



BEST PRACTICES GUIDE

HOW TO IMPLEMENT AN eCOA STRATEGY

Practical guidance for sponsors and CROs of all sizes

PEOPLE, PROCESSES AND PRODUCTS REQUIRED FOR SUCCESSFUL eCOA IMPLEMENTATION

Moving from paper to electronic clinical outcome assessment (eCOA) can seem like a costly or daunting task. However, with proper planning and the right resources in place, sponsors and CROs of all sizes can cost-effectively implement and benefit from an eCOA strategy.

This step-by-step guide explains how to implement eCOA in your next trial, including the people, processes and products required for success.

- 1. IDENTIFY WHO IS RESPONSIBLE FOR IMPLEMENTING eCOA**
- 2. PLAN FOR INTERNAL PROCESS MODIFICATIONS**
- 3. DEFINE YOUR eCOA STRATEGY & SELECT THE BEST DEVICES**
- 4. ENSURE eCOA DEVICES ARE ADEQUATE AND LICENSED**
- 5. DETERMINE MODALITY STRATEGY**
- 6. SELECT PROCUREMENT METHOD AND CREATE DATA TRANSMISSION AGREEMENT**
- 7. CUSTOMIZE REPORTS FOR ACTIONABLE INTELLIGENCE**
- 8. DEVELOP A DEVICE SHIPMENT AND DEPLOYMENT PLAN**
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- 10. DEVELOP AND CONDUCT USER SITE TESTING**

1 IDENTIFY WHO IS RESPONSIBLE FOR IMPLEMENTING eCOA

How you assemble your core eCOA team is largely dependent on the size and capacity of your organization. Let's review a suggested course of action based on your specific circumstances.



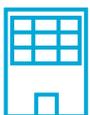
Larger sponsors and CROs

For larger sponsors and CROs, an internal eCOA team should be put in place, including those with direct eCOA data collection experience and therapeutic expertise. You can either mandate that a separate eCOA team is centralized internally and used for all eCOA trials or you can deploy eCOA experts across different groups in your organization to serve in an advisory capacity, consulting with clinical trial teams as needed.



Tip

If centralizing an eCOA team, include cross-functional groups of experts such as clinical science, data management and clinical operations augmented with representatives from outsourcing and marketing (pricing) functions. In addition, regulatory personnel should be included as part of a regular review cycle to ensure compliance. Gain efficiencies when teams—rather than individuals—are updated and trained on new instruments, devices and medical instruments.



Smaller sponsors and CROs

Smaller sponsors and CROs may not have the resources to maintain an internal eCOA team. In this case, select an eCOA provider who can advise and support your organization throughout implementation and the trial lifecycle. For more information on how to properly vet and select the right eCOA provider for your next clinical trial, refer to [Appendix A](#).



Tip

Here are a few questions to ask potential eCOA providers:

- > Do you have audited evidence of adherence to all appropriate regulations, including to US 21 Code of Federal Regulation (CFR) Part 11 and the General Data Protection Regulation (GDPR)?
- > How will eCOA data align with the rest of the trial data?
- > How easily can sites and patients use your solution? Can I get a demo?
- > Do you offer BYOD, and what are your device purchasing and lease options for provisioned devices?
- > How will you support any additional training for site staff and patients?
- > Do you have a full-service 24/7 help desk?

**CAREFULLY VET
POTENTIAL PARTNERS
TO CONFIRM eCOA
EXPERIENCE**

2 PLAN FOR INTERNAL PROCESS MODIFICATIONS

Careful up-front planning can save time and money during study execution. When developing your initial project plan, take into consideration any internal process modifications required for eCOA data endpoint collection, including modifications related to protocol specifications, data collection, management, analysis and reporting.



Protocol management

If working with an eCOA provider, your team should be engaged in the process as early as possible, including providing input into protocol specifications. Leverage your provider's operational experience by including them during protocol writing and all planning phases so that reasonable endpoint data and instruments are used for protocol development.



Tip

Smaller sponsors and CROs may not have formal processes for implementing eCOA. Therefore, it's important to adjust your plan accordingly early in the process.



Data source management

Study team tasks, internal processes and regulatory submission methods change when a protocol specifies eCOA data endpoint collection. Collecting electronic source (eSource) data is the subject of many draft guidelines¹ and special regulatory concerns and should be carefully planned for prior to study start.

OTHER PROCESSES AND SYSTEM CONSIDERATIONS FOR eCOA DATA COLLECTION

- > Site personnel and patient training
- > User acceptance testing of eCOA
- > Software programming to include logical branching, randomization and other device-level calculations

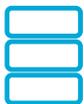


Tip

Anticipate that some study sites may be reluctant to participate in clinical trials that use eCOA² — plan for training of site staff and patients.

1. US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health. (2013). *Guidance for industry. electronic source data in clinical investigations*. Maryland: Center for Drug Evaluation and Research.

2. Fleming, S., Barsdorf, A.I., Howry, C., O’Gorman, H., Coons, S.J. (2015). Optimizing electronic capture of clinical outcome assessment data in clinical trials: the case of patient-reported endpoints. *Therapeutic Innovation & Regulatory Science*, 49, 797-804.



Data management

eCOA front-loads software programming decisions to avoid data variance, reconciliation, attribution and verification issues common with paper COA trials. For example, integrations with objective measures from medical devices, labs, images and electronic medical records (EMR) may contain primary and secondary endpoints required for protocol analyses. These integrations increase the complexity of each trial and require planning from your data management team to address potential cleaning and reconciliation issues.

OTHER PROCESSES AND SYSTEM CONSIDERATIONS FOR eCOA DATA MANAGEMENT

- > Specify data clarification form (DCF) conditions and processes
- > Confirm electronic data transfer formats
- > Clarify timing and frequency of data transmission and transfer



Tip

The volume of eCOA data can be very high given multiple data streams from medical devices, wearables, centralized labs, clinicians, observers, caregivers and patients. Your data management team should anticipate and proactively plan for this volume.



Data analysis and reporting

eCOA provides the opportunity to better manage site performance and avoid study risk by enabling access to real-time study data. Predictive analytics and real-time reporting allow you to visualize performance and risk metrics, predict potential areas of risk before they happen and identify areas for proactive mitigation.

OTHER PROCESSES AND SYSTEM CONSIDERATIONS FOR eCOA DATA ANALYSIS & REPORTING

- > Define how often interim analyses will be conducted to determine enrollment, compliance and power achievements
- > Define how eCOA trial data will be integrated and reconciled with other clinical data
- > Document how eCOA trial data will be evaluated with other clinical trials and programs
- > Train site and trial personnel on how to access real-time data online

**BETTER MANAGE
PERFORMANCE AND
AVOID STUDY RISK**

3 DEFINE YOUR eCOA STRATEGY & SELECT THE BEST DEVICES

eCOA providers will be able to support you in defining your eCOA strategy, including which devices are most suitable for your particular study—handheld, tablet or web. Let’s review a few considerations when developing a strategy and selecting devices for your next eCOA trial.



Migrating paper instruments for eCOA implementation

If you’re migrating from paper-based instruments to electronic data collection modes, you must ensure that respondents interpret and respond the same way regardless of the data collection mode. Many instrument developers continue to be paper-centric and fail to contemplate alternative data collection modes when developing their items and selecting response scales.

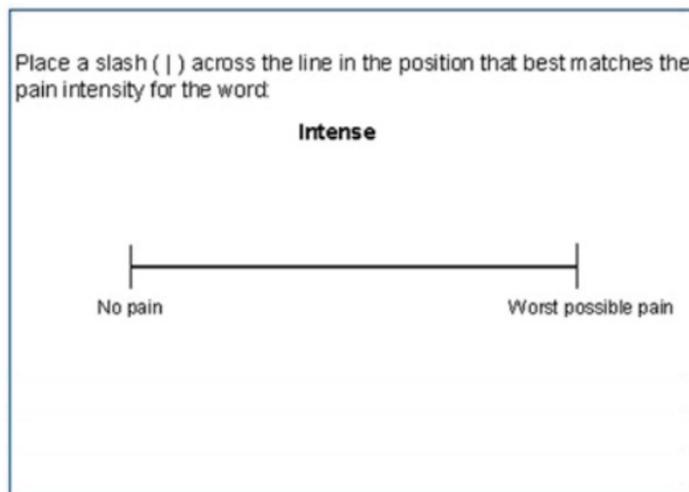
**PROPERLY PLAN
AND EXECUTE FOR
CONSISTENT
MULTI-MODALITY
DATA COLLECTION**

For example, a true visual analog scale (VAS) has descriptive verbal anchors at each end with an uninterrupted line in between. On a self-administered paper-based questionnaire, the respondent can be asked to place a mark or 'X' at the point on the line that best reflects his or her response; however, smartphone or tablet versions of the same questionnaire must be converted to a numeric rating scale.³

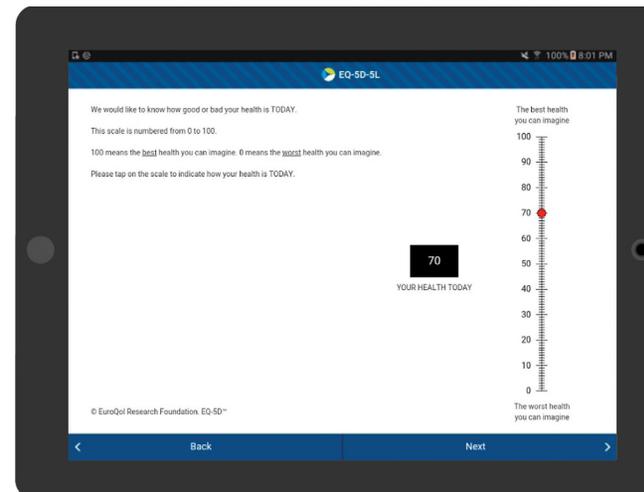


Tip
Schedule time for modifying existing paper-based questionnaires for electronic implementation. A cognitive debriefing may be required.

REDUCE PATIENT BURDEN WITH EASY-TO-USE VISUAL SCALES



PAPER VAS SCALE



eDIARY

3. Coons, S.J., Eremenco, S., Lundy, J.J., O'Donohoe, P., O'Gorman, H., Malizia, W., (2015). Capturing patient-reported outcome (PRO) data electronically: the past, present, and promise of ePRO measurement in clinical trials. *Patient* 2015, 8, 301-309.



Patient population characteristics

When developing your eCOA strategy, it's very important to consider factors regarding your target patient population. Compliance evidence should be referenced in order to understand if that patient population prefers telephone, smartphone or web-based technologies. Where are patients located and how widely available is the technology you want them to use? Should you consider provisioned devices? If your patients are unable to use technology or input data in their eDiaries, a caregiver, observer or clinician modality may be appropriate.



Data collection processes

Today, a single eCOA device or browser may be used to collect data from a patient remotely or from a patient visiting a clinic. Your eCOA strategy should take into consideration the number of eDiary questions expected per required form, frequency of data collection and the type of data to be collected. For example, will you be integrating ePRO with objective measures from integrated devices such as a peak expiratory flow (PEF) meter or some other medical device or wearable?



Tip

Each strategy should account for the proliferation and adoption of consumer electronic technologies in the study's countries. If eCOA devices are to be provisioned, for example, the strategy should confirm the availability of local devices and/or local customs consent.



General pricing for eCOA devices

When developing your eCOA strategy, certain cost considerations come into play. Device costs are driven by the number of clinical sites, countries and the study duration. Those used for industry research can be priced most commonly per language and/or per administration, or (rarely) by a flat fee per study.



Regulatory components

For optimal patient compliance, devices should be simple, regulatory-compliant and integrate easily with other required systems. All devices must be validated to store and transfer data privately and safely, within a tamper-proof eCOA data collection system. All integrations with additional systems must be validated for accuracy and safety.



Patient-facing communications

The strategy should also include electronic versions of all patient-facing communications, including evidence of how each instrument will be seen on each device screen for the patient. Screenshots are required for approval by the IRB and/or ethics committee. It is also useful for the clinical trial team to view screenshots live, with a demo device or via simulation.



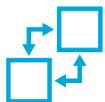
Tip

A bring-your-own-device (BYOD) strategy, which allows patients to use their own devices, may be suitable, potentially realizing substantial cost savings since a much smaller number of provisioned devices would be required in this situation.



Data management standard and governance

Each strategy should define data management standards and governance, including specifications for User Site Testing (UST). This is defined as testing that takes place outside of the eCOA provider's controlled environment.⁴



Encourage collaborative selection

One effective way to recommend devices is to establish an internal web page hosted by the eCOA team, which lists devices pre-selected and supported with service-level agreements, along with provider information. This type of resource enables the trial manager to collaborate with the eCOA team to select devices based on the key factors reviewed above. The combination of required services and devices helps identify those providers to be considered.



FOR A COMPLETE CHECKLIST ON OTHER CRITICAL ELEMENTS TO CONSIDER WHEN SELECTING eCOA AND INTEGRATED MEDICAL DEVICES, REFER TO APPENDIX B.

4. User Site Testing [Def 1.] In *CDISC Glossary Controlled Terminology*, Retrieved April, 2018, from <https://www.cdisc.org/system/files/members/standard/foundational/glossary/CDISC%20Glossary%20v11.pdf>.

4 ENSURE eCOA DEVICES ARE ADEQUATE AND LICENSED

If using an electronic version of an instrument or diary (eDiary), you should, according to the FDA PRO guidance, provide evidence to confirm the new instrument's adequacy. Larger sponsors and CROs are likely to have a database of instrument and diary copyright holders, including contacts, so that materials can be reused and recycled.

The process for licensing and translating electronic instruments may be handled by the trial sponsor, eCOA provider, CRO or translation provider. Each instrument must be *"fit for context of use"* as required by FDA and licensed for use by the copyright owner or agent. Each instrument must be validated for electronic implementation and undergo translation and localization.

ADDITIONAL RESOURCES

Included below are databases and resources with information on COA instruments, eCOA migrations and endpoint descriptions used to support specific indication claims.

- > [CenterWatch Clinical Trials](#)
- > [ClinicalTrials.Gov](#)
- > [COMET Clinical Trials Consortium](#)
- > [FDA Clinical Outcome Assessment Compendium](#)
- > [Physiopedia](#)
- > [ePROVIDE™](#)
- > [PROMIS®](#)

5 DETERMINE MODALITY STRATEGY

Some protocols or clinical trial teams elect to collect data with eCOA using more than one modality. However, mixing modalities carries additional data integration and regulatory risk. The FDA PRO Guidance states, *“We intend to review the comparability of data obtained when using multiple data collection methods or administration modes within a single clinical trial to determine whether the treatment effect varies by method or mode.”*



Smartphone

Patient/clinician⁵ completes instrument(s)⁶ on a provisioned or personal smartphone that sends data to a central system for web review of data by site and sponsor



Tablet

Patient/clinician completes instrument(s) on a tablet with a central system that allows for web review of data by site and sponsor



Web browser

Patient/clinician completes questionnaire(s) via a web-based browser with a central system that allows for web review by site and sponsor



Interactive voice response system (IVRS)

Patient/clinician answers questions posed by an automated voice recording. Data are captured with a central system that allows for web review by sites and sponsor

EFFECTIVE AND WIDELY-ACCEPTED eCOA MODALITIES

5. European Medicines Agency. (2014). *Reflection paper on the use of patient reported outcome (PRO) measures in oncology studies*. United Kingdom: European Medicines Agency.

6. Eremenco, S., Coons, S.J., Paty, J., Coyne, K., Bennett, A.V., McEntegart, D. (2014). PRO data collection in clinical trials using mixed modes: report of the ISPOR PRO mixed modes good research practices task force. *Value in Health*, 17(5), 501-516.

Mixed modality use requires consistent measure, privacy and security

Mixed modalities are also reviewed in the 2014 Report of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) PRO Mixed Modes Good Research Practices Task Force entitled, 'PRO Data Collection in Clinical Trials Using Mixed Modes.'⁷ This report states, “we also strongly discourage the mixing of paper and electronic field-based instruments and suggest that mixing of electronic modes be considered for clinical trials and only after equivalence has been established.”

If supporting a claim, regulators require consistent measure of displays, patient privacy protection and data security. A back-end system must securely receive all data sent in accordance with regulations and guidelines; all eSource data systems must provide authorized investigator staff with the ability to prepare and maintain records throughout the life of the trial and beyond. When eCOA devices are used to collect data for post-marketing purposes, such as pricing decisions, requirements may differ. Check with your regulatory specialist for more information.



Tip

Work with your internal eCOA team or eCOA provider to select the most appropriate modality for each of your studies.

eCOA MODALITY SELECTION IS CONTINGENT ON A NUMBER OF FACTORS, INCLUDING:

- > Trial size
 - > Indication
 - > Complexity
 - > Length
 - > Locations
 - > Patient demographics
 - > Survey elements
 - > Budget
-
- Smartphone
 - Tablet
 - Web browser
 - IVRS

7. GBI Research. [2009]. *The future of eClinical trial solutions—Market forecasts to 2015*, competitive benchmarking and case studies. United Kingdom: GlobalData.

6 SELECT PROCUREMENT METHOD AND CREATE DATA TRANSMISSION AGREEMENT

Your next eCOA trial may use fully-provisioned devices or a mixture of BYOD and provisioned. BYOD reduces trial costs and increases patient engagement levels. If working with an eCOA provider, verify they are able to cater to both of these options.

Data transmissions vary widely depending on location, so it's important to verify whether target patients live in areas that support wireless transmission of data. There are areas worldwide that do not have adequate cellular reception to support wireless transmission. Therefore, it's best to provide each eCOA device with a choice of transmission methods, both digital and analog. Having options avoids downstream frustration for both patients and the investigative sites.

Data transmission agreement (DTA) is a document that defines the structure of data transfer. Typically, the data management study team creates this document, while your eCOA provider (if applicable) reviews and comments.



Tip

In the event of transmission disruption, you must ensure study data is retained until transmission is possible. This is vital for preserving eSource data required by global regulators.

7 CUSTOMIZE REPORTS FOR ACTIONABLE INTELLIGENCE

Monitoring reports are standard documents that can be customized to provide actionable intelligence across your studies, sites and patients. If working with an eCOA provider, you should expect to receive reports that meet your trial needs, while your study team can review and approve. While paper-based studies require your team to anticipate when reporting can begin, with eCOA, you can train site personnel and study team(s) on how to access real-time data online.



Tip

While traditional business intelligence solutions require that you organize your study data, look for an eCOA provider that completely automates this process.

Integrating all of your clinical and operational data in one centralized location can provide real-time insight into what's going on in your study, in real-time. Let's review some of the qualities to look for in your eCOA solution's reporting capabilities.



Filtered insights

Filtered reports allow you to visualize performance, predict milestone achievements and identify root causes of risk across date ranges, geography or subsets of studies and sites.



Configurable timelines and milestones

Reduce start-up cycle times by configuring study timelines and milestones, setting enrollment targets, adding contacts and automating study document tracking, reporting and collaboration across multiple dimensions, including patient enrollment, compliance and safety.



Intuitive, role-based interface

Can you access all of your study data in real-time? With an intuitive, role-based interface, every study team member can visualize performance metrics and predict milestone achievements. Collaboration is greatly enhanced as all stakeholders have shared visibility into risk and performance indicators.

**REAL-TIME INSIGHTS
WITH CENTRALIZED
CLINICAL AND
OPERATIONAL DATA**



Automated triggers

Study administrators can detect data variances and outliers by configuring key performance indicators (KPIs) and key risk indicators (KRIs), set data thresholds and pre-determine remediation actions based on automated triggers.



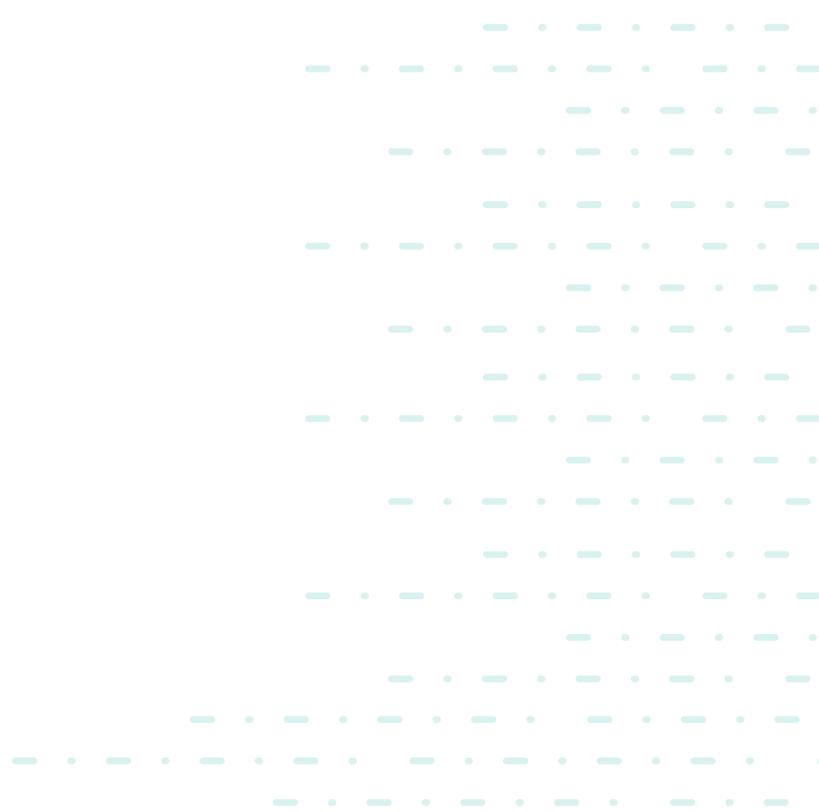
At-a-glance view of issues and trends

Study sponsors can get an at-a-glance view of potential issues and trends across your entire development portfolio, while study managers can drill down into each study to pinpoint problem areas and direct project teams to take the next-best action. Sites are better informed, too, with a detailed view of performance and problem areas for their location.



Study requirement configurations

System administrators should ensure study indicators, timelines, budgets and other requirements are configured according to criteria set by the study leader.



8 DEVELOP A DEVICE SHIPMENT AND DEPLOYMENT PLAN

When developing an eCOA device shipment and deployment plan, include information on shipment timelines to your study sites and consider custom requirements and other regional and local regulations. Typically, if working with an eCOA provider, they should provide background on their experience procuring and shipping devices around the globe, as well as review your planned delivery timelines. Your eCOA study team should review those country details and provide necessary logistical details for shipment and customs clearance.

Don't forget that the success of any clinical trial is largely determined by the investigative sites that enroll patients, so have adequate eCOA devices when and where they are most needed. Costs add up quickly when devices must be shipped urgently overnight, so stock additional devices on-hand at your high-performing sites.



Tip

Consult with your eCOA provider on the number of devices to order during the contracting process; this will keep trials on time and on budget. Consider a provider who has regional logistic depots for additional devices that may be required in countries with challenging import regulations.

9 DEVELOP A TRAINING PLAN AND TRAINING MATERIALS

The quality of your site's data improves with consistent support and training. Therefore, we recommend developing a training plan, user manuals and other training materials that include components for clinicians, investigator site staff, patients, observers and caregivers. eCOA providers are typically responsible for providing the training plan and related documentation, while your study team reviews and approves the training plan and materials. Additional internal reviewer approval may be required. Here are some recommended training materials to account for in your training plan.



eCOA device training kit

Your training plan should include an eCOA device training kit for study coordinators with directions on how to use the eCOA device and instructions for training patients, who can practice on the training device before being issued their own. Patients should be allowed as much time and practice as necessary to feel comfortable using the eCOA device.

**REDUCE DATA
VARIANCE
AND IMPROVE
COMPLIANCE WITH
ELECTRONIC RATER
TRAINING**



Site support guide

Develop a site support guide specific to each trial, including directions on how to log into the study system, expectations of each study visit and how to train and work with participants for eCOA study success.



Getting started guide

A pictorial step-by-step “getting started” guide should provide instruction on how to use your eCOA system, and should be approved by the Institutional Review Board (IRB). Power adaptors, power cords and other support materials should also be provided.



Tip

Schedule at least two hours for eCOA training during the investigator’s meeting so that everyone has plenty of time for hands-on training. Consider refresher training for sites and monitors to bridge any gap between the investigator meeting and first-patient-in (FPI). Stay involved with your sites: Ultimately, it’s your responsibility to keep sites and patients actively engaged.

10 DEVELOP AND CONDUCT USER SITE TESTING

User site testing (UST) verifies that the eCOA system and devices comply with the Requirements Document and written specifications of your study.⁹ This testing does not typically involve target patient populations; rather, it is conducted between your study team and your eCOA provider.

Your provider can offer instructions and feedback for how to conduct testing. However, developing the testing strategy should not be solely their responsibility. Those who wrote the protocol and provided study requirements at the start of the project should contribute to verifying that these requirements are satisfactorily covered.⁹ Actual testing typically takes place outside of the eCOA provider's controlled environment.¹⁰

Executing test scripts and ad-hoc scenarios determine whether the eCOA system is ready to go live. Once your clinical trial team has determined the system is ready for deployment, they should prepare and sign a formal document that accepts the system as validated for its intended purposes. Test results will be needed later for the test data transfer.



Tip

Review the eCOA Requirements Document carefully, as this determines what the trial will look like, and all that is required at each step along the way. Any change to the Requirements Document later, even a minor modification, can impact your trial budget and timeline.

9. McKenna, S.P., (2011). Measuring patient-reported outcomes: moving beyond misplaced common sense to hard science. *BMC Medicine*, 9, 86.

10. User Site Testing [Def 1.] In *CDISC Glossary Controlled Terminology*, Retrieved April, 2018, from <https://www.cdisc.org/system/files/members/standard/foundational/glossary/CDISC%20Glossary%20v11.pdf>.

ENSURE SUCCESS IN YOUR NEXT eCOA TRIAL

Implementing eCOA may require more work up-front, but in the end, proper planning will save time, money and frustration. Experts that have deployed and implemented eCOA agree that success has five prerequisites:



Plan early

eCOA strategy development and implementation should be led by a team rather than a single individual, and team members should not only be experienced in eCOA but also committed to replacing paper-based methods.



Pick an experienced eCOA provider

An experienced provider will be familiar with data transfers, communication, training and integration of eCOA with other technologies, so it's important to pick a knowledgeable partner.



Properly educate and allow hands-on training

Build and strengthen the scientific knowledge and medical viewpoint of eCOA data collection and device modalities. Lessons learned and operational intelligence gained from previous eCOA trials are a significant asset and should not be lost.



Anticipate some mistakes

Even with a carefully-laid plan in place, mistakes can still happen. Ensure that processes used to implement eCOA are simple and effective, with competence in place before deployment.



Provide ongoing training and communication of best practices to sites

Ongoing training and regular communication can improve the consistency, reliability and quality of subjective data collected by clinicians, patients, caregivers and observers.



APPENDIX A

Selecting your eCOA provider and investigative sites

Smaller sponsors and CROs without the necessary resources to assemble an internal eCOA team should research and select a provider who can advise and support their organization throughout the entire trial lifecycle. How can you go about selecting the right eCOA provider to meet your trial needs?

- > **Select early and get to know your team**

Select your ePRO provider early and take the time to understand their processes, document flows and timelines. Ensure handoffs are smooth by getting to know your Project Manager and Coordinator to establish who is responsible for what at each stage of the study.

- > **Ensure audited evidence of regulatory adherence**

Fundamentally, your eCOA provider must provide audited evidence of adherence to all appropriate regulations, including, but not limited to, US 21 Code of Federal Regulations (CFR) Part 11 and the General Data Protection Regulation (GDPR).

- > **Confirm range of services offered**

Further, your eCOA provider must meet the needs of all of your clinical team members, sites and participants. As such, you must review and vet your provider's full range of services, including usability of devices and systems by sites and patients, device purchasing or lease options and whether the vendor has a full-service help desk.

- > **Evaluate data integration and formatting capabilities**

In addition, your clinical trial team should evaluate the provider's commitment level, transparency and capability for data integration. While most providers can provide trial data in any standardized format, can they provide trial data that will easily integrate with the rest of your clinical trial data? How will the eCOA variables match other trial data?

Larger sponsors and CROs must ensure they have access to a global network of investigator sites committed to maintaining the highest quality data. Here are a few considerations when selecting sites and ensuring their success for your next eCOA trial.

> **Confirm mobile network and signal strength**

It's important to confirm and verify each site's mobile network and signal strength so you can properly determine which transmission devices to ship to the site for an eCOA study.

> **Select sites and coordinators with technology experience**

If possible, select "tech savvy" sites and study coordinators. If the site is eCOA naïve, be sure the study coordinator is familiar with electronic devices such as computers, mobile phones and tablets. Consider adding an extra study coordinator if the study coordinator is not comfortable with technology.

> **Plan adequate time for investigator meeting**

Study coordinators are training the patients enrolled in the trial, so plan adequate time for the investigator meeting—preferably 2 hours. The better they know how to use the eCOA device, how to charge it and transmit data, the better the patients will be trained. Better training means higher compliance.

> **Keep sites involved and informed**

Consider publishing a monthly newsletter featuring questions and answers about the trial, or the most frequently-asked questions addressed by your eCOA provider's customer support team. This can be a very effective reminder for sites reluctant to ask questions of the sponsor.

The following table presents the range of factors to consider when selecting an eCOA provider.

Data management	Flexible data change processes and workflow?	Consistency checks executed by provider?	
Data security	Server uptime?	Number of redundant servers?	Does the device perform a quality check upon data transfer?
Data transfer options	SAS, SASII, ASCII, SDTM, 'Normalized' tables and Oracle Clinical® formats?		
Provisioned devices	Are purchase and lease options available?	Is Logistics Management in-house or contracted?	Are regional distribution depots available?
Patient's device used with BYOD app	FDA/EMA NDA approvals?	Recommended screen size(s)?	Experience with patient compliance?
Global transmissions management	Type of transmission options: 3, 4, 5G, Wifi, internet or analog?	Transmission metrics?	Transmission experience in a given country - which options works best?
Global trial experience	Number of sites which have used the vendor's eCOA system?	Number of countries which have used the vendor's eCOA system?	Number of languages that have been used in the vendor's eCOA system?
Indication experience	Number of trials conducted in the specific indication?	Experience helping sponsors get PRO-based label claims approved by regulators?	Experience with specific instruments and development/migration of instruments?
Internal business processes	Are quality standards & processes formalized?	Enterprise resource planning?	ISO 9001:2008 Certification?
Project management	In-house or contracted?	PMP-certified professionals?	Repeatable process with backup options in place?
Regulatory experience	Number of site audits?	Number of company audits?	Number of warning letter(s) received?
Support center/help desk	In-house or contracted?	24/7?	For sites and/or patients?
System design	Is eCOA scientific consulting free or fee-based?	Are eCOA best practices provided free or fee?	Are libraries available for standardization?
System testing	Process and documentation for validating the trial-specific system and system complies with all relevant regulations and guidance?	UAT process - tested only by sponsors or by provider and sponsor?	
Training	Investigator meeting training?	Online training available?	Proof of training in archive?
Trial close	Archive for sites, sponsors?	Are all trial components archived so the trial can be recreated upon inspection by regulators?	
Provider continuity	Financial stability?	Profitability?	Staff longevity?

TABLE 1. Checklist for eCOA provider selection (alphabetical)

APPENDIX B

Considerations for selecting eCOA and integrated medical devices

Critical eCOA device requirements	The display screen is large enough to display entire question and answers, to avoid possible scrolling bias.
	The screen is bright and clear with legible text, numbers, buttons and scales.
	The exact device selected will be available and supported throughout trial duration, in order to avoid mid-study delays with cognitive debriefs. If the exact device selected is not available through study end, the replacement device must operate in the same manner.
	The screen is large enough in height and width to accommodate translations, especially of voluminous languages such as German.
	The device has sufficient memory to host all diaries and questionnaires required of protocol.
	The device performs on-device calculations (without requiring server connection) for eligibility determinations, safety calculations, etc.
	The device is sturdy, able to withstand regular use in a clinic and by a patient without damage.
	The device battery will sufficiently power one full day, and comes with a convenient charger pack.
	The device vendor provides operational metrics and best practices gleaned from similar trials, at no cost.
	The device is able to transmit data via 3, 4, 5G, Wifi and analog networks.
	The device can be used "offline" so patients and sites can enter and store data at any time regardless of network availability.
	The device is secure with no ability to tamper or change the data stored on the device or the application itself.
Device can be used for more than one patient in a trial — e.g. a patient completes the trial, same device can be used by another patient.	
Options that improve study power	Wireless integration with medical devices, such as PEF meters, glucometers and activity meters, to collect objective data in addition to PRO.
	The device clock automatically adjusts to changes in time zones, to accommodate patient travels.
	Mid-study changes are managed electronically, without having to exchange devices.
	The device can trigger email alerts to clinicians for safety concerns, based on data input and on-device calculations.
	The device can trigger email or text alerts to patients for reminders of diary entry and/or medication.
Critical requirements for integrated medical devices	Patient privacies are protected.
	Data are eSource.
	Data are attributable, contemporaneous, original, accurate, complete, consistent, enduring and available.
	Device data are sufficiently sensitive for clinical trial use.

TABLE 2. Checklist for eCOA and integrated medical device selection

ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, ERT's solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. In 2017, ERT supported 60% of all FDA drug approvals. Pharma companies, biotechs and CROs have relied on ERT solutions in 13,000+ studies spanning more than three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.

