Insight Paper

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IRT/RTSM Vendor Checklist

There are so many things to consider when looking at the right vendors for your RTSM needs, we've created a full checklist breaking down those things to consider into three areas, Process, People and Technology.

Process

Area	Question
Help Desk / Customer Support	Do they have an issue escalation process with SLAs (for timeline of issue resolution)? Do they have a prioritization process for participant-waiting requests?
Timelines	Can my FPI timelines be met?
User Acceptance Testing	Do they provide full support for my UAT?

People

Area	Question
Help Desk / Customer Support	Is their helpdesk available 24/7/365? Is their helpdesk in-house? Is a translation service for non-English speakers available for incoming calls?
Data Management	Do they have a dedicated data management team?
Integration	Does their integration team manage communications, requirements gathering and user acceptance testing with your 3rd party vendors?
Trial Supply Management	Can they offer expert guidance about the optimal supply settings at the start of the trial and how best to amend those settings as the study progresses to address changes and challenges?

Area	Question
Experience and Expertise	Do they have the experience required to support my trial? - *Considering similar trial designs supported and relevant therapeutic area experience* Do they provide access to RTSM SMEs during the life of the trial?
Relationship Management	Do they provide a dedicated project manager for the life of the trial? Can our teams work collaboratively/effectively? Can we form a partnership? Will they support our goals and KPIs?

Technology

Area	Question
Regulatory Compliance	Do they comply with industry regulations? - *For example with ISO 31000 Risk Management; with the ISO/IEC 27000-series of control standards (Certification IS 761405); with Good Clinical Practices (GCP), the U.S Food and Drug Administration (FDA) including with FDA 21 CFR Part 11, with the European Union "Clinical Trials Directive" (2001/20/EC), with data protection regulations, and other regulatory bodies*
User Management	Can the sponsor/study team both grant and revoke user access? Does the system manage both user permissions and blinding status on a per role basis?
Reporting / Data Access	Is their management and protection of the blind robust in all their reporting capabilities? Do they provide standard reports, which are able to be downloaded? Can they provide a full audit trail?
Integration	Are they able to integrate with other systems? - *consider both 1 and 2-way integration* Do they have experience with and/or standards in place for common integrations? - *global depot vendors, EDC systems*
Randomization	Do they provide essential randomization capabilities/functionality, considering the most used methodology of blocked randomization? Essential must include: - allocation of randomization list records to participants as per the protocol - stratification across multiple factors - maintenance of the blind Can they create validated randomization lists in-house? Can they support the randomization methodology you need for your trial? Can they support adaptive and platform trials?

Area	Question
Trial Supply Management	Do they provide essential trial supply management capabilities/functionality to support all activities? - *Considering from releasing new batches of medication following manufacture and labelling and managing QP approvals of those lots, to distribution of approved drug to depots and sites, tracking study drug to the smallest unit throughout its journey from release to participant allocation to destruction.* *Essential must include:* - *efficient supply of drugs across global sites* - *the right drugs sent to each site at the right time for all ongoing participants* - *automatically ensuring participants can be resupplied* - *management of expiry to remove the risk of medication expiring in the participant's hands* - *robust maintenance of the blind* Do they include the ability to quickly amend supply chain parameters to manage supply shortages? - *for example, temporary exipry overrides to respond to delay in new batch release* Do they include the ability to manage shipments in addition to the automated system? - *for example, cancel a shipment, raise a shipment with 1-click* Do they include the ability to forecast future orders, allowing the supply manager to enter a date the system should predict site resupplies to? Can they support the specific supply management needs of my trial? - *considering medication sourcing changes and Direct-to-Participant shipping* Can they create validated packaging/kit lists in-house?
Study Management	Do they provide essential study management capabilities/functionality to support all activities? - *considering study, country and site levels* *Essential must include:* - *study management: opening and closing* - *country management: opening and closing* - *site management: activation and deactivation* - *participant management: participant capping on screening and randomization at all levels* - *data access to study data with insights* Can they build in flexibility to allow an immediate response to common study management challenges, such as the need to add new countries and depots to respond to slow recruitment?
Data Management	Do they provide on-demand access to full audit trails?
Participant Management	Do they give sites control over the data they own, allowing for immediate corrections with an audit trail and update files triggered to other systems if needed?
Site Management	Is the user experience designed to reduce the training burder for users/sites?
Change Management	Do they have a robust and traceable change management process?

For more support from an expert in IRT/RTSM, contact us today!

www.perceptive.com/contact-us/ | hello@perceptive.com