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WHITE PAPER

Redefining the Standards for eCOA: Legacy vs. Modern

Legacy standards for eCOA introduce significant problems that can compromise study timelines, raise operational risk, and degrade the site and patient experience. Why? These outdated standards were formed according to paper-based workflows and vendor-led constraints that no longer serve the speed of modern drug development.

In contrast, a modern eCOA strategy redefines the industry standard, enhances effectiveness and efficiency, and can reduce build timelines by up to 50–75%.

This white paper examines eight core standards for eCOA, providing a side-by-side analysis of legacy versus modern methods.

1. Connected ecosystem
2. Site and patient experience
3. Data accessibility and visibility
4. Study build and management
5. Data change requests
6. eCOA library
7. Study app
8. Service model

50–75%

Reduction in build timelines

STANDARD 01.

eCOA as part of a connected ecosystem

Respondents of ISR's 2025 eCOA/ePRO Benchmarking & Market Dynamics survey rate integration with other data systems as the most important attribute for vendor/provider selection criteria, and 40% of respondents place it in their top five selection criteria.

Connected clinical ecosystems shift how clinical trials run by removing the need for custom integrations, separate logins, and extensive manual data reconciliation. When these systems work together, it benefits all trial stakeholders like sponsors, sites, and patients.

Legacy Approach	New Standard
eCOA functions as a disconnected single platform	eCOA functions like other clinical applications as part of a connected ecosystem. The ecosystem includes applications like RTSM, EDC, and eTMF
eCOA is embedded in EDC with build timelines dependent on CRF mapping	
Study information and patient data are entered across multiple systems, increasing the chance of manual data entry errors	Data is entered once then automatically sent to other applications by leveraging the connected ecosystem

BENEFITS

Single source of truth

Remove the need for duplicate data entry and reconciliation across systems

Reduced task redundancy

Patients are only enrolled in one application, saving time on redundant enrollment in other applications after the patient is entered in RTSM

Fast, controlled decision-making

The system pulls through data entered to make decisions in real-time

Connect sponsors, sites, and patients to save time and effort

STANDARD 02.

Site and patient-optimized eCOA solutions

Disconnected eCOA solutions add administrative burden to clinical sites and complicate the patient experience. Research sites are managing multiple trials, devices, and siloed systems, all while acting as frontline technical support for patients struggling with clunky study applications.

It is no surprise that usability is now a paramount concern for study execution. According to a recent ISR survey, 39% of respondents ranked "ease of use for sites" and 46% ranked "ease of use for patients" among the top five critical attributes for eCOA/ePRO selection. To enhance the clinical trial experience, the industry needs a new standard that aligns with both site processes and patient's daily lives. Deeply integrated systems and easily navigable interfaces make next steps obvious for patients and improve the overall experience.

	Legacy Approach	New Standard
Protocol training & review	Sites lack easy-to-use workflows, often relying on fake test accounts or manual tracking to understand the schedule of assessments	Ability to review the protocol schedule and assessments without creating "test participants" that skew compliance metrics. Updates in real-time if an amendment is introduced
Patient application scope	Complex, disconnected systems forcing users to juggle multiple tools on provisioned devices	A single, unified app handles consent, eCOA, documents, training, and telehealth with a BYOD approach where applicable to the patient
Offline capabilities & syncing	Data pushes only once per day, meaning if connectivity is missed, the sponsor waits another 24 hours for data	Offline capability with automated data synchronization to the database the second connectivity is reestablished
Mid-study configuration updates	Sites must individually ensure participants install app updates, leading to version control issues and delays	Real-time study updates. Approved configurations are instantly pushed to the participant and site without requiring an app store update
Paper transcription & data entry	Siloed systems require duplicate data entry, often forcing sites to transcribe paper COA data into the EDC manually	Paper transcription is built directly into the system, completely eliminating duplicate data entry and keeping COA data out of the EDC. Clear dashboards and reporting for monitors, indicating when surveys were transcribed to support targeted SDV

BENEFITS

Improved site experience

Automated tasks, simplified processes, and streamlined device management lighten manual work

Improved patient experience

Single app for all study activities, simple to use, and flexible access view to ease trial participation

Improved data quality

Eliminated duplicate data entry increases data quality and consistency

Streamlined, user-friendly workflows for better site and patient experience

STANDARD 03.

Complete data accessibility and visibility

Legacy eCOA methods limit data and study progress visibility. Sites cannot see important actions, next steps in the study, or real-time patient responses. Study teams must wait for vendor input, which leads to delayed issue identification, increased workloads for all stakeholders, and potentially compromised decision-making. Real-time visibility into study progress, key performance indicators, and patient-level data allows study teams to effectively monitor study execution.

With interactive dashboards and self-service data access, users can track eCOA status and compliance, identify emerging trends, and anticipate potential challenges. Built-in workflows ensure sites have the necessary information to manage their responsibilities and monitor patient progress efficiently.

Legacy Approach	New Standard
Data is siloed and inaccessible in disconnected eCOA systems	All patient data is immediately accessible to both the site and sponsor
Limited inbuilt site workflows, reports, dashboards, and data access	Sites access easy-to-consume patient data with workflows and actionable dashboards to review scoring, KPIs, and upcoming actions in real time
Study teams reliant on vendor processes and contractual agreements to access data	On-demand data access for study teams throughout the study, without the need for complex data transfer agreements
Limited ability to track study compliance	Real-time dashboards to track site and patient compliance
Study teams are reliant on custom reporting that require regular review to ensure patient safety	Study staff are notified when a sensitive response or combination of responses are entered by a patient. Data driven notifications are available in real-time and can be utilized to maximize patient safety

BENEFITS

Improved site performance

Real-time access to patient data and insight into next steps enhance the site experience and compliance

Proactive study management

Real-time dashboards allow proactive issue identification and resolution

Better decision making

Comprehensive visibility empowers stakeholders to make faster, more informed study decisions

Faster database lock

Effective monitoring and issue resolution accelerate data review

Better study control from design to database lock

STANDARD 04.

Flexible build

Legacy eCOA builds have been synonymous with slow, custom-coded builds, with siloed data, that cause frustrating user experiences and drive down site satisfaction.

By shifting to a validated configuration framework that provides full flexibility to meet study requirements, without the need for custom coding, can drastically reduce both the initial build times and mid-study amendment timelines often by 50 to 75 percent.

	Legacy Approach	New Standard
Study configuration	Design specification required to begin development	Interactive design process enables customizable survey build to begin directly from the protocol, for granular control over study configuration
Study configuration	eCOA mock-ups available for review when build is near completion	Ability to automatically preview eCOA assessments across all device types throughout the build process
Study configuration	Manual screenshot generation for site review and IRB/ethics packs	Auto-generated screenshot documents
Study management	Mid-study changes require additional build cycles	Rapid implementation of mid-study changes without the need for lengthy build cycles
Study management	Manual mid-study data access requests	On-demand data exports throughout the study
Study management	Lengthy site and user set-up process	Self-service site and user set-up

BENEFITS

Enhanced stakeholder collaboration

Interactive build process engages stakeholders early and reduces costly interactions

Reduced risk

Continuous visualization throughout the build process helps de-risk validation and user acceptance testing (UAT)

Increased efficiency

Automation and self-service capabilities eliminate manual processes and optimize study resources

More adaptable trials

Custom survey builds meet the needs of complex trials and improve efficiency

Achieve critical milestones more efficiently while reducing site and study team burden

STANDARD 05.

Self-service data change requests

Data change requests (DCRs) are often treated as difficult, vendor dependent processes. When an error is identified in source data, sites are typically forced to rely on lengthy, manual DCRs often involving vendor, sponsor, and/or CRO intervention. This slow process frustrates sites, increases administrative burden, delays data review and database lock, and complicates regulatory compliance review due to fragmented audit trails.

Self-service DCRs empower site staff to update data directly in a system without involving unnecessary vendor oversight. Modern eCOA platforms must align self-service capabilities with global regulatory expectations to maintain data integrity. For instance, the EMA dictates that data clarification procedures should not prohibit changes when justified, requiring a clear procedure for when a data originator realizes they have submitted incorrect data by mistake[1]. However, because patient-reported data relies on contemporaneous entry to minimize recall bias, systems must balance flexibility with control; regulations emphasize that corrections should not occur at a much later stage without strong justification[2].

To meet these standards, modern platforms must pair self-service corrections with system enforced guardrails and comprehensive oversight options. Most importantly, as outlined by the FDA, the system must maintain an unalterable audit trail that captures any changes made to electronic patient data the moment it leaves the device[3]. This ensures every modification remains completely transparent, justifiable, and fully inspection ready.

Legacy Approach	New Standard
Site corrections require time consuming vendor involvement that delays updates	Sites are empowered with self-service capabilities to directly correct data errors within defined submission windows
Audit trails are often fragmented between paper forms, vendor helpdesks, and the final database	Automated, unalterable audit trails instantly capture user identity, exact timestamps, reasons for change, and old vs. new values
Data changes require manual reconciliation between the eCOA system and the EDC, risking data integrity and delaying timelines	Approved data changes flow seamlessly into the central clinical database without requiring manual reconciliation

BENEFITS

Regulatory compliance and inspection readiness

Automated, unalterable audit trails ensure all data modifications are transparent, justified, and fully compliant with global agency guidelines

Reduced site burden

Self-service capabilities empower site staff to correct justifiable errors contemporaneously, eliminating the frustration and delays of vendor-managed Data Clarification Forms (DCFs)

Data integrity

System enforced submission windows and approval workflows balance flexibility with control, ensuring corrections are made promptly while preserving historical data

Streamline data corrections and maintain compliance

STANDARD 06.

Centrally-controlled library of pre-validated eCOA instruments

Instrument code libraries have long been used to "accelerate" eCOA build times. However, these libraries require extensive manual intervention, validation, and version control for each study. In addition, sourcing appropriate instrument versions, obtaining author approvals, and managing translations adds complexity and risk. While these rudimentary libraries offer some time savings, they deliver minimal impact on build times.

A centrally controlled repository to manage validated eCOAs, and to control for only allowable study customizations during build. All available instruments, translations, versions, and license status can be viewed and instantly added to new studies. This enterprise library approach removes the need for manual build and validation and enables a more holistic strategy for eCOA use across the organization.

Legacy Approach	New Standard
Basic content library with no/limited version control	Central library to create, validate, and manage eCOAs centrally for all studies
Code and content not validated or controlled, leading to inconsistency in eCOAs across studies	Pre-validated, fully reusable assessment with license holder review, removes need for custom configuration
Reusing and editing the last study build requires customization and isn't validated or controlled	Complete visibility and transparency of version, license, and translation status
No ability to view eCOAs across the organization	Study teams can view their organization's complete eCOA portfolio with a central hub for collaboration

BENEFITS

Accelerated build times

A pre-validated instrument library significantly reduces development time and effort

Rapid mid-study changes

Protocol amendments are not subject to lengthy build, validation, and approval cycles

Improved author collaboration

Gain licensing status visibility and protect author copyright, reducing the need for repeated approvals

Simplified translations management

View all available languages and translation versions

Build eCOA in a fraction of the time, with a fraction of the effort

STANDARD 07.

Single app for all eCOA studies

Traditional eCOA solutions create a new patient app for every study, often for both iOS and Android operating systems, which extends build timelines and increases management complexity. Each app must also be assessed 3-4 times yearly due to operating system updates. Additionally, a separate code base can be required to support a web version of the system.

Mid-study amendments require site approval that further delay updates. Sites must individually contact patients to request app updates, leading to multiple app versions in use across the study.

The move to a single app for each operating system enhances operational efficiencies by reducing build, approval, and management requirements.

When mid-study updates are required, sites independently approve the new app version, triggering automatic app updates for their patients. This reduces the "tech support" burden on sites, accelerating app updates and minimizing the number of versions in circulation.

Legacy Approach	New Standard
New app must be built from scratch for each study	Single patient app for all studies streamlines build and amendments
Delay while waiting for app store approval	App already approved in the app stores, with web-based access for sites for login from any device
Mid-study updates must be approved by all sites prior to release	Independent site approval of app updates
Sites must ensure patients install app updates	Site approval triggers automatic app updates for their patients' apps
Certificate of translation required for full app every time	Core elements do not need a certificate of translation for every study
Apps must keep pace with operating system updates, which becomes harder over time	Single app to maintain and keep up-to-date for each operating system

BENEFITS

Increased efficiency

Simplified build, deployment, and mid-study amendments streamline operations for sites and study teams

Enhanced control

Greater visibility and control over app version and updates

Future scalability

Simplified app management and maintenance supports long-term scalability

Streamline app build and management

STANDARD 08.

Flexible service models

eCOA solutions are typically delivered through a fully managed service model with limited sponsor visibility and control during the build process. Similarly, study management activities, such as data extracts and reporting, rely heavily on vendor services. Fully managed service models reduce eCOA scalability and create bottlenecks throughout the study.

Flexible service models allow organizations to choose from a fully managed vendor-led solution, a service provider-managed approach, or a self-sufficient model. A scalable SaaS platform underpins all options, providing the infrastructure for efficient study build and management, with 100% configuration that enables flexible delivery models. Insights dashboards and on-demand access to data enable teams to create an accurate picture of study progress in real time, alongside other clinical data sources.

Legacy Approach	New Standard
Inflexible service models	Flexible service models
Vendor-build only	Optionality for self-build, service provider-build, or vendor-build
Scheduled data extracts	On-demand data extracts
Study-by-study silos	Enterprise-wide utilization

BENEFITS

Increased sponsor control

Greater flexibility and predictability of eCOA management across studies

Accelerated timelines

Standardized components and self-service options reduce build times and increase study management efficiency

Cost efficiency

Enterprise-wide adoption increases reusability and optimizes resource deployment

Scalable eCOA with the optionality to self-build or outsource

Time to take eCOA off the critical path

When we keep doing the same things, we get the same results

Legacy Approach Limited eCOA adoption		**New Standard** Scalable eCOA adoption
Disconnected single platform	**Clinical ecosystem**	**Connected platform within clinical ecosystem**
Complex, disconnected systems increase site workload and patient burden	**Site and patient experience**	**Streamlined, user-friendly workflows for better site and patient experience**
Inaccessible, siloed data	**Data accessibility and visibility**	**Self-service data access for sites and study teams**
Inefficient build processes and lengthy mid-study support cycles	**Study build and management**	**On-demand study configuration and ongoing management**
Manual, paper-based DCRs	**Data change requests**	**Real-time, self-service DCRs**
Study-by-study customization	**eCOA library**	**Centrally-controlled library of pre-validated eCOA assessments with translations**
New app for every study	**Study app**	**Single app for all studies**
Study-by-study, service-heavy approach	**Service model**	**Flexible service model with optionality to self-build or outsource**

REFERENCES

[1] European Medicines Agency. (2023, March). Guideline on computerised systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023). Annex 4.1.1.4 (Data changes).

[2] European Medicines Agency. (2023, March). Guideline on computerised systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023). Section on Electronic Clinical Outcome Assessments.

[3] U.S. Food and Drug Administration. (2009, December). Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Section: Additional Considerations for Electronic PRO Data.

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