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WHITE PAPER

Raise the Bar: Setting New Standards for the eCOA Industry

Electronic Clinical Outcome Assessments (eCOA) can offer significant benefits for clinical research, including increased patient compliance, enhanced data quality, and streamlined data access.

However, despite being in use for decades, eCOA adoption lags behind that of other clinical trial systems. Why? Traditional eCOA solutions have frustrated sites and study teams: **lengthy (16+ week) build times, operational complexity, and siloed systems put eCOA on the critical path to study start and database lock.**

As a result, rather than increasing uptake of eCOA, some organizations are reverting to traditional paper-based COAs for non-pivotal studies due to the perceived ease of implementation.

A paradigm shift is necessary to fully realize the potential of eCOA. The following standards outline a new approach to meet the challenges head-on, reduce the complexity of eCOA delivery, and drive greater efficiency in clinical trials.

A new approach to take eCOA off the critical path

STANDARD 01.

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 eliminates the need for study-by-study customization 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 Code / Content Libraries	New Standard Centrally Controlled Library
Basic content library: No / limited version control	**Central library management and control:** Create, validate, and manage eCOAs centrally for all studies
Code and content copy-pasted study-by-study: Not validated or controlled, leading to inconsistency in eCOAs across studies	**Pre-validated with license holder review:** Fully reusable assessments, so no need for custom configuration
Reuse and edit the last study build: Requires customization and not validated or controlled	**Transparent:** Complete visibility of version, license, and translation status
Uncontrolled: Requires same level of author review as build-from-scratch	**Controlled:** Pre-validated to reduce author review and licensing cycle time
Limited visibility: No ability to view eCOAs across the organization	**Central hub for eCOA collaboration:** Study teams can view their organization's complete eCOA portfolio

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 02.

On-Demand Study Configuration and Management

eCOA management slows down study teams. From initial build and mid-study amendments to data access, teams rely on vendors to prepare what they need, resulting in extended timelines, increased costs, and potential delays in study initiation and conduct.

By shifting to an on-demand model, study setup and management become dynamic processes. Teams can access real-time information, make data-driven decisions, and quickly implement changes to improve study efficiency and agility.

	Legacy Approach	New Standard
Study Configuration	Design specification required to begin development	Interactive design process enables build to begin directly from the protocol
	Only eCOA mock-ups available for review until build is near complete	Preview actual eCOAs across all device types throughout the build process
	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
	Paper-based data change request (DCR) process	Real-time, self-service DCRs with complete audit trails
	Manual mid-study data access requests	On-demand data exports throughout the study
	Lengthy site and user setup process	Self-service site and user setup

BENEFITS

Enhanced Stakeholder Collaboration

Interactive build process engages stakeholders early and reduces costly iterations.

Reduced Risk

Continuous visualization throughout the build process helps derisk validation and user acceptance testing (UAT).

Continuous Data Access

On-demand exports support eCOA data and adherence analysis, alongside EDC and other data sources.

Increased Efficiency

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

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

STANDARD 03.

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.

Mid-study amendments require site approval that further delay updates. Sites must individually contact participants 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
Mid-study updates must be approved by all sites prior to release	Independant site approval of app updates
Sites must ensure participants 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
Limited app functionality due to complexity of study-by-study build	Ability to scale functionality
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 streamlines operations for sites and study teams.

Enhanced Control

Greater visibility and control over app versions and updates.

Future Scalability

Simplified app management and maintenance supports long-term scalability.

Streamline app build and management

STANDARD 04.

Complete Visibility Throughout the Study

eCOA systems 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 to access data	On-demand data access for study teams throughout the study
Limited ability to track study compliance	Real-time dashboards to track site and patient compliance

BENEFITS

Improved Site Performance

Real-time access to patient data and next steps enhances 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, informed study decisions.

Faster Database Lock

Effective monitoring and issue resolution accelerate data review.

Better study control from design to database lock

STANDARD 05.

Site-optimized eCOA Solutions

Historically, eCOA solutions added extra burden to sites and their workflows. Sites manage multiple trials, devices, and systems, while also providing technical support and switching between systems during patient visits. These challenges, combined with difficult-to-navigate systems and duplicate data entry, mean paper COAs are often preferred by sites. This trend back to paper can erode data quality, accuracy, and traceability.

To enhance the site experience, it is critical to design easily navigable systems that align with site processes. This includes fully integrating systems to trigger actions and automate information transfer. Additionally, enabling eClinRO completion within the eCOA web portal removes the need to switch between devices during patient visits. A BYOD-first approach further reduces device management and support needs.

	Legacy Approach	New Standard
Device setup and management	Sites manage, store, and provide patient "tech support" for provisioned devices	BYOD-first approach reduces the provisioning and "tech support" burden
	Separate tablet for eClinRO on every study	Complete eClinROs within the eCOA management portal (no need for a separate device)
Systems	Too many systems and logins	Single login across all studies and sponsors
	Limited flexibility for sites to use existing systems	Ability to use site-owned systems, such as email, teleconferencing, and calendars
	Restricted information flow across siloed systems	Connected systems centralize eCOA management for sites
Workflows	Siloed systems require duplicate data entry	Automated transfer of patient data between systems
	No clear workflow path for sites to follow	Easy navigation, including automatic workflow paths across systems

BENEFITS

Improved Site Experience

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

Reduced Errors

Automated data transfer and workflows minimize human errors.

Improved Data Quality

Eliminated duplicate data entry increases data quality and consistency.

Streamlined, user-friendly workflows for a better site experience

STANDARD 06.

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. 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 study management
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

For too long, eCOA solutions have burdened study teams. Industry can no longer afford to keep doing things the way they have always been done. It's time for a new approach that takes eCOA off the critical path and drives faster, more efficient trials. It's time for study teams to realize the full potential of eCOA and deliver a better experience for sites and patients.

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

New Standards to Simplify eCOA Implementation and Management

Legacy Approach Limited eCOA adoption		**New Standard** Scalable eCOA adoption
Study-by-study customization	**Study Build**	**Centrally controlled library of pre-validated eCOA assessments with translations**
Inefficient build processes and lengthy mid-study support cycles	**Study Management**	**On-demand study configuration and ongoing management**
New app for every study	**Study App**	**Single app for all studies**
Inaccessible, siloed data	**Data Accessibility**	**Self-service data access for sites and study teams**
Complex, disconnected systems increase site workload	**Site Experience**	**Streamlined, user-friendly workflows for a better site experience**
Study-by-study, service-heavy approach	**Service Model**	**Flexible service model with optionality to self-build or outsource**

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