TECHNOLOGY VENDOR REQUIREMENTS – MANA METHOD

eSource/ePRO/eConsent

Requirement	Meets	Comments
Hardware		
Deployment to variety of tablet/device platforms (iPad and Android)		
App sits on device to optimize speed		
Data collection can be online or offline.		
System can be used on tablets or via desktops or laptops (web portal).		
Subjects can use their own devices.		
Hardware can be locked down with access only to Study, eTMF/eISF or other study applications.		
Query Functionality		
Robust query functionality within form, across forms and visits; hard and soft queries (must have); across databases – e.g., between clinical data and ops database (nice to have)		
Exports		
Exports must be immediately available at time of study launch.		
Exports can be customized to include source questions or just analysis databases.		
Download data sets at will		
Exports can be transmitted daily to repository without additional costs.		
Export of query data set to Repository can be accomplished and automated.		
Export can include audit trail information to be defined by MANA RBM.		
Randomization		
Randomization incorporated; can do stratified, central randomization		
Integration with drug supply from STAR Database or other IP supply function		
Web Services Interface		
Can integrate with IWRS system, if required (bi-directional data transfer required)		
Workflow Customization		
Workflow can be customized to denote SDR instead of SDV and to have consecutive review by DM and monitors.		
STAR Database		
Ability to provide operational database (preferably with headers customized to denote site instead of subject)		
ePRO/eDiary or other functionality to allow collection of feasibility questionnaires		
Robust pre-population so that once data have been collected in one portion of the database or audit trail, it can pre-populate other forms or fields (e.g., PI name, monitor name)		
eSource		
Can collect source questions as well as data for analysis		
Can identify when data entry is outside the time that is being listed for study visit (e.g., audit trail says 21 April, but eSource data entry shows 20 April)		
Easy to navigate		
Fast		

Access Control		
Capture training on system and require completion before access granted		
Export of training documentation is available.		
Customize access to form/field based on User Role and Site Assignment		
Flexible access control that can be defined for a role and then applied across users with that role		
eSignature functionality can be used by multiple roles based on form; multiple eSignatures can be applied to a single document.		
eSignature meets 21 CFR Part 11 compliance.		
ePRO/eDiary		
Can incorporate pictures into diaries		
Can incorporate Visual Analog Scale		
Text reminders available		
Release of diaries/ePRO at specific time available		
Multi-language capabilities available		
eConsent		
Versioning by site available		
Release of versions of ICF can be performed on site-by-site basis.		
Multi-language capabilities		
Can add visuals (video and/or audio files)		
Can add questions to test knowledge		
Can show IRB approval seal		
Can capture other aspects of IC process—who presented, time to review, eSig. of Study Staff		
Date of IC can be exported into eSource.		
Can prevent any additional actions in eSource until eConsent is signed		
Design and Build		
Ideally MANA RBM would like to build, but if not possible, then build and internal testing of eSource can be done within 4 weeks of approval of specifications.		
21 CFR Part 11 and Validation		
System meets the technology requirements for 21 CFR Part 11 including eSignature.		
There is evidence of a software development life cycle design, testing, and release.		
Change control process is in place, which assures appropriate versioning for new releases.		
Hosting, Backup, Recovery		
Must have hosted solution (cloud or servers with backups at external location); Regular backup process		
Redundant internet		
Backup power		
Physical security		
Server monitoring with intrusion detection		