another layer of complexity. The IRT setup should be designed to allow for these types of fluid changes so that costly change orders are minimized. A vendor with a strong track record in oncology will understand this need from the start.

2

Rare disease trials

Meeting challenging enrollment targets might mean more flexibility is needed to attract and retain patients in rare disease trials. Many of these trials have adopted decentralized elements to better accommodate patients where they are. Look for a vendor who offers both IRT flexibility and can support virtual solutions such as direct-to-patient shipping.

3

Global trials

From recruitment and retention to communication and supply chain, clinical trials are challenging. Add a multinational element with a large patient population and the complexity is further compounded with multiple languages and time zones. Look for a vendor that has the system, service, and experience necessary to support these trials.

Beyond protocol complexity or navigating the unexpected, there are additional operational complexities to be considered in vendor selection. Be sure to evaluate how vendors handle complications.

1 ## Direct-to-patient (DtP) shipping

If patients must travel a significant distance to a site, you may be considering a decentralized or hybrid model with direct-to-patient shipping. In this scenario, you will need to understand how vendors are equipped to help you with the logistical challenges of DtP shipping. Beyond tracking the drug to the destination, can the vendor certify the chain of custody if it has been shipped directly to the patient? In all instances, your IRT needs to ensure timely delivery, that patient blinding is intact, that GDPR requirements are met, and that the right drug made it to the right destination.

2 ## Investigator and site preferences

There are many things that add to the complexity of a trial. For example, sponsors might request adaptive randomization or re-randomization. The randomization might need to handle multi-arm and single-flow trials. There may be considerations as to blind and double-blind design, as well as dynamic cohort design. For trials to proceed efficiently and on time, the vendor needs to be nimble at adjusting to your preferences.

In all instances, your IRT needs to ensure timely delivery, that patient blinding is intact, that GDPR requirements are met, and that the right drug made it to the right destination.

With the many operational challenges, it is important to characterize and assess the vendor response for every possible scenario. Consider whether the vendor approaches their work in a consultative manner by documenting your needs and exploring the best options for you. This approach stands a better chance of getting ahead of potential problems and reducing the element of surprise.

Alternatively, some vendors might proceed more directly with what they believe is the answer and then proceed to implementation. This approach is not recommended as it does not fully examine the nuances, variabilities, and preferences you and your team will need.

Finally, consider what you believe will be the likely duration of the vendor's support. Vendors are often strong at the start of an implementation, but sometimes their focus is not sustained. The average trial length is 30+ months, which is why it is important to find a vendor that will be steadfast and committed throughout the trial.

BOTTOM LINE

Changes happen. Questions constantly arise. The vendor that has the experience to anticipate the unexpected and a track record of successfully managing urgent moments — giving you full command of your trial — is the one to go the distance with.

Valuing the Intangibles

When evaluating tangible factors of vendor selection, remember that intangible aspects of the company and how they approach trials can make a significant difference to the success of the trial.

We've explored some of the vital technical considerations in selecting an IRT vendor. Yet there is another aspect of vendor evaluation that is equally important, even if it's viewed as being soft. Most companies view picking a vendor as an opportunity to choose a strategic partner whom they hope they can go the distance with.

Why do they care about a long-term fit? Primarily because there are so many variables to manage in successfully running a trial and no one wants to miss any detail. To the extent that you can eliminate some of the variables, it will make running the trial easier. Working with a vendor who is with you for the entire trial duration and provides consistent technology and support frees up time needed elsewhere. Below are four vendor factors that are usually considered very important.

Built for the long-term

A solid IRT vendor has structured its business model to ensure longevity. Be sure to probe with questions that get to the heart of their operations. What processes are in place to ensure continuous improvement? How experienced is their management team? What are their core values? How do they measure success — both theirs and their customers? Does their product roadmap make sense?

Integration capabilities

Integration is critical for reducing or eliminating data redundancy and manual input of data. In discussions with vendors, it is wise to probe the vendor's approach toward integration. Do they have the expertise to offer for integrating the system you envision? Do they take a problem-solving approach to the integration of systems? Can they tailor the data flow to your specific needs and timing?

Services approach and capabilities

Examining services is not as simple as looking at response times. If you need help, chances are that you need someone well-acquainted with your protocol and IRT setup that can step in immediately. Is the vendor collaborative? Do they feel like an extension of your team? What is their process to stay educated and up-to-date with the latest information? Do they work well with other vendors? Do they have sufficient global capabilities—around-the-clock support and native language skills? In the end, what it comes down to is whether they can function as a true partner and work shoulder-to-shoulder with your team for the life of the trial.

Innovation

Within IRT, new functionality is often being developed to support more efficient, flexible, and secure clinical trials. Does their programming leverage the latest technology? Does their approach support patient-centric trials? Are additional solutions offered as part of the IRT workflow? What is their perspective on the possibilities for IRT?

BOTTOM LINE

When evaluating vendors, don't be afraid to go soft and ask whether their team is built for the long run and whether they have the means to ensure improvement with each passing day and each lesson learned. Will they use those lessons to innovate and create a fresh approach to seemingly intractable problems? Those are the types of vendors to bet on.

Frequently Asked Questions

Q: CHANGE ORDERS. How can I tell when something should be a change order or just a minor modification during implementation? Are there ways to reduce the incidence of change orders so I can stay within budget?

Answer:

Some vendors have the capacity to allow customers to make changes within the system without a change order, such as a protocol amendment that requires you to alter how you manage drug supply. When you engage with an IRT vendor, you should ask them how they manage some of the more common changes and whether any self-service options are offered in the functionality. Some vendors have designed their UI with this in mind.

The best way to manage the number and extent of changes is to start by engaging the vendor in early discussion and leveraging the best practices of their team. There will always be protocol amendments and the like to create flux, but a seasoned team should be able to ask you a series of questions and give you good guidance to limit the risk. The design decisions that you make upfront will improve how you go about implementing the change. Most importantly, though, sometimes change orders result from our rushing to complete the planning at the start. We are too focused on time and efficiency, and so we cheat ourselves of the deliberate process needed to get all the angles right. Thoughtful time spent upfront will pay off.

Q: INTEGRATION. Will I know my integration needs at the start of the implementation or is this something we identify later? What suggestions are there to best manage the process?

Answer: More often than not, you will know early on what technology needs to be integrated. For example, IRT might need to be integrated with EDC. Sometimes new integration needs become apparent later in the process, but this is less common. The key is to pay as much attention to your integration needs as you do to IRT and to do so as early as possible. This will make coordinating among vendors easier.

There are a few simple suggestions for managing the integration process. First, it is good practice to determine, at an early stage of setup, which systems will be considered and ways to avoid data inconsistency. Be prepared to act as the go-between early on as vendors examine what needs to be done. Be aware of and try to understand the dependencies — what the IRT and the EDC vendor need from each other. Also, keep in mind what the purpose of the integration is, as this will help manage the scope and stay focused. A successful outcome can and should be expected, but planning and coordination are important from the start to the finish line.

Q: IMPLEMENTATION TIMING. How often do vendors meet the schedule, and what can I do to ensure they do?

Answer: You should expect your vendor-committed timelines to be met. Vendors understand that it is a contract with a commitment to dates. However, as the customer, you also bear a responsibility to be organized and responsive to help meet the milestones. At the start, your IRT vendor needs the protocol design to be firmly determined, the packaging vendor to be selected, and other odds and ends to be tended to for a smooth operation. You will need to do a timely review and approval of user requirement specifications (URS), conduct user acceptance testing (UAT), and more to ensure your First Patient First Visit (FPFV) date is met and that you and the vendor work as a team without barriers.

Meeting the timelines is a true partnership between the company and the IRT vendor. This also means periodic checks along the way to make sure the schedule is being kept.

Q: EFFICIENCIES OVER TIME. Should I expect that if I use the same IRT vendor for multiple trials, we will get faster and better performance because we know the tool?

Answer: You There are a variety of efficiencies that can be gained in using the same IRT vendor including cost savings, time savings, and reduced friction in your operation. For example, you may want to invest time with the vendor to develop standards and templates that you can use in subsequent trials. Not only does this improve consistency across trials but makes it easier for trial teams to implement the IRT with more of a focus on protocol specifics.

Q. OUT-OF-THE-BOX VS. CUSTOMIZED. We prefer out-of-the-box because it will be cheaper and should be easier to implement. However, many trials seem to require customization and out-of-the-box seldom fits. Are there rules of thumb as to which one to choose?

Answer: Start by examining how specialized your needs are and what is truly needed for your trial protocol. With some vendors, the IRT system is built to meet the needs of specific protocols. Diving into your requirements will help you to isolate parts of the trial that are unique or inherently pose more risk, in which case customization might be needed.

Be sure to probe into the vendor's experience and best practices from other trials. They have many prior instances to draw upon. You might hear them tell you that the software does what you need "natively," which means out-of-the-box is a good option. Or you might have some specialized requirements which means at least some customization will be needed. Finding the right solution for your trial has the best chance for long-term success when you look carefully at the details of your requirements.

Q. SITE SUPPORT. Our sites are not very experienced at running trials and will need support. What can we expect a vendor to do for site support?

Answer: Central to effective support are knowledge and access. From an access perspective, you want to look at the hours and days they will be available. Ideally, they will offer support around the clock every day. They will also be multilingual, which ensures that sites in every location can be supported. These factors are essential but only the beginning.

You will want a vendor with a strong relationship between the front-line support of the technology and the team who designed and implemented the IRT. Responding to your support needs may require in-depth knowledge of the protocol. When you talk to vendors, spend some time probing how tightly aligned the front-line support is with the project management team that understands the details. Strong alignment leads to faster resolution.

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Q. THERAPEUTIC EXPERTISE. How important is it that the vendor has specific experience in a therapeutic area?

Answer: Start Designing and implementing a system that is tailored to your trial has a higher chance of success when the vendor is experienced with your therapeutic area and understands the specific trial supply chain processes required for your trial. They are positioned to draw from experience and best practices with similar trials. And while therapeutic experience is desirable, technological expertise is where they need to shine. The vendor should bring a strong systems background, excellent communication skills to explain recommendations, and flexibility in the system itself and their approach.

Q. STANDARDIZATION. Is it important to standardize on one IRT vendor, or is it ok to use different vendors for different trials?

Answer: Sometimes large companies will select more than one IRT vendor as a backup or for capacity reasons. Additional vendors can make sense in these settings but you should also realize that additional vendors add complexity. As your operation matures, you will want to create functional and procedural standards, and this becomes more difficult as more vendors are added. Typically, small to mid-size organizations choose a single IRT vendor to simplify operations.

When it comes to whether to pick one vendor who has a large footprint that includes IRT, or an IRT specialty vendor, you will need to ask yourself how important "best of breed" is in your decision. If you are running a complex oncology trial, you might want a focused IRT vendor whose value is in offering more robust functionality.

Q. HYBRID AND DECENTRALIZED TRIALS. What should I look for in a vendor if I think that we will be running hybrid and/or decentralized trials?

Answer: Look for a vendor that has the capability within their technology and experience within the project team. Virtual elements, such as direct-to-patient (DtP) shipping, eConsent, and eCOA, are solutions that you may want so be sure to ask about these additional options. The IRT needs to support these elements.

Q. REGULATORY COMPLIANCE GLOBALLY. Should I expect my IRT vendor to be familiar with regulatory compliance abroad? How global is their regulatory expertise typically?

Answer: You should not expect to spoon-feed your vendor, nor should you abdicate responsibility for global compliance. It is a partnership. Both parties should pay attention, but you should assume you are at the helm. It's your trial, and it's too important to leave it in the hands of any vendor, no matter how seasoned or capable they are. However, as issues come up, you should expect them to understand possible compliance repercussions as design and implementation proceed.

Appendix

Request for Proposal (RFP) Sample Questions

When exploring your IRT vendor options, there are many factors you will want to consider. The sample questions below have been organized by system expectations and service needs. These are intended to be a helpful guide but are not a comprehensive list of all considerations to make.

System

Category	Sample Questions
DESIGN AND BUILD	1. Does the IRT support escalation and de-escalation designs? Cohort management? Temperature excursion management? 2. Does the IRT support eSignature functionality to acknowledge randomization assignments? 3. Does the IRT offer internal and external alerts and notifications? Please list all alerts and notifications available.
SITE MANAGEMENT	1. Describe how the system manages site activation, deactivation, and re-activation for drug supply at trial, region, country, and site levels. 2. Describe how satellite sites are managed. 3. Will it be possible to configure the system for local or central sourcing of comparators?
INVENTORY MANAGEMENT	1. Describe how the system supports trial supplies at a trial and site level. Can it manage drug pooling? 2. How does the system support trial supply prediction at country, site, and patient levels? 3. Describe how you support supply forecasting and modeling.
SUBJECT MANAGEMENT	1. Describe how subjects are screened, enrolled, re-screened, identified, and withdrawn within the study. 2. Describe how the system handles changes in subject demographics, visits, etc.
REPORTING	1. Describe and list your standard reports at the trial and site levels. 2. Describe custom reporting options.
SECURITY	1. Do you provide any reports or certifications attesting compliance with applicable security standards? 2. Describe processes and controls in place to ensure security. 3. Do you have a regularly maintained business continuity and security incident response plan? Is the plan regularly tested?

Service

Category	Sample Questions
SERVICE TEAM EXPERIENCE	1. Does each member of your service team have a thorough understanding of clinical trials and experience with complex studies? 2. Will the service team analyze the protocol? 3. Will the service team identify challenges, risks, and ambiguities? 4. Does the service team understand and have experience with [therapeutic area]?
IMPLEMENTATION	1. Describe how the service team will provide end-to-end management of the IRT system set-up, monitoring, maintenance, study protocol management, and change. 2. Describe how testing will be performed to ensure functionality, protocol adherence, site and patient experience, and usability operate according to specifications. 3. Describe how integration with other systems will be performed and what the experience will be.
DOCUMENTATION AND TRAINING	1. Describe the system documentation that will be provided and illustrate how protocol adherence and regulatory compliance will be included. 2. Describe your process for system training. Will a guide be provided that is aligned with the protocol?
MANAGEMENT AND CHANGE	1. Describe how the system is monitored to reduce risks and mitigate issues. 2. Describe how the service team responds to questions and general guidance for system use. What are the hours for support? What is the average time for issue resolution? Can you provide reports of helpdesk tickets? 3. Describe the process for changes to the system. Will the system offer functionality for 'self-service' types of changes?

About Suvoda

Suvoda is a global clinical trial technology company that specializes in complex, life-sustaining studies in therapeutic areas like oncology, central nervous system (CNS), and rare disease. Founded in 2013 by experts in eClinical technologies, Suvoda empowers clinical trial professionals to manage the most urgent moments in the most urgent trials through innovative trial design and advanced IRT, eConsent and eCOA solutions. Headquartered outside Philadelphia, Suvoda also maintains offices in Portland, Oregon; Barcelona, Spain; Bucharest, Romania; and Tokyo, Japan. The company consistently boasts customer satisfaction scores of 9 out of 10 and has been selected by trial sponsors and CROs to support more than 900 trials across 65 countries.

To Speak with an IRT expert about your specific business needs visit **suvoda.com.**

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