Clinical Technology Challenges and Solutions

SCRS
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Clinical research sites face mounting pressure to adopt new technologies and remote services, but implementing these solutions comes with real operational, financial, and regulatory challenges. This document outlines critical obstacles and their practical solutions, providing sites with actionable strategies to navigate technology adoption while maintaining quality and sustainability.

Challenge 1: Integration and Operability of Systems

The systems and technology that sites and patients are asked to use lack a sufficient amount of inter-operability and integration with other systems and technology. Stand-alone, or non-integrated solutions that do not allow data to flow seamlessly, or that don't work together in concert are significant sources of inefficiency at the site level. This causes an inordinate amount of time and resources spent, as well as additional costs when compared to trials that do not use these technologies.

Short-Term Solutions (Immediate to 1 Year)

1. Unified Patient Identification (Documentation Approach)

- Document how patient identifiers are defined and map them appropriately

- Encourage suppliers/technology to act as a linking mechanism

- Utilize existing sponsor data formats where possible

- Start with a unified patient identification number to streamline processes

2. Device Provisioning

- Ensure provisioned devices allow the installation of necessary applications

- Pre-load and test required applications to prevent failures

- Address issues of apps "dropping off" due to third-party provisioning inconsistencies

3. IT Adoption Capabilities

- Identify and support site technology that integrates more readily

- Enhance resourcing for technology needs at research sites

- Work with site solution providers to implement easy-to-adopt technologies

- Improve site-based IT adoption capabilities to facilitate network integration

4. Data Quality & Query Process Improvement

- Implement systems that prevent poor-quality data from entering the system

- Reduce unnecessary or invalid queries that sites should not need to address

- Address issues of bad data entering the system from sites

5. Data Entry Timelines

- Establish clear commitments to adhering to data entry timelines

- Improve tracking and accountability mechanisms for timely data entry

- Commit to adhering to data entry timelines to ensure data accuracy and timeliness

Mid-Term Solutions (1-3 Years)

6. Single Sign-On (SSO) Implementation

- Develop a unified login system across multiple platforms to reduce complexity

- Implement a single sign-on solution for simplified access, requiring only one login for all systems

- Ensure access management is a priority and control security measures accordingly

- Engage sponsors to implement SSO at the sponsor level for consistency

- Management of systems involved will be important components and demonstrated ability within this space

7. Deep Linking and Integration

- Utilize deep links to connect and share data, thereby simplifying workflows

- Address mobile application challenges to enable seamless data flow

- Investigate solutions from companies already working on digital data flow

8. Reduce Duplicate Data Entry

- Integrate intermediate steps to minimize duplicate data entry where full data flow isn't possible

- Implement intermediate steps to minimize duplicate data entry, even if full data flow isn't possible

- Align duplicate data reduction with other integration solutions to ensure effectiveness

Long-Term Solutions (3+ Years)

9. Priority System Connections

a. eSource to EDC Integration

- Ensure integration between eSource and Electronic Data Capture (EDC) systems

- Address challenges of integrating site-owned eSource systems with EDC

- Develop APIs that facilitate seamless data flow between systems

- Investigate existing technology solutions and determine resourcing needs

- Consider allowing patients to own and manage portions of their data

- Ensure these systems align with internal site systems (may require deep dives into necessary APIs and assuring they are conducive to the technology-technology relationship)

b. eDiary/ePRO to EDC Integration

- Integrate electronic diaries (eDiary) and electronic patient-reported outcomes (ePRO) with EDC

- Establish stronger integrations between eDiary/ePRO systems with EDC

- Ensure these align with internal site systems to facilitate smoother workflows

- Conduct deep dives into necessary APIs and data-sharing mechanisms

10. Sponsor/CRO Challenges & Ownership Issues

- Address restrictions and ownership issues imposed by Sponsors/CROs to allow high-level data integration

- Ensure solutions are built with the necessary flexibility for high-level integration

Challenge 2: Regulations

There is a significant amount of ambiguity surrounding the regulatory ramifications at the site level when remote services and technology being employed on a trial fails or does not perform as expected. This centers around, but is not limited to delegation, insurance, and oversight. Sites are unaware of, even in general terms, what should be done in certain instances when the oversight and control of clinical trial activities falls outside of the traditional site framework. It is also a question of who's liability it is when there is an issue in this space, between the investigator and the sponsor. Global context should be taken into consideration when determining appropriate regulatory needs.

Short-Term Solutions (Immediate to 1 Year)

1. Educational Resources & Awareness

- Educate sites on relevant regulations and potential ramifications

- Develop and distribute a clear checklist outlining site vs. sponsor responsibilities

- Standardize materials across sponsors to ensure consistency in site expectations

- Create a simple decision tree or workflow to clarify actions in cases of technology failure or oversight issues

- Provide easy-to-access educational resources (e.g., recorded sessions, PDFs, in-platform reminders) about delegation, oversight, and documentation responsibilities

2. Risk-Based Implementation Guidance

- Promote trials that involve less risk to mitigate potential issues

- Shift focus from "low-risk trials" to **low-risk technology applications** within trials

- Identify non-essential tasks or complex workflows that can be simplified through risk-based approaches

- Encourage sponsors and CROs to implement technology based on impact and complexity

- Provide risk assessment templates or tools to evaluate technology needs before deployment

- Provide guidelines on how to assess risks in trial environments

- Implement mitigation strategies using technology in risky environments

Mid-Term Solutions (1-3 Years)

3. Contract Language & Liability Protection

- Indemnify sites' liability, particularly in instances of systems, technology, and services that are not managed by them

- Promote adoption of standardized contract clauses around:

  - Indemnification in cases where technology is not managed or owned by the site

  - Coverage for insurance gaps involving remote systems and digital services

  - Clarity on cost burden for malfunctioning or poorly supported tech

- Include both personnel and system accountability language

4. Global Regulatory Alignment

- Collaborate with global partners to create flexible guidance for cross-border trials

- Include international oversight requirements when drafting risk and responsibility protocols

- Enable sponsors to tailor global templates with localized clarity for site responsibilities

- Take global context into consideration when determining appropriate regulatory needs

Challenge 3: Lack of Support

Sites and patients do not have the support necessary to successfully implement the technology and remote services as required by the protocols. Often, support is insufficient for the needs of a patient or site, but is in some instances non-existent. This includes onboarding support, as well as ongoing technical and trial support when utilizing these technologies and remote services.

Short-Term Solutions (Immediate to 1 Year)

1. Enhanced Technical and Patient Support

- Establish direct lines of communication with appropriate response times

- Implement multiple support methods: Chat, Phone, and Email

- Provide immediate 24/7 assistance in the local language for both sites and patients

- Define response time standards and publish vendor SLAs to sites

- Align vendor contracts with real-time support demands (e.g., weekend hours, urgent issue triaging)

Mid-Term Solutions (1-3 Years)

2. Support System Assessment & Cost Strategy

- Assess support needs per system, protocol, and region; tailor solutions accordingly

- Identify systems where support is insufficient or misaligned with trial expectations

- Build a business case for including enhanced support in trial budgets without cost burden to sites

- Implement sponsor-level messaging to set expectations on support availability and escalation routes

3. Sandbox or Trial Environment

- Provide a sandbox or trial environment before the trial or patient enrollment

- Enable sites to trial and test the technology or service

- Make this a standard offering for all trials upon site request

- Offer trial sites the option to engage in simulation environments to test technology prior to deployment

- Provide opportunities for study-specific or system-wide trial runs

- Establish early access timelines and consistency across studies and vendors

- Use Key Opinion Leader (KOL) sites to pilot new technologies before broader rollout

- Incorporate sandbox testing outcomes into site training and readiness evaluations

4. Centralized Tier 1 Support

- Centralize tier 1 support across vendors to provide consistent basic support

5. Sponsor/CRO Responsibilities

- Ensure Sponsors/CROs include sandbox environments and support offerings

6. Site Preparedness

- Equip sites with necessary information to address potential issues

- Provide guidance on what sites should ask for from vendors and Sponsors/CROs

- Ensure this information is available before issues arise and is shared with patients

Long-Term Solutions (3+ Years)

7. KPI Development and Standardization

- Create KPIs around site technology readiness, including sandbox utilization and support responsiveness

- Integrate these KPIs into vendor selection and site onboarding metrics

- Advocate for consistent timelines and expectations across all sponsors for early technology delivery and testing environments

Challenge 4: Financial Viability

Due to the increased time and resources required by sites to implement technology and remote services on their clinical trials, sites are seeing an increase in costs associated with conducting trials. These costs can be directly associated with the implementation and operationalization of technology and remote services being required for use by sponsors and CROs. While sites do see the value in these new elements and that they are the path forward, the costs associated with their use are not appropriately reimbursed.

Short-Term Solutions (Immediate to 1 Year)

1. Early Information Sharing for Budget Planning

- Provide sites with detailed information about trial technology and remote services early in the budget and contract negotiation cycle

- Provide sites with detailed technology and remote services information during initial feasibility discussions

- Ensure this information is sufficient for sites to estimate associated costs accurately

- Establish standardized information packages that include resource requirements, training needs, and support expectations

- Create template cost estimation tools that sites can use for preliminary budget planning

- Ensure vendor selection timelines allow adequate lead time for budgeting processes

2. Cost Analysis Framework Implementation

- Enable sites to perform a thorough cost analysis to understand the actual costs of utilizing the technology or services on the trial

- Develop standardized cost analysis templates that sites can use to evaluate technology implementation costs

- Require that this analysis is shared with the appropriate party in a timely manner before budget and contract negotiations conclude

- Require sites to complete comprehensive cost assessments including hidden costs (integration fees, training, downtime)

- Establish clear timelines for cost analysis completion and sharing with sponsors/CROs

- Create guidelines for distinguishing between general technology costs vs. specific vendor costs

- Sites must also evaluate the costs of implementing technology and remote services as part of the trial preparation process

3. Timely Vendor Communication

- Conduct vendor selection with adequate lead time to allow for the necessary budgeting, cost analysis, and preparation steps

- Identify key time points for communicating vendor details (e.g., during site selection)

- Identify key communication time points during site selection and contract negotiation phases

- Clarify whether the trial involves the use of technology or services in general or whether specific suppliers or vendors have been chosen

- Establish clear distinction between trials using technology "in general" vs. specific pre-selected vendors

- Implement vendor selection processes that occur early enough to support accurate budgeting

Mid-Term Solutions (1-3 Years)

4. Implementation Cost Standardization

- Develop industry-standard cost categories for technology implementation across different trial types

- Create benchmarking tools that allow sites to compare costs across similar technology implementations

- Establish cost-sharing models between sponsors and sites for technology implementation

5. Budget Negotiation Process Enhancement

- Implement structured negotiation frameworks that account for technology-related costs

- Develop contract templates that include technology cost provisions and reimbursement structures

- Create escalation processes for cost disputes related to technology implementation

Long-Term Solutions (3+ Years)

6. Technology Cost Reimbursement Standards

- Establish industry-wide standards for technology cost reimbursement that ensure sites are appropriately compensated

- Develop sustainable funding models that account for long-term technology adoption and maintenance costs

- Create incentive structures that reward sites for successful technology implementation while covering associated costs

Challenge 5: Training

The amount and quality of the training sites are asked to execute in order to utilize these technologies is a resource and time intensive component. Sites are asked to complete numerous, complicated training programs that are on a per-technology or service basis that often go unreimbursed and take an inordinate amount of their time. These trainings are also not delivered in a way that is respectful of their skill level or built based on adult-learning methodologies, is not comprehensive, specific enough, and doesn't align with practical use.

Short-Term Solutions (Immediate to 1 Year)

1. Training Categorization and Streamlining

- Training should be identified as either protocol-specific/unique to the trial or standardized/universal

- Implement clear categorization of training as either protocol-specific/unique or standardized/universal

- Universal training (e.g., Good Clinical Practice (GCP)) should not require repetition if previously completed

- Eliminate redundant universal training requirements for previously certified staff

- Credentials like Certified Principal Investigators (CPI) or Certified Clinical Research Coordinators (CCRC) should exempt staff from retaking basic AE/SAE training

- Recognize existing credentials to exempt staff from basic training repetition

- Create training exemption processes for experienced staff with relevant certifications

2. Role-Specific Training Implementation

- Avoid unnecessary training requirements for staff whose roles do not require it

- Develop training programs tailored to specific staff roles and responsibilities

- Ensure training is relevant to individual responsibilities and trial-specific needs

- Eliminate unnecessary training requirements for staff whose roles don't require specific technology knowledge

- Create role-based training matrices that clearly define required vs. optional training components

3. Training Cost Tracking and Justification

- Track training costs at the site level

- Implement systems to track training costs at the site level for each trial

- Justify and appropriately cost training for specific trial needs

- Develop cost justification frameworks for protocol-specific training requirements

- Create transparent pricing models for training that can be included in trial budgets

Mid-Term Solutions (1-3 Years)

4. Platform-Specific Training Standardization

- Provide gap training or generic platform training for systems like Interactive Response Technology (IRT) or Electronic Clinical Outcome Assessments (ECOA)

- Develop standardized training modules for common platforms that are accepted across sponsors

- Sponsors and CROs should accept and recognize supplier-provided training to prevent redundancy

- Create gap training programs that build on existing platform knowledge rather than starting from scratch

- Establish supplier-provided training recognition programs to prevent redundant training requirements

- Implement cross-sponsor training certification that reduces repetitive training across trials

5. Structured Training Delivery

- Organize training into stages or sections based on trial visit milestones

- Implement just-in-time training delivery to prevent information overload

- Avoid overwhelming staff by delivering information incrementally rather than all at once

- Create modular training programs that can be completed incrementally based on trial progression

- Ensure training requirements do not delay system access

- Training should be completed efficiently to align with trial timelines

- Develop training scheduling systems that align with trial timelines and don't delay system access

Long-Term Solutions (3+ Years)

6. Industry Training Standards

- Define a "basic" training level that is widely accepted

- Establish industry-wide "basic" training standards that are universally accepted across sponsors and CROs

- Tailor additional training for unique or advanced requirements

- Create advanced training tiers for complex or unique technology requirements

- Develop continuing education programs that maintain staff competency without requiring complete retraining

- Implement training reciprocity agreements between sponsors to reduce training burden on sites

Challenge 6: Quality

The industry in general is concerned with the quality of the data that comes with the use of technology for collecting that data. Sites are focused on being able to assure that the process in which they or their agents collect data assures an end-to-end collection of correct information that ultimately is submitted, minimizing errors, omissions, and queries. Including potential omissions by the patients as well. Industry partners are also concerned with assuring sites and patients are able to provide accurate and complete data despite challenges surrounding collection and submission of this data. As a result, there can be the potential to lose data when technology fails. This could be both the devices used, or services employed for trial conduct execution outside of the site itself.

Short-Term Solutions (Immediate to 1 Year)

1. Backup Plan Development and Communication

- Establish detailed backup plans for essential data collection in case of technology failures

- Communicate backup plans clearly to sites to ensure preparedness

- Provide alternatives, such as paper diaries, for use if electronic tools malfunction or if patients cannot use the technology

- Create clear communication protocols to ensure sites understand backup procedures

- Provide alternative data collection methods that can be implemented immediately

- Develop simple, accessible backup solutions that maintain trial quality standards

- Ensure backup solutions are straightforward, easy to implement, and readily available to maintain trial quality

2. Failure Tracking and Documentation

- Implement mechanisms to document technology issues, with a defined process for follow-up and corrective actions

- Implement systematic tracking mechanisms for technology issues and failures

- Create standardized documentation processes for technology-related deviations

- Review and document deviations caused by technology failures

- Clearly differentiate whether failures are due to the technology itself, the site, or the study participant

- Establish clear categorization of failures (technology, site, or participant-related)
- Develop follow-up and corrective action protocols for documented issues

3. Regular Data Collection Monitoring

- Provide sites with routine reports on data collection to monitor compliance and address issues promptly
- Provide sites with routine data collection compliance reports
- Implement real-time monitoring systems that identify data quality issues promptly
- Create alert systems for missing or problematic data that require immediate attention
- Establish regular communication schedules between sites and sponsors regarding data quality

Mid-Term Solutions (1-3 Years)

4. Vendor Qualification and Security Standards

- Ensure vendors meet required qualification and security standards to maintain data integrity
- Implement comprehensive vendor qualification processes that ensure data integrity capabilities
- Establish security standard requirements that all technology vendors must meet
- Create ongoing vendor performance monitoring systems that track data quality metrics
- Develop vendor accountability measures for data quality issues

5. Data Quality Prevention Systems

- Implement systems that prevent poor-quality data from entering the database at the point of collection
- Create validation rules and quality checks that occur during data entry rather than after
- Develop predictive analytics that identify potential data quality issues before they occur
- Establish automated quality control processes that reduce manual error detection needs

Long-Term Solutions (3+ Years)

6. Comprehensive Quality Assurance Framework

- Develop end-to-end quality assurance systems that cover the entire data collection and submission process
- Create integrated quality metrics that span across all technology platforms and data sources
- Implement machine learning-based quality prediction and prevention systems
- Establish quality benchmarking standards that can be applied across different trial types and technologies

Challenge 7: Bring-Your-Own-Tech

In recent times, there has been an increase in the number of sites that have been utilizing their own adopted technology to enable their patients to conduct trial activity remotely. However, this approach comes with its own set of challenges. These include cost analysis, internal usability, operationalization, sponsor usability, and validation. Sites need to be made aware of these challenges so they can anticipate them when considering investing into and implementing their own technology solutions.

Short-Term Solutions (Immediate to 1 Year)

1. Comprehensive Cost Assessment Framework

- Sites should conduct a thorough cost assessment of the technology, considering not only the upfront expenses but also hidden costs

- Develop standardized cost assessment tools that include upfront, hidden, and ongoing costs

- These might include integration fees, training resources, and potential downtime during implementation

- Create evaluation checklists that cover integration fees, training resources, and implementation downtime

- A holistic financial evaluation will help sites make informed decisions and plan for long-term sustainability

- Establish cost-benefit analysis templates that help sites make informed technology investment decisions

- Implement financial sustainability evaluation processes for long-term technology adoption

2. Internal System Capability Evaluation

- Evaluating the technology's capabilities and limitations is essential

- Create assessment tools for evaluating technology capabilities against operational needs

- Sites should ensure that the system aligns with their operational needs and offers the functionality required to manage clinical trials effectively

- Develop system compatibility checklists that ensure alignment with existing site workflows

- This includes an assessment of system optionality, usability, and overall reliability to confirm that it supports the intended trial activities

- Establish usability testing protocols that validate technology effectiveness for intended trial activities

- Implement system reliability evaluation processes that assess performance under trial conditions

3. Sponsor Requirements and Data Quality Standards

- The technology must meet the sponsor's minimum criteria, ensuring it collects quality, validated data that aligns with clinical trial standards

- Establish clear minimum criteria that site-owned technology must meet for sponsor acceptance

- Sites must verify that the system is robust and meets regulatory requirements, providing the necessary data integrity that sponsors expect

- Create data quality validation checklists that ensure compliance with clinical trial standards

- Develop regulatory compliance assessment tools (21 CFR Part 11, GCP E6 R3)

- Implement data integrity verification processes that demonstrate sponsor-acceptable data quality

Mid-Term Solutions (1-3 Years)

4. Data Management and Security Framework

- A critical component is the technology's ability to manage data securely while facilitating seamless portability

- Develop comprehensive data portability standards that ensure seamless data transfer between systems

- Sites need to ensure that data can be transferred efficiently between systems while maintaining compliance with privacy regulations

- Create security and privacy compliance frameworks that meet regulatory requirements

- This ensures sponsors can access and use the data effectively, making the technology valuable from their perspective

- Establish data access protocols that allow sponsors to effectively utilize site-collected data

- Implement data governance structures that maintain compliance while enabling efficient data flow

5. Operational Integration and Workflow Optimization

- Sites should focus on how the technology integrates with their existing workflows and IT capabilities

- Create integration assessment tools that evaluate how technology fits within existing site workflows

- This includes testing how well it functions within current processes, gathering usage data, and validating that the technology enhances site operations

- Develop operational testing protocols that validate technology performance within current processes

- A detailed operationalization plan should incorporate regulatory compliance checks and facilitate clear communication channels between the site, sponsor, and Contract Research Organization (CRO)

- Establish workflow optimization frameworks that demonstrate efficiency gains from technology adoption

- Additionally, adequate training for site personnel is necessary to ensure smooth adoption and efficiency gains

- Implement change management processes that support smooth technology integration

Long-Term Solutions (3+ Years)

6. System Validation and Compliance Framework

- Proper validation procedures are crucial to confirm that the technology works as intended

- Develop comprehensive validation procedures based on regulatory guidance (21 CFR Part 11, GCP E6 R3)

- Sites should implement testing protocols based on regulatory guidance to guarantee compliance and reliability

- Create ongoing monitoring and validation systems that ensure continued compliance and reliability

- Regular validation and monitoring help mitigate risks and demonstrate to sponsors that the technology is trustworthy and effective

- Establish risk mitigation protocols that address potential technology failures or compliance issues

- Implement continuous improvement processes that enhance technology effectiveness over time

7. Industry Standardization for Site-Owned Technology

- Develop industry-wide standards for site-owned technology that are accepted across sponsors

- Create certification programs for site technology that streamline sponsor acceptance processes

- Establish interoperability standards that ensure site technology can work effectively with sponsor systems

- Implement collaborative frameworks that encourage innovation while maintaining quality and compliance standards