BRING YOUR OWN TECHNOLOGY (BYOT)

A playbook for how clinical research sites can utilize their own technology investments within industry sponsored clinical trials.

Decentralized Trials and Research Alliance (DTRA)
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Executive Summary

The **Bring Your Own Technology (BYOT) initiative** aims to enable clinical research sites to use their own validated technology systems in industry-sponsored clinical trials while maintaining regulatory compliance and sponsor oversight. The objective is to reduce operational inefficiencies, improve data quality, and enhance site and patient experiences.

Problem Statement

Sites are overwhelmed by the increasing number and complexity of technology solutions expected to be used in executing clinical trials. This is exacerbated by the increasing number of solution providers selected to be used. Currently, research sites are often required to use sponsor-provided technology systems. As a result, site personnel are managing an average of 22 different platforms per trial**.** [1] This redundancy leads to increased risk of non-compliance and protocol deviations at sites, leading to potential trial delays, quality issues and increased costs for sponsors. As sites increasingly invest in digitizing their own operations and workflows, BYOT presents an opportunity to align these investments with trial operations, benefiting both sites and sponsors with efficiency gains increased speed and higher quality.

What BYOT may offer

- **For Sites**: BYOT reduces redundant systems, allowing sites to use familiar platforms, streamline operations, and improve staff efficiency. Quality by design is a core tenant, enabling sites to use trained tools instead of forcing unfamiliar ones. Sites enabled in this way could attract more trials from sponsors due to the quality benefits.
- **For Sponsors & CROs**: Greater site efficiency and higher quality could support faster trial execution, faster data capture and acquisition turnaround times, speedier data review, cost reductions, reduced protocol deviation and increased compliance.
- **For Participants**: Standardized site-led processes enhance participant engagement, experience, and retention. In general, sites utilizing their own systems to interface with participants will provide better, more efficient training for participants about the system's proper usage as well as faster, easier support for participants. Participant satisfaction is often improved, potentially leading to better overall retention in the study by reducing the burden of technology on the participants, which can include lengthy trainings as coordinators are often learning right along with the participants, and challenges to obtain adequate support since support is provided by a third party.

Challenges & Considerations

While BYOT could lead to significant benefits, industry concerns regarding data consistency, regulatory compliance, and patient safety must be addressed. Sponsors need assurance that site-selected systems meet validation, security, and oversight standards. A structured approach, including certification and accreditation, is necessary to ensure compliance with regulatory requirements.

[1] Recent ACRP article suggests up to 22 systems used of site systems and sponsor provided. https://acrpnet.org/2025/03/05/clinical-research-trends-to-expect-in-2025-more-complex-less-connected

Site-Owned Technology Adoption

Sites must be able to bring consistency and scalability to their operations. The ability to use the same technology across multiple studies can significantly reduce costs and improve quality. Increasingly, sites are purchasing their own technologies, with CTMS, eTMF/eReg, and eSource dominating as site-owned platforms. However, nearly 30% of sites cite cost and integration challenges as primary barriers to purchasing their own technologies.

In a recent survey of research sites across the globe by the Society of Clinical Research Sites (SCRS), the overwhelming majority of sites have implemented some sort of enterprise technology to support study conduct. The influence of site networks has accelerated the implementation of common infrastructure to improve efficiency and digitally transform operations at sites.

Sites are asking sponsors to use their chosen systems in industry sponsored trials. If accepted, sites still have the manual step for data capture / transcription into the sponsor systems. In this case, remote monitoring and source data verification / source data review by sponsors and CRO's would still apply.

Almost none of these technologies are connected to a sponsor's infrastructure for interoperable data exchange. A goal of the BYOT initiative would be to normalize that connection through standards and quality control. One of the major success factors of the BYOT initiative will be to increase operational and clinical data interoperability between clinical research sites and industry sponsors. In essence, the long-term goal is to directly connect a site's chosen clinical research systems to the sponsor's data acquisition infrastructure.

Path Forward

This initiative will be scoped in phases, beginning with eConsent as the first use case (Horizon 1.)

Future phases (Horizon 2 - 2025 and beyond) will expand to more complex systems, including eSource and Direct Data Capture (DDC), and Electronic Investigator Site Files (eISF), further modernizing trial operations across stakeholder groups, while prioritizing the site experience.

This initiative is not an "all or nothing" approach. The ideal model supports a hybrid data acquisition strategy from pharmaceutical and biotechnology sponsor organizations and clinical research organizations (CROs) allowing sites with validated technology to use their own systems while others choose to use sponsor-provided solutions. This shift will create a more efficient, site-friendly clinical trial environment without compromising regulatory rigor or data quality.

This document includes an implementation section that is meant for operators to review and influence how this model might become a reality. By implementing BYOT in a fit-for-purpose manner, the industry can move towards a more interoperable, flexible, and efficient clinical trial ecosystem, reducing inefficiencies while ensuring compliance and improving trial outcomes.

Introduction

This playbook serves as a customizable framework, not a rigid standard operating procedure (SOP), adaptable to end-user organizations' requirements. While sponsor-provided technologies are common, they often create operational burdens and require redundant training for sites managing multiple platforms. Sponsors favor these solutions for quality, accountability and standardization, but this can hinder site efficiency and satisfaction. The goal of BYOT is to enable site-driven technology use while maintaining data collection rigor.

Resistance to BYOT stems from concerns about data integrity, patient safety, regulatory validation, inspection readiness, training concerns, and general risk aversion. Sponsors worry about inconsistencies, varying security levels, and oversight challenges. This highlights the need for a structured framework ensuring site-selected technologies meet rigorous standards.

Despite challenges, allowing sites to use their preferred, validated systems offers significant advantages. It can positively impact data consistency, accuracy, site efficiency, and participant satisfaction. Sites report that using familiar technology leads to faster visits and fewer patient support issues, aligning with patient-centric trial designs.

The ideal state and success of this initiative would be for sponsors to support multiple data acquisition strategies from sites such that today's "all or nothing approach" is replaced with a hybrid model. **In this model, those sites that have invested in technology that is "BYOT-enabled" may use it within a trial, while those sites requiring technology would continue to have tools selected and provisioned by the sponsor and CRO.** This playbook details how such a framework can be achieved.

The supporting research in this whitepaper was collected over the past 1.5 years from 2024-2025 where new insights were gained from interviews, workshops, literature review, and the synergy of decades of experience from the combined workstream members that has resulted in the strategy and opinions within this document.

Scope and Objectives

Purpose

The **Bring Your Own Technology (BYOT)** initiative enables clinical research sites to use their own validated technology systems—such as eConsent, eSource, etc—within industry-sponsored clinical trials and reduce or replace the need for using specific sponsor-provided systems like Electronic Data Capture (EDC) at a site. The goal is to let sites work the way they want to work while providing sponsors with scalable optionality in how they acquire data from many sites around the world.

Scope

In Scope: Systems that clinical sites use themselves that **overlap** with sponsors.

Horizon 1

The primary focus is on implementing **eConsent** as the first use case for BYOT.

- Aims to streamline the consent process, enhance participant engagement, and ensure compliance with electronic records/signatures regulations.
- Establishes foundational BYOT practices, addressing validation, data privacy, and oversight.
- Demonstrates acceptability of site-preferred solutions over sponsor-preferred ones.
- **Does not** initially include direct site-to-sponsor EDC integration.

This whitepaper has documented the summary requirements that need to be in place for sites to use their own preferred eConsent solution in an industry sponsored clinical trial and is available in APPENDIX A. The goal is to improve quality and drive efficiency for sites when an eConsent solution that meets these requirements is used.

Horizon 2
For 2025 and beyond:

- Expands to more complex systems: eSource, Direct Data Capture (DDC), and electronic Investigator Site Files (eISF) maintained by sites.
- Aims to clarify site-managed source data, improve quality, and reduce reliance on sponsor systems.
- Standardize how site systems are integrated into sponsor systems via direct connections or 3rd party middle ware or data ingestion tools.
- Suggest a flexible framework for sponsors to ingest data at scale from many clinical sites with differing systems across the globe.

Out of Scope: Systems that sponsors use that clinical sites **do not** use on a regular basis or are covered in other guidance documents. (i.e. eCOA, IRT, etc.)

Key Objectives

Through the BYOT initiative, the goal is to achieve many of these key objectives across the value chain of conducting clinical trials.

Greater Site Efficiency

- Minimize the amount of sponsor preferred systems used across studies at the same site.
- Reduce training time and IT overhead
- Leverage existing site SOPs and workflows

Higher Data Quality & Compliance

- Maintain alignment with global regulatory standards (e.g., 21 CFR Part 11, GDPR, ICH E6(R3))
- Ensure validated systems with audit trails, change control, and secure access
- Introduce a standardized Compliance Dossier for sponsor review

Faster, More Cost-Effective Trials for Sponsors

- Accelerate study startup and data acquisition
- Reduce protocol deviations and support risk-based quality management
- Foster a hybrid trial model, allowing both site and sponsor-led technology approaches

Industry-Wide Standardization & Interoperability

- Promote integration via industry standards and open APIs
- Improve data traceability and automation readiness
- Encourage vendor “Trust Centers” to simplify sponsor reviews

BYOT is not an “all or nothing” model—it supports hybrid adoption tailored to site capabilities. Initial use cases like eConsent (Horizon 1) will expand to more complex systems (Horizon 2+), ultimately transforming trial operations into a more connected, compliant, and efficient ecosystem.

IMPACT Assessment

In the evolving landscape of clinical trials, the concept of Bring Your Own Technology (BYOT) for research sites represents a significant shift, offering potential benefits and challenges across the spectrum of trial stakeholders. This assessment explores the multifaceted impact of BYOT, with a particular focus on clinical sites, sponsors, and participants.

BYOT allows clinical sites to use their preferred technology platforms for trial processes, particularly electronic systems such as eConsent. While this approach promises enhanced efficiency and familiarity, it also introduces complexities in integration and oversight.

Impact Across Stakeholders

For Clinical Sites: Clinical sites stand to gain considerably from BYOT. By leveraging data and quality standards, sites may achieve greater efficiency and compliance with internal SOPs, local and regulatory standards. Staff morale and job satisfaction may improve due to reduced complexity and training needs associated with sponsor-selected study-specific systems.

For Sponsors and CROs: Benefits include accelerated study conduct, faster data access, better GCP compliance, and reduced errors/costs. One of the more frequent FDA 483 findings at clinical sites still relates to ICF issues[2]. Allowing sites to use their chosen eConsent system could reduce these findings. However, challenges include extensive system reviews, complex monitoring across diverse systems (potentially increasing initial workload for study teams), and ensuring data standards are met. Sponsors retain ultimate accountability but must place more trust in sites (with oversight). This presents an innovation opportunity for sponsors to utilize new tools that can ingest data from many different sites while letting sites use the technology they prefer for their business.

For Participants: Participants may benefit from familiar systems by site staff, leading to smoother and more efficient study visits and assessments. This enhances their overall trial experience. Fewer technology issues at the site may improve participant retention and reduced dropout rates. However, inconsistencies in multiple systems can cause trial staff confusion and a less-than-ideal patient experience.

For Technology Vendors: The BYOT initiative can lead to market expansion and innovation by supporting site-level solutions such as eConsent and eSource. Vendors can establish themselves by offering validated, compliant systems suitable for registrational trials. There will be an increased demand for interoperability, API configuration, compliance tools, validation documentation, and the acceptance of emerging standards among more vendors.

BYOT can improve efficiency, compliance, and experience. Ignoring BYOT leaves inefficiencies unaddressed. Adoption requires careful consideration of integration and monitoring challenges. A thoughtful approach is needed as technology evolves.

[2] FDA Inspection Observations - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations#:~:text=These%20observations%2C%20are%20listed%20on,indicate%20that%20an%20FDA%2Dregulated

Table: Impact Across Stakeholders

Affected Party	Category	Metric	Expected Impact	Burden
Participant	User Experience	User Experience Burden	The participant will have a more guided experience with less burden because the site is comfortable with the technology that is used as a norm on studies	Decreased
Site	Data Capture	Reduction in duplicate data entry	Overall improvement in data capture process will result.	Decreased
Site	Support	# of Helpdesk Tickets	If the site selects the technology used, the number of technology-related helpdesk tickets may decrease, decreasing frustration for the site and patients. The sponsor may experience reduced escalations.	Decreased
Site	Training	Reduction in duplicative training for site-owned systems	Reduced site burden. Only new-to-technology users, or new technology features will require training, rather than requiring training for all users for every study for every technology platform. This will decrease workload, training, documentation and admin work.	Decreased
Sponsor	Risk Reduction	# of Patient Dropouts per Site	Patient dropouts may decrease if patient experience improves when sites use using their preferred technology and workflow.	Decreased
Sponsor	Security / Access	Reduction in technology account management effort	Reduced sponsor burden associated with site support. Sponsors may increase account access needs across multiple site systems, but sites will decrease their support asks to sponsor systems.	Decreased
Site	Site Contracts	Increased pass-through costs from sites to sponsors / CROs	Potential increased pressure on trial budgets should per-study budgets rise in costs due to new tech.	Increased
Sponsor	Trial Monitoring	Number of technology platforms used per trial increases	Increase in complexity and systems used by clinical research monitors (CRAs) at CRO / Sponsor. Impacts training, access and ease of use for CRMs.	Increased
Sponsor	Reporting	Difficulty in merging oversight	Increased burden to sponsor staff and monitors	Increased

		metrics and reports		
Sponsor	Study Startup	Sites manage their own study builds, increasing study instances across a trial.	Increased burden to vendor, site, sponsor	Increased
Sponsor	Study Startup	Challenges in oversight of study build.	This is a change in control. Sponsors are accountable for every study build based on the regulatory frameworks.	Increased
Sponsor	Study Startup	Qualifying sites who use a BYOT model is more work for sponsors	Sponsors typically define technology aligned to trial data collection. There may be an increased effort to qualify site technology. This will eventually decrease if industry-wide standards are accepted.	Increased
Sponsor	Training	Number of systems used per study	Increased training and system oversight time if the sponsor requires access to the site's system for monitoring or data management. As will all systems used in trial conduct, users will require training to be granted access.	Increased

Key Objections and Possible Solutions

Key Objection	**Stakeholder**	**Possible Solution**
Regulatory Compliance - Site technology may not meet Sponsor's regulatory/compliance requirements	Sponsor /CRO/ Site	Implementation of standardized Compliance Dossier containing required validation documentation, security protocols, and regulatory attestations
System Oversight – Sponsor remains accountable for study level implementations even when the site controls the study build using their own system.	Sponsor	A change in thinking may be needed to limit the need for UAT at every site using a BYOT solution for every study. Sponsors are accountable to ensure that the data collected meets the requirements of the trial; if the data is used in the clinical data set sponsors may want to confirm all data requirements are met.
Data Quality and Standardization - Multiple data collection systems could compromise data quality and standardization as	Sponsor/ CRO	Establishment of minimum technical requirements including interoperability, standardized data formats, and automated quality checks

well as increasing complexity of data traceability		
Operational Oversight - Increased complexity in monitoring and maintaining data traceability across different systems	Sponsor	Implementation of monitoring approaches aligned to ICH E6 R3, specifically Risk-based Quality Monitoring and the establishment of quality tolerance limits, as well as a fit-for-purpose approach to monitoring and oversight. Standardized human readable audit trails.
Inconsistent participant experience across sites using different systems.	Sponsor	Establish minimum user experience (UX) requirements and standardized participant-facing elements. The participant themselves may not be impacted because they will have one experience, unless software UX is modified during trial participation
Using site technology for eConsent could increase risk to data acceptability.	Sponsor	If the site is entering data manually after using eConsent, the risk to data quality is the same as when paper consent processes are used. If the data is eventually integrated from eConsent direct to the central clinical database, verification of data integrity will be required (complete, accurate, traceable) at least initially.
Validation & Compliance – the cost and timelines to validate each site's tech before the study, even with a standard approach, could make BYOT infeasible.	Sponsor	Suggestions for an agreed-upon accreditation process may reduce the need for sponsor-driven technology qualification/ validation. Ideally an initial validation will suffice, with confirmations performed commensurate with significant system / software updates.

Final Thoughts and Recommendations

The Bring Your Own Technology (BYOT) initiative marks a bold step toward empowering clinical trial sites with greater control over their own eClinical systems. By enabling the adoption of site-selected technologies, this initiative offers opportunities to streamline operations, improve site and participant engagement, and reduce administrative burdens of clinical sites. This will allow sites to do more with less work, retain top talent and attract more trials by being "BYOT Ready."

The vision for the future includes a digitally inspired protocol design, modeled after frameworks like USDM (Unified Study Definitions Model)[3], where standardized files seamlessly inform and operate site systems such as eSource, eConsent, and eTMF/ISF. This evolution would transform clinical trials into a more connected and interoperable ecosystem, promoting plug-and-play flexibility akin to an "app store" experience.

To achieve broad adoption, stakeholders across the industry—sites, sponsors, CROs, and vendors—must work together to:

- Promote standardization and interoperability (FHIR, CDISC).
- Streamline validation and compliance while ensuring flexibility.
- Foster knowledge sharing and adopt innovations

As the industry evolves and decentralized clinical trials become more mainstream and BYOT is adopted by more and more sites, this document will continue to be revised, reflecting the growing contributions and learnings from all stakeholders. It is up to you—the research community—to shape this future, ensuring clinical trials remain effective, efficient, and participant-centered. Together, we can build a robust, interoperable ecosystem that drives innovation and advances healthcare.

[3] CDISC Digital Data Flow - https://www.cdisc.org/ddf

Case Studies and Pilot Programs

GSK Case Study:

GSK received feedback from sites that they have invested in their own systems to enhance their own practice workflows and patient experience, including eConsent systems. Sites have requested approval to use their own systems to perform clinical trial activities.

Details of the Solution: Create an easy-to-use tool that could be used to assess and approve a site's own eConsent system. Key components for assessment criteria included Global eSignature (21 CFR Part 11, eIDAS) and computerized systems (FDA Guidance for Industry - COMPUTERIZED SYSTEMS USED IN CLINICAL TRIALS, EU Annex 11) guidance, as well as GDPR and ICH GCP regulations.

Implementation: eConsent System Assessment Tool (eCSAT) was produced. Reviewed and approved by Global Process Owner for Site Monitoring, Clinical Systems Quality Assurance, and Written Standards. Associated existing guidance documents updated. Training created. Process changes and training communicated to impacted stakeholders.

The eCSAT outlines the necessary software requirements to maintain regulatory compliance. The tool is to be completed by the site, typically by an appropriate delegate such as the IT Department and assessed/approved by CRA before the eConsent system is used. If the system fails the eCSAT, an alternative method for the consenting process, such as paper ICF or a GSK-provided eConsent, must be used.

Additional Case Studies

Do you have a case study showcasing the successful implementation of BYOT within your organization? Send an email to secretariat@dtra.org to inquire about the submission process for new case studies.

Implementation Model

The successful implementation of a **Bring Your Own Technology (BYOT)** strategy in clinical trials requires a structured approach to ensure compliance, data integrity, and operational efficiency. This section outlines the key considerations, processes, and roles that stakeholders—including sites, sponsors, CROs, and technology vendors—must address to support BYOT adoption. A **swim lane chart** illustrating a high-level implementation model has been included below to provide a visual representation of stakeholder roles, decision points, and workflow processes. This does not reflect the specific processes each organization uses to comply with their SOPs and policies. Rather, it is meant to be a guide for stakeholders to use as they consider whether processes need to be changed or added to enable BYOT implementation.

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1. Structured Decision-Making Framework

To address the complexities building a BYOT technology approach, clinical sites must implement process flows and checklists to guide technology selection and adoption. These tools ensure alignment with data collection and usage requirements, enabling sites to make informed choices when selecting, qualifying and deploying eConsent, eSource, or other electronic systems.

- Sites must evaluate vendor platforms, processes, and validation practices before adopting technology.
- Vendors should incorporate automation checks to confirm system builds align with specifications, reducing site and sponsor burdens.

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2. Integration of Roles and Responsibilities

Clear **role definitions** and responsibilities are essential for smooth collaboration and data exchange among sites, sponsors, CROs, and technology vendors:

- **Sites**: Evaluate technology, implement system validation processes, and ensure compliance with data handling and security practices.
- **Sponsors**: Confirm system compliance with regulatory requirements and conduct periodic audits of vendor practices.
- **CROs**: Support coordination between sites and sponsors when it comes to BYOT at sites with CRO relationships.
- **Vendors**: Provide validated, compliant software solutions and support documentation for audit preparedness.

This integration ensures all stakeholders are aligned on expectations and responsibilities throughout the BYOT lifecycle.

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3. System Validation and Compliance Procedures

Clinical sites adopting their own technology must maintain robust internal operating standards (e.g. **Standard Operating Procedures (SOPs)**, or system-operations checks) to ensure similar standards to those a sponsor would apply to system used in clinical trial management and data collection

- Data Integrity: Data and records are not altered in value or meaning during collection, transfer, and storage.
- System validation and **change control procedures** are documented and followed, both at initial implementation and following any systems changes
- Only **authorized individuals** are granted appropriate access to electronic systems.

Sites should also establish **system administration practices**, including access roster reviews and technical service provider contracts that define vendor responsibilities.

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4. Site Data Management and Security

Sites must develop detailed procedures for:

- **Data collection, modification, and storage** to maintain integrity and reliability.
- **Data management plans** covering data security, handling, and transfer.
- **Staff training records** to ensure personnel are qualified to operate and maintain the selected software.
- **Conforming with local requirements** around local data hosting (in country as applicable.)

Adopting these practices is critical to achieving regulatory compliance and ensuring data quality throughout the trial.

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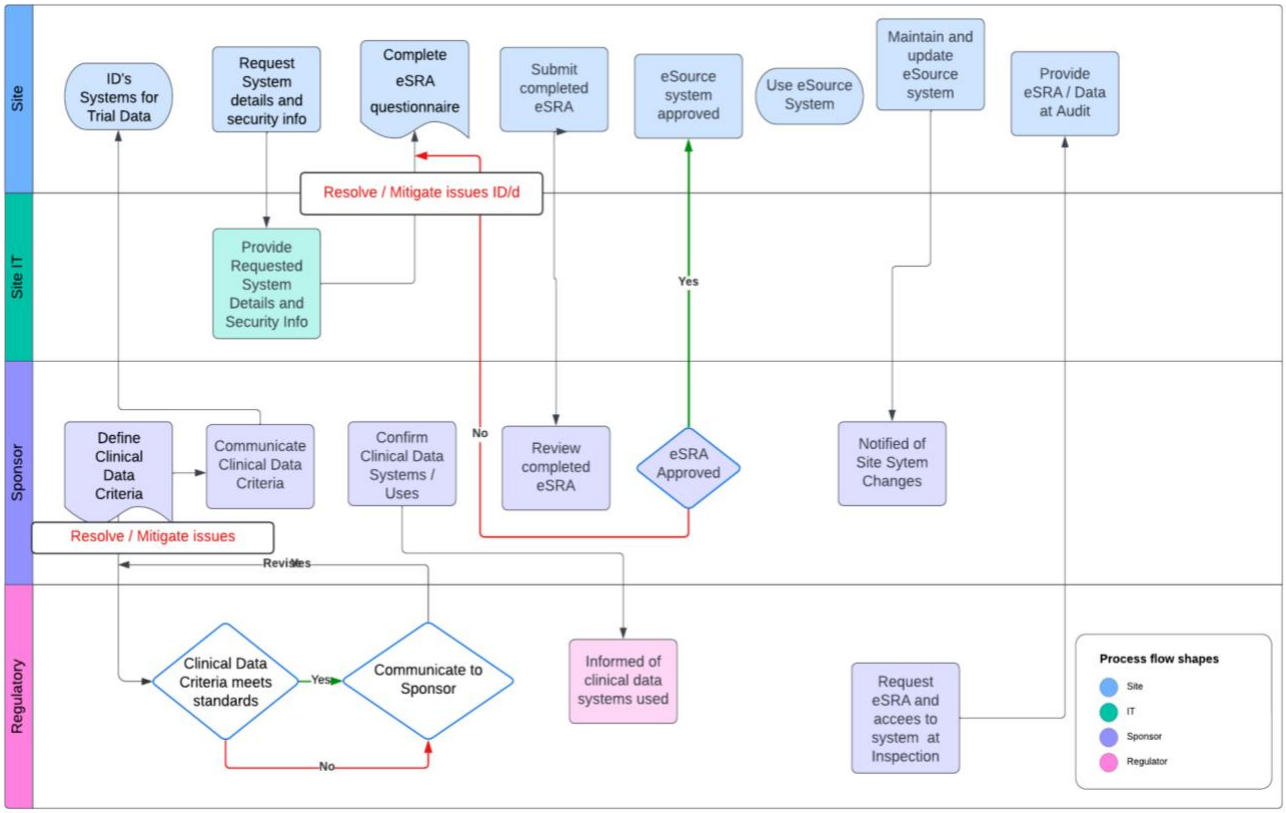
5. Audit Preparedness and Ongoing Monitoring

Sponsors may opt to conduct **periodic audits** of site-selected software vendors to ensure compliance with regulatory standards. Like all clinical trial documentation expectations, sites must maintain:

- Detailed **audit trails** and records of system activities.
- Comprehensive **Compliance Dossiers** that document system validation, change controls, and vendor qualifications.

These measures foster confidence among sponsors and regulatory authorities, supporting long-term BYOT adoption.

Flow Chart of Implementation



Software Implementation Process Steps:

Step 1: Initiation (Site Staff)

1. Site staff begins the process by defining ID requirements for signatures on trial data. This step identifies what electronic signatures and data criteria are needed to support trial conduct.
2. The site then requests system details and security information from the vendor or relevant stakeholders. This ensures the system aligns with regulatory and trial needs.
3. The vendor or responsible party provides the requested system details and data security information back to the site.

Step 2: eSRA Questionnaire and Submission (Site Staff)

4. The site completes the eSRA (eSource Readiness Assessment) questionnaire. This comprehensive assessment reviews the system's compliance with technical, data security, and regulatory requirements.
5. Once completed, the site submits the eSRA for review.

Step 3: Review and Approval Process (Sponsor and Regulatory)

6. The sponsor or designated reviewer conducts a thorough review of the eSRA submission.
    - At this stage, if any issues or gaps are identified, they are flagged for resolution or mitigation by the site staff.
    - The site must resolve or mitigate the identified issues and resubmit the eSRA for another review.
7. If the eSRA passes review, it is marked "Approved", and the site can proceed with further system setup.

Step 4: System Deployment and Maintenance (Site Staff)

8. Following eSRA approval, the site proceeds to implement the eSource system or update the relevant platform.
9. Site staff then maintains and updates the eSource system as needed, ensuring ongoing compliance and system readiness.
10. The site provides System Evaluation and Security Assessment data and audit documentation to demonstrate ongoing compliance with system security, integrity, and regulatory requirements.

Step 5: Regulatory Verification and Approval

11. At the Regulatory level, the defined clinical data criteria are reviewed:

    - If the clinical data meets standards, this is communicated to the sponsor.
    - If standards are not met, the regulatory body flags this, and the site must return to resolving or mitigating issues.

12. Once clinical data systems are confirmed as acceptable, the sponsor is informed of the systems being used at the site.

Final Steps: Ongoing Monitoring and Compliance

13. Regulatory bodies and sponsors can request eSRA documentation and inspect the system as part of standard monitoring processes. This ensures compliance remains intact throughout the trial.
14. Site staff must also notify sponsors and stakeholders of any changes to the eSource system configuration or system processes, maintaining transparency and data integrity.

Regulatory Considerations

Implementing BYOT requires navigating a complex regulatory landscape and ensuring site-selected systems meet rigorous standards for validation, data integrity, security, and privacy. Both sponsors and sites have responsibilities in this model.

Regulatory Landscape (US & EMA):

- Systems must comply with regulations such as FDA 21 CFR Part 11, EMA guidelines (e.g., Annex 11), ICH E6(R3), GDPR, HIPAA, Good Clinical Practice (GCP) and other local requirements.
- US Considerations: The FDA's 2024 guidance on Electronic Systems, Records, and Signatures emphasizes data integrity, quality, and compliance for all trial systems. It requires rigorous, risk-based validation. Recent FDA guidance and ICH E6(R3) advocate for flexible, risk-proportionate approaches, supporting innovations like eConsent when aligned with regulations.
- EMA Considerations: Similar principles apply regarding electronic systems, data integrity, and validation as outlined in relevant EMA guidelines and EU regulations, like GDPR. (EMA Regulatory considerations will be expanded in Horizon 2.)
- Key Principle: Regulatory authorities support electronic solutions like eConsent provided they meet existing informed consent, data protection, and system validation standards.

Sponsor and Site Responsibilities:

- Sponsors retain ultimate responsibility for trial data quality and participant safety, regardless of the technology used. While not obligated to validate site systems, sponsors must confirm these systems meet regulatory requirements for the trial's context (e.g., data for submission) and have been validated by end users. Sponsors may still need to audit site systems (or vendors) as needed and may need ‘to perform additional validation steps in accordance with their internal SOPs.
- Sites adopting BYOT take on increased responsibility for ensuring their systems are compliant, validated, and maintained according to GCP and other applicable regulations. This includes managing system administration, access controls, change management, and staff training.

Most sites comply with these guidelines during study conduct, but the data is usually not electronically transferred directly from the site data platform to the sponsor clinical database. In site-driven BYOT scenarios, the sponsor and site team will need to agree on the validation documentation and testing needed to assure data traceability, rigor and quality.

US Regulatory Considerations

The FDA's updated 2024 guidance on Electronic Systems, Records, and Signatures reflects the agency's recognition of technological advancements since the publication of initial 21 CFR Part 11 regulations. This new guidance emphasizes the importance of maintaining data integrity, quality, and compliance for electronic systems used in clinical trials, whether sponsor-provided or site-controlled. Key requirements include rigorous system validation, encompassing functionality assessments, IT provider documentation (e.g., change control, testing logs), and risk-based evaluation to ensure systems are technically suitable and aligned with participant safety and data reliability standards.

With the finalization of ICH E6 R3 (the draft of Annex 2 underway) and the **Conducting Clinical Trials With Decentralized Elements** FDA guidance in 2025, there is further advocacy for a flexible, risk-proportionate approach to integrating technologies like eConsent. Regulatory authorities, including FDA, explicitly support Consent provided it aligns with existing informed consent regulations and data protection standards, fostering innovation while maintaining trial data integrity and participant safety.

US clinical trial sites using a BYOT model must oversee and manage their eConsent solutions, ensuring they meet FDA's 21 CFR Part 11 requirements. This involves validating systems for data integrity, audit trails, security, and participant safety. Sites must document validation, track system changes, and maintain testing results to prove compliance. This includes all versions of the informed consent document and any addenda.

From a BYOT perspective, this shift means that sites will need to invest in robust system validation protocols and ongoing compliance oversight. Sponsors, while not obligated to validate site systems, will still need to confirm that site-controlled eConsent platforms meet data and compliance standards commensurate to regulatory context of the trial data (e.g. submission vs publication) Sponsors remain accountable for the data quality, regardless of where or how that data is collected which is why there will be additional scrutiny on how BYOT is implemented.

ICH E6R3 Section 3.6.6.
A sponsor may transfer any or all the sponsor's trial-related activities to a service provider in accordance with applicable regulatory requirements; however, the ultimate responsibility for the sponsor's trial-related activities, including protection of participants' rights, safety and well-being and reliability of the trial data, resides with the sponsor.

By empowering sites to use their preferred eConsent solutions, BYOT aligns with the FDA's emphasis on innovation and flexibility, offering opportunities to enhance participant engagement and trial efficiency. However, it also demands meticulous preparation, system oversight, and adherence to evolving regulatory frameworks to ensure both compliance and data integrity.

For further reading and resources on eConsent and its adoption in clinical trials, consider exploring the following sources that also cover several of the regulatory concerns in the US and EU.

Unraveling the Impact of ICH E6(R3) on Good Clinical Practice

Electronic Informed Consent in Clinical Research

Key Considerations for Adoption of eConsent by Sites

Validation Process for Site-Selected Solutions

Validating site-selected solutions in clinical trials involves a series of technical and regulatory steps to ensure compliance with industry standards and guidelines. Here are the key procedures in what could be considered Minimum Viable Validation (MVV).

Technical Validation

1. **System Design and Development**: Ensure the solution is designed and developed according to industry best practices, including secure coding standards and robust architecture.
2. **Testing and Quality Assurance**: Conduct thorough testing, including unit tests, integration tests, and user acceptance tests (UAT), to ensure the solution functions as intended.
3. **Performance Validation**: Assess the system's performance under various conditions to ensure it can handle the expected load and usage patterns.
4. **Data Integrity and Security**: Implement measures to protect data integrity and security, such as encryption, access controls, and regular security audits.

Regulatory Validation

1. **Compliance with Guidelines**: Ensure the solution complies with relevant regulatory guidelines, such as ICH E6 R3, FDA, and EMA requirements. This includes adhering to Good Clinical Practice (GCP) standards.
2. **Documentation**: Maintain comprehensive documentation, including validation plans, test scripts, and results, to demonstrate compliance and support regulatory submissions.
3. **Audit Trails**: Implement audit trails to track changes and access to data, ensuring transparency and accountability

Key Considerations

- **Risk Management**: Conduct risk assessments to identify and mitigate potential issues that could impact the solution's performance or compliance.
- **Continuous Monitoring**: Implement continuous monitoring and periodic reviews to ensure ongoing compliance and performance.
- **Training and Support**: Provide training for users to ensure they understand how to use the solution correctly and comply with regulatory requirements.

By following these procedures, sites can ensure their selected solutions are technically sound and compliant with regulatory standards, ultimately supporting the integrity and success of clinical trials

Technical Requirements and Standards

While direct, real-time integration may not be standard initially, adopting systems that support clinical data exchange standards is crucial for future interoperability.

- Recommendation: Begin with CDISC ODM (Operational Data Model) and CDISC USDM standards where feasible.
- Future Direction: Plan for evolution towards FHIR-based frameworks for more seamless integration. Initiatives like Project Vulcan offer guidance. The global adoption of FHIR HL7 standards is trending, even in non-EHR systems.

BYOT Technical Levels:

Entry Level (MVP):
The site can use their own eConsent solution instead of paper or the sponsor-chosen eConsent solution and enter data manually into EDC, as is current standard practice. The monitoring teams then need to review the site's eConsent system during study conduct, instead of paper source.

- Site has validated system (e.g., eConsent) and documented processes.
- Makes system available for review/audit access.
- Uses own system (e.g., eConsent instead of paper).
- Data is manually entered into sponsor EDC (swivel chair).
- Monitoring teams review the site system (like reviewing paper source). [Targeted] SDV process remains.

Benefit: Improved site experience using own system. Challenge: Still requires manual data entry. Sponsors may still prefer their own automated eConsent.

Advanced Level:

- Includes all Entry Level requirements.
- PLUS: Full interoperability via standardized, real-time API connections.

Benefit: Improved site experience AND eliminates swivel-chair manual data entry. Benefit: Enables modernized sponsor processes (e.g., SDR instead of SDV for consent data), facilitating remote monitoring.

A requirements checklist to evaluate platforms against technical and regulatory standards is available.

BYOT Acceptance Criteria

Building Sponsor Confidence in Site-Selected Technology

For clinical sites to use their own technology in sponsor-led trials, they must meet clear criteria that ensure **data quality, security, and regulatory compliance**—comparable to sponsor-provided systems.

Recommendation: Sites should create a **Compliance Dossier**—a standardized digital packet, document repository or web portal with documentation on the system's architecture, security, and validation. This gives sponsors confidence that the technology meets global standards and helps manage regulatory and operational risk. Some companies may also call this a "Validation Portal."

The Compliance Dossier Concept:
To streamline sponsor review and build confidence, this initiative recommends sites maintain a "Compliance Dossier." This standardized digital package should contain comprehensive documentation demonstrating the system's compliance, including:

- System architecture and server locations.
- Information security protocols (encryption, privacy measures).
- Validation documentation (validation plan, test scripts, results, UAT evidence, change control logs).
- Evidence of compliance with relevant regulations (e.g., 21 CFR Part 11, eSignature rules).
- Audit trail functionality evidence.
- System access control procedures

Vendors are encouraged to establish centralized "Trust Centers" to house standard compliance documents, reducing redundant requests. Platforms like SafeBase could be used. Industry consortia like DTRA could help create common templates for such dossiers. Here is a sample trust center from OpenAI. Sites should consider having a portal like this available.

Sites must also demonstrate:

- **Validated systems and strong quality controls**, including change management and user access protocols
- **Readiness to integrate** with sponsor platforms (e.g., sharing data extracts or granting audit access)
- A willingness to **address issues quickly** or switch to sponsor systems if needed

Note: Meeting these criteria helps sponsors trust that site-selected tools are reliable, while giving sites more control and flexibility. These recommendations reflect minimum requirements based on global compliance standards. Individual sponsors may adapt or build upon them.

Key Elements for Sponsor Acceptance:

1. Submission of a Compliance Dossier: This package should digitally provide key information for sponsor assessment (see details in "Regulatory Compliance and Validation Requirements" section). It centralizes evidence of:
   - System architecture and security protocols.
   - Comprehensive validation documentation.
2. Demonstrated System Validation: Evidence that the technology is validated for clinical trial use according to regulatory standards.
3. Robust Process Management: Proof of established processes for:
   - Change control.
   - System and user administration.
   - User Acceptance Testing (UAT) standards and documentation.

4. Data Provision and Integration Capability: Ability to provide data to sponsors accurately and on schedule. This may involve generating sample data or demonstrating data extract capabilities. Readiness to integrate with sponsor platforms (e.g., via data extracts or APIs using standards where possible) is key.
5. Audit and Review Access: Willingness to provide sponsors with necessary access (direct or via data extracts) for compliance verification and monitoring.
6. Issue Resolution: A commitment to address any identified system quality issues promptly or revert to sponsor-provided technology if necessary.
7. Maintained Operational Readiness: Ongoing maintenance of SOPs, staff training records, and processes for audits, updates, and change control.

APPENDIX A – eConsent

Getting Sponsors to Approve Site-Selected eConsent Tools

Introduction
This appendix provides a checklist summarizing key requirements for securing sponsor approval to use a site-preferred eConsent solution in industry-sponsored trials. It assumes the site has a validated system and aims to streamline the sponsor review process. Refer to the main body of the playbook for detailed explanations of these concepts.

Checklist for Sponsor Submission Package:

1. BYOT Compliance Documentation (The "Compliance Dossier" Specific to eConsent):
    - Completed BYOT Checklist (if provided by sponsor) addressing specific requirements.
    - System Architecture Overview (relevant to eConsent functionality).
    - Information Security & Privacy Documentation:
        - Data encryption methods.
        - Privacy protection measures (adherence to GDPR, HIPAA etc.).
        - System access controls and user authentication protocols.
    - Validation Evidence:
        - Comprehensive system validation package/summary report.
        - Evidence of testing procedures and results (including UAT specific to eConsent workflow).
        - Documentation of version control.
        - Evidence of compliant electronic signature functionality (e.g., per 21 CFR Part 11, eIDAS).
        - Evidence of robust, verifiable audit trail capabilities.
    - Regulatory Compliance Statements:
        - Confirmation of adherence to relevant FDA, EMA, ICH guidelines for electronic systems/records/signatures.

Note: Much of this can be provided by an eConsent vendor (if a vendor solution is in use.)

2. Data Transfer & Integration Specifications:
    - Defined data format for consent-related data elements.
    - Confirmation of ability to meet sponsor's required data transfer schedule/method (e.g., extracts, potential for future API/CDISC ODM use).
    - Plan for transferring key data points (e.g., Consent date/timestamp, Consent status, Participant ID linkage).
    - Plan for integration with enrollment/randomization triggers if required.

3. Electronic Source Record Assessment (eSRA):
    - Completed eSRA questionnaire (e.g., from eClinical Forum) demonstrating compliant electronic source capabilities for eConsent data.

4. User Acceptance Testing (UAT) Evidence (Study Specific if applicable):
    - Documentation of UAT completion for the specific study's consent form configuration.
    - Test scenarios and results verifying key functionality (e.g., correct form version display, signature capture, date/time stamping).

5. Access Management Plan:
    - Procedure for creating/managing sponsor/monitor user accounts (if direct access is required for monitoring/audit).
    - Documentation of proposed access levels/permissions for sponsor users.
    - Plan for providing training/support for sponsor users if needed.

6. Operational Considerations:
    - Confirmation of defined roles/responsibilities between site and sponsor teams for eConsent process.
    - Plan for communication and issue escalation.
    - Confirmation of staff training on the eConsent system and process
    - Defined monitoring and oversight procedures for the eConsent process.

Conclusion
Sites want to use their own eConsent solution because they are already trained, they use it across trials, and if something goes wrong, in site support can fix the issue. Securing sponsor approval for site-preferred eConsent solutions requires thorough preparation and documentation. Addressing these areas improves the chances of approval while ensuring regulatory compliance and data integrity during clinical trials. As technology adoption grows at Clinical Research Sites, similar requirements will apply to other systems, making this process a valuable investment in your site's preferred workflow.

APPENDIX B – Links

The following is a consolidated index of links contained throughout the document for quick reference

Clinical Research Trends to Expect in 2025: More Complex, Less Connected (ACRP)	https://acrpnet.org/2025/03/05/clinical-research-trends-to-expect-in-2025-more-complex-less-connected
CDISC ODM	https://www.cdisc.org/standards/data-exchange/odm
CDISC USDM (Digital Data Flow)	https://www.cdisc.org/ddf
Project Vulcan (FHIR HL7)	https://www.hl7vulcan.org/
ICH E6 (R3) Impact on GCP	https://pharmaphorum.com/rd/unravelling-impact-ich-e6r3-good-clinical-practice
eConsent in Clinical Research (Medidata)	https://www.medidata.com/wp-content/uploads/2022/02/Electronic-Informed-Consent-in-Clinical-Research-White-Paper-Feb-22.pdf
Key Considerations for the adoption of eConsent for Sites	https://www.appliedclinicaltrialsonline.com/view/key-considerations-adoption-econsent-sites
The eSource Readiness assessment (eClinical Forum)	https://eclinicalforum.org/site-system-assessments/category/esra
Conducting Clinical Trials with Decentralized Elements (FDA Guidance for DCT)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements
FDA Inspection Observations (Aggregate)	https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations
Decentralized Trials Research Alliance	www.dtra.org
Safebase (a Trust Center Vendor)	https://safebase.io/
OpenAI's Trust Portal (Sample)	https://trust.openai.com/