Insight Paper

What to look for in your IRT/RTSM solution for simpler trial execution

We understand that RTSM is one service among several that you need to run a trial. Many solutions in the market offer varied levels of technology and/or service. We have developed this guide to help you know what to focus on when looking for an IRT solution, hopefully avoiding solutions that may not be suitable for your trials.

Expertise

Despite the belief within part of the industry that IRT is just a tool, our experience over the years has shown that you need the support of a team that knows exactly how to translate your protocol into an efficient randomization and trial supply management design.

You do not need to wait for the protocol to be fully developed before engaging with your IRT vendor. You can consult during protocol design if there are elements of randomization, recruitment or supply management that are new to you; it is likely that the vendor will have seen similar protocols in the past.

The IRT vendor will also make a considerable difference in situations you may face during the trial execution; when you are under pressure, you realize the true quality of a service. We recommend collaborating with a vendor whose IRT/RTSM subject matter experts are available for the duration of the trial, to help solve your challenges quickly and smoothly.

Experience

Breadth of experience across different designs and requests, from all phases and all therapeutic areas, will translate into the quality of the recommendations made by the IRT vendor.

Your vendor should understand and analyze the unique requirements of every protocol and develop a strategy that will meet those requirements, as well as anticipate future needs related to the IRT.

Experience translates into risk identification, anticipation, and mitigation.

There are risks you may expect - related to the randomization algorithm and balance, to participant dispensing and dosing, and to unintentional unblinding.

There are risks a good IRT vendor should anticipate – related to the potential for future amendments, recruitment, medication shelf-life and scarcity, data reconciliation, and supply chain concerns – these are just a few examples.

In RTSM, only certain therapeutic areas require specific considerations e.g., oncology may require the ability to switch between visit schedules and between local and central sourcing strategies. Experience within the trial phase and experience with similar trial designs are equally, if not more, important.

Flexibility

An IRT that can be adapted to all protocol and packaging needs is key.

If you invest time in onboarding an IRT/RTSM vendor, it is important to know that they can cover the full range of protocol designs, from the very simple to the very complex.

Understand from your vendor what their standard system offering is. If they offer an existing set of pre-validated functionality, this can reduce your time discussing requirements and performing User Acceptance Testing.

The next critical question is if and how the IRT vendor can customize that core functionality to best meet the needs of each protocol. Your vendor's system must be able to match the protocol design, with no limit to the level of complexity it can address.

Flexibility in the supply chain could also result in better efficiency of your drug supply budget; for example, allowing a per visit 'Do Not Dispense' expiry check (ensuring kit/s assigned do not expire whilst in the participant's possession for the duration of each specific visit) uses kits for longer when they get close to expiry. This alone could have a significant impact on your study budget.

You should be able to make instant updates as and when needed, to make study execution simpler, these include:

- **Study, country and site management** - open and close screening and randomization, set and amend caps on various levels (study, country, cohort, site, stratum, etc.)
- **Inventory management** - cancel shipments, amend site resupply amounts for all recruitment levels, raise shipments outside the IRT's automatic algorithm.
- **Participant management** - correct demographic details, with automated updates sent to EDC

Adaptability

Initial IRT/RTSM study settings are based on educated guesses. How is your system going to evolve if you have a protocol amendment or if you need to expand recruitment in more countries? You need to know whether the system can manage both planned and unplanned changes.

Planned changes can be managed via self-service tools, giving users the ability to make simple changes by themselves with immediate effect. If it is known up-front that the study design will change during the trial e.g., treatment arm closure for an adaptive trial, or new cohorts/doses may need adding, the IRT should be customized during the original build to include the ability for appropriate sponsor team members to perform these actions themselves online at any time.

A good IRT should also be able to adapt to known changes automatically, without user monitoring and intervention. For example, changing what medication is sent to a site based on the actual number of participants 'in screening,' or when the first participant at a site is approaching a new study phase. The system should also automatically change associated settings following an update made via a self-service tool, for example, to amend checks of what stock is on-site before a participant allocation when a treatment arm is dropped.

Unplanned changes also need to be considered. You need to be able to react to in-study challenges, such as a delayed batch and the need to extend the use of existing medication. Your vendor should be able to adapt settings to support such challenges.

Integration

Your IRT/RTSM vendor needs to support a range of integrations with a range of systems, to reduce data entry, increase data quality, and reduce the need for reconciliation between systems.

They need to be able to manage standard integrations needed for the trial's administration - EDC, the distribution vendor and, CMO. Your protocol may also require additional integrations – ePRO/eCOA, laboratories, eConsent, and supply simulation.

Integration can be a complex topic requiring the management of multiple vendors. You should be able to rely on your vendor to manage all the integrations you require without too much involvement from your team.

Your vendor's Integration Analyst should understand your requirements and consult directly with the third party/integration vendor to confirm all requirements for each specific integration. They should also build the integration/s required and support User Acceptance Testing.

Summary

When selecting an IRT/RTSM vendor, you should consider how all your needs will be supported.

Randomization and Trial Suply Management are critical to the success of your trial, but a good vendor can offer much more.

You can greatly benefit from the service they offer, acting as a partner to provide guidance and recommendations and supporting the inevitable challenges you will face - allowing you to focus on successful trial execution.

Ready to find out more about what Perceptive eClinical can do for your trial, contact us for a product demonstration.

hello@perceptive.com

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