Insights

perceptive eclinical

IRT/RTSM Vendor Checklist – The Essentials

Below is a list of essentials to consider when selecting an IRT/RTSM vendor who can support the successful implementation of your trial, considering both the technology *and* the people.

Area	Question
Randomization	Do they provide essential randomization 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 ▪ Robust maintenance of the blind
Randomization	Can they support the randomization methodology you need for your trial, considering not only common methods but also complex, adaptive, dynamic designs?
Randomization	Do they offer expert guidance on the most appropriate methodology, including providing consultation on rare randomization methods?
Trial Supply Management	Do they provide essential trial supply management functionality: tracking study drug to the smallest unit throughout its journey from release to participant allocation to destruction? Essential must include: ▪ Efficient supply of drug across global sites ▪ The right drug sent to each site at the right time for all ongoing participants ▪ Automatically ensuring participants can be resupplied, regardless of the complexity of the visit schedule/s and participants treatment regimen ▪ Management of expiry to remove the risk of medication expiring in the participant's hands ▪ Robust maintenance of the blind
Trial Supply Management	Can they support the specific supply management needs of your trial? Considering: sourcing changes, medication pooling across studies, just-in-time shipping, direct-to-participant shipping, a participant-led supply chain (for personalized/precision medicine)
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, enabling you to meet your study goals and quickly deal with your supply challenges?

Area	Question
Study Management	Do they provide essential study management functionality to support all activities, considering study, country, and site? Essential must include: ▪ User/access management: granting and revoking access ▪ Site management: activation and deactivation ▪ Country management: opening and closing ▪ Participant management: capping on Screening and Randomization ▪ Access to study data with insights
Study Management	Do they provide the ability to make immediate changes as and when needed – from increasing enrolment caps and activating new countries to reflect changes to recruitment, to immediately adding new doses for new cohorts of participants or closing treatment arms following a safety review?
Participant Management	Do they give sites control over the data they own, allowing for immediate authorized corrections with a full audit trail and update files triggered to other systems if needed?
User Experience	Is the user experience for users/sites considered, with tailored design and messaging for ease of use and improved compliance?
Data Management	Is the system designed for first-time data quality, minimising data reconciliation?
Integration	Are they able to handle complex and novel integrations, integrating with any system, any vendor, by any method?
Integration	Does their integration team manage communications, requirements gathering, and user acceptance testing with your 3rd party vendors?
Customer Support	Do they have an 24/7/365 Help Desk, with access to a translation service?
Customer Support	Do they have an in-house support team who direct requests to teams with relevant expertise and study-specific knowledge?
Experience and Expertise	Do they have the experience required to support your trial? Considering: similar trial designs supported, relevant Therapeutic Area experience
Experience and Expertise	Do they provide access to RTSM expert teams for the life of the trial? Considering: helping you meet your study goals and KPIs, supporting challenges you will face such as medication shortages.
Collaboration and Communication	Do they provide a dedicated and proactive Project Manager for the life of the trial?

Ask us for an extended list, including additional questions for your IRT/RTSM vendor covering technology, people & process.

www.perceptive.com | hello@perceptive.com