

Site Tech Implementation Checklist

Ensure your site is prepared to successfully adopt and sustain technology solutions.

Goal: Solve operational inefficiencies before implementing tech.
Technology is not a fix for broken processes—solid workflows must exist first.

PRE-IMPLEMENTATION PLANNING

➤ Define the Problem & Objective

- Clearly define the problem that the technological solution aims to address.
- Confirm that current processes are robust prior to implementing any technology.
- Establish ROI objectives, including time savings, resource efficiency, quality enhancement, and more.

➤ Document Pain Points to determine ROI

- Duplicate data entry
- Use of multiple systems
- Eliminate paperwork, optimize paperless solutions
- Time inefficiencies
- Poor user experience
- Resource drain/redundancy
- Data quality/analysis challenges

STAKEHOLDER ENGAGEMENT

➤ Identify End Users

- Involve site staff in feedback on workflow and tech selection
- Ensure stakeholders understand how tech impacts their role
- Solicit needs from both informed and uninformed users

➤ Engage Sponsors & CROs

- Clarify the “why” and benefits of tech adoption
- Communicate confidentiality do’s/don’ts
- Set expectations for documentation
- Address stack variability across sites
- Discuss support, accountability, and vendor flexibility

TECHNICAL READINESS & SUPPORT

➤ Tech Requirements & Support

- Integration ability with current systems
- Mock visit testing for barriers and training validation
- Cost evaluation (initial, maintenance, upgrades)
- Migration and change management plan
- Personnel/infrastructure needs assessment
- Consider experts/consultants/other site resources who can support roll out

➤ Internal/External Support Planning

- Define internal & external points of contact
- Set up clear communication channels
- Establish tech support and escalation processes
- Identify support team responsibilities across Operations / Compliance / Vendor
- Understand service tiers and support pricing

TRAINING & ROLLOUT

➤ Training Program

- Develop user training: onboarding and re-training
- Use visual aids, key documents, and scenario-based practice
- Provide “how-to” guides and documented support processes

➤ Implementation Plan

- Secure necessary equipment and infrastructure
- Consider pilot testing or phased rollout
- Assign tech advocates or champions
- Track adoption issues and questions
- Evaluate user feedback regularly

COMPLIANCE & DATA GOVERNANCE

➤ Regulatory Requirements

- CFR Part 11
- HIPAA / Privacy equivalent compliance
- ALCOAC principles

➤ Compliance Processes

- Review login/password sharing risks
- Ensure global compliance considerations are addressed
- Address ownership of systems/data – site vs. sponsor
- Ensure PI access and data rights

POST-IMPLEMENTATION FOLLOW-UP

➤ Monitoring & Optimization

- Define success metrics (workflow, adoption, efficiency)
- Gather user feedback to improve processes
- Plan for scalability and future needs
- Reassess ROI and benefits of implementation

➤ Data Management

- Confirm data accessibility across all stakeholders
- Validate data integrity and cleanliness
- Ensure ongoing access and audit trails for Sponsor/CRO
- Document lessons learned and share best practices