7 REASONS TO IMPLEMENT ELECTRONIC DATA COLLECTION IN YOUR NEXT CLINICAL TRIAL

Your guide to improving study performance and timelines
WHAT EXACTLY IS eCOA?

Let’s take a brief look at some fundamentals of electronic clinical outcome assessment (eCOA):

- **Patient diary**: Tool used to collect subjective data from a patient, including symptoms, condition and other measures; traditionally, this has been paper-based

- **Electronic patient diary (eDiary)**: Electronically registers patient data and automates data entries on, for example, a handheld mobile device, tablet or computer

- **Clinical outcome assessment (COA)**: Measurement used to evaluate patient safety and quality of life; COA measures include:
  - **Patient-reported outcome (PRO)**: Health outcome reported directly by the patient
  - **Performance outcome (PerfO)**: Measurement based on task[s] performed by a patient according to instructions administered by a healthcare professional; medical devices can be integrated to collect and record objective measures such as motor, sensory and cognition
  - **Clinician-reported outcome (ClinRo)**: Using their clinical judgement, physicians, nurses or other site staff report patient health outcomes after observing the participant’s health condition
  - **Observer- or caregiver-reported outcomes (ObsRo)**: Health outcome reported by the patient’s family or other caregiver

- **Electronic clinical outcome assessment (eCOA)**: Employs technology such as handheld devices, tablets or web to allow patients, clinicians and caregivers to directly report outcomes, resulting in more granular endpoint data; eCOA measures include ePRO, ePerfO, eClinRO and eObsRO
7 REASONS TO IMPLEMENT eCOA

Are you introducing unnecessary risks into your clinical trial by relying on outdated, error-prone paper diaries to collect patient outcomes? Instead, accelerate your research and improve data quality with eCOA.

In this guide, we explain the fundamentals of eCOA and discuss how sponsors and CROs of all sizes can cost-effectively reduce risk and generate higher-quality data by collecting data electronically in their next study. Click on each chapter below to jump to that section of this guide.

1. GENERATE HIGH-QUALITY DATA
2. PROVIDE REAL-TIME INSIGHTS INTO PATIENT SAFETY
3. PROVIDE REAL-TIME INSIGHTS INTO STUDY PERFORMANCE
4. ENABLE SHORTER STUDY TIMELINES
5. REDUCE STUDY DEVELOPMENT COSTS
6. INCREASE PATIENT ENGAGEMENT AND COMPLIANCE
7. EASILY INTEGRATE WITH DIFFERENT DATA SOURCES

FOUR STUDY CONDITIONS IN WHICH eCOA IS MOST APPROPRIATE

- When patient enrollment is potentially difficult
- When sensitive or personal data are collected
- When data are used for an FDA/EMA/other agency for Fast Track, Accelerated Approval or Priority Review
- When data are used to support new drug approvals
GENERATE HIGH-QUALITY DATA
A growing majority of clinical trial stakeholders, including sponsors, CROs and regulatory bodies, view eCOA as the most effective way to deliver higher-quality and more reliable data. Here are some of the ways eCOA does this.

Meets global regulatory standards
Regulatory bodies recommend that the data collection method ensures data are collected and reported according to protocol requirements. Unlike paper diaries, eCOA ensures data meet regulatory quality guidelines, including ALCOA standards, meaning data must be fully Attributable, Legible, Contemporaneous, Original and Accurate. By meeting these fundamental elements of quality, regulators’ queries regarding patient-entered data are virtually eliminated.

Prevents inconsistent or conflicting data
Digital data collection uses branching and logic sequences to guide patients through the appropriate questionnaire in the order set out in the study protocol. Patients are prevented from skipping questions or entering inconsistent or conflicting data.


REDUCE DATA VARIABILITY BY 40% WHEN USING eCOA
Eliminates transcription errors

Paper studies require site personnel to manually transcribe data into the trial management system or spreadsheet, leaving greater opportunity for errors and other inconsistencies. With eCOA, those steps are automated electronically, eliminating transcription errors. Any inconsistencies, missing data and other data quality issues are detected in real-time at data capture.

Avoids study bias with predictable data collection

Global regulatory bodies mandate that the validity of the data capture process is fundamental to ensuring that high-quality data are generated as part of a trial. Regardless of whether data is collected electronically or by paper, the process must ensure all required data are captured in a consistent manner. You can facilitate predictable data collection and avoid study bias with the universal screen features and functions offered by eCOA.

Tip

Paper may be a viable option for COA data that are not personal in nature, where there are no plans for COA data submission or for supervised COA data collection such as in clinics. However, before settling on paper-based collection, consider whether any potential benefits outweigh paper’s very low patient compliance rates, poor data quality, inability to integrate with EDC systems, medical devices and other systems.

DOWNLOAD THIS CASE STUDY TO LEARN HOW ONE PHARMA USED eCOA TO REDUCE DATA VARIABILITY BY 40%.
2 PROVIDE REAL-TIME INSIGHTS INTO PATIENT SAFETY

Access to real-time data promotes early detection of potential safety concerns, including abnormal diary entries, extreme patient dosages and adverse effects. Any out-of-range data can be flagged and immediate action taken by site staff. With paper, these data might not be flagged or picked up until the next scheduled clinic visit. Let’s review a few of the ways eCOA provides real-time insights into patient safety.

Pre-built key risk indicators

With eCOA, your study administrators can pre-configure key risk indicators (KRIs), set data thresholds and identify areas for proactive mitigation. This allows you to rapidly predict and identify root causes of risk by date ranges, geography or other subsets of studies and sites.

RECEIVE AUTOMATED EMAIL ALERTS BASED ON PRE-DETERMINED KEY RISK INDICATORS
Automated trigger alerts and customized messaging
Site personnel can track patient safety and KRIIs in real-time, including low compliance and symptom worsening. If a patient assessment is flagged for a potential risk indicator, the system automatically triggers a notification and designated users at the site are immediately alerted via automated emails. Site personnel can then take appropriate corrective action per the trial protocol. None of these automated measures are available with paper-based COA collection.

Predictive analytics
Looking in the rear-view mirror at retrospective or historic data does not enable you to proactively identify and mitigate risks before they develop into more substantial issues. With eCOA, you can incorporate real-time reporting and predictive analytics to proactively mitigate risks—or avoid them altogether—and affect positive outcomes.

Tip
Ask your eCOA provider to provide a demo of their analytical and reporting capabilities. Do they provide role-based, real-time access to trial data and risk indicators? Does the solution include pre-built KRIIs that are informed by industry best practices and regulatory standards?
3 PROVIDE REAL-TIME INSIGHTS INTO STUDY PERFORMANCE

With paper data collection, you must wait for manual data transcription, quality checks and verification that require additional resources and tend to be more error-prone. Only then will you discover queries and issues that must be resolved before study close-out. Let’s review how eCOA provides real-time insights into study performance.

Centralized study data

With eCOA, you have the opportunity to centralize all of your clinical and operational data in one location to provide actionable intelligence across studies, sites and patients. You can access that data in real-time to view early and interim study results to better manage your development pipeline, including for regulatory review or to seek funding.

Tip

Ask your eCOA provider to provide a demo of their analytical and reporting capabilities. Does the solution allow you to visualize performance metrics and predict milestone achievements? Does the solution include pre-built KPIs that are informed by industry best practices and regulatory standards?

DOWNLOAD THIS CASE STUDY TO LEARN HOW CELGENE STREAMLINED MONITORING AND DATA CLEANING WORKFLOW BY USING eCOA.
Plan next-best steps
eCOA allows you to take these real-time insights and plan any improvements or remedial actions, assign tasks to your project team and then track status to ensure appropriate steps are being taken. For example, interim analysis reports can help you identify underperforming sites to help get them back on track or monitor compliance and encourage patient participation where necessary.

Heat mapping for at-a-glance risk analysis
Rather than relying on retrospective or historical data, eCOA allows you to leverage real-time data to better manage and predict trial performance. Heat mapping can provide at-a-glance identification of problem areas related to patient and site enrollment, compliance and trending issues, visit schedules and device inventories.

Role-based views of study performance data
eCOA provides greatly enhanced collaboration across all stakeholders with shared visibility into key performance indicators (KPIs). Role-based user views provide stakeholders access to detailed reporting of performance issues and other problem areas, as appropriate.
ENABLE SHORTER STUDY TIMELINES

Higher-quality data leads to operational efficiencies and, ultimately, shorter study timelines. For example, using eCOA leads to fewer queries, enables faster query resolution and avoids time-consuming manual source document verification. Here’s how eCOA can help shorten time-to-market.

**Creates operational efficiencies**

eCOA processes and workflows are much more efficient than paper. Simple log-in procedures, easy patient set-up and streamlined visit management reduce site burden. In addition, real-time data collection, centralized data management and wireless information exchange with integrated medical devices and wearables dramatically reduce site workload and the volume of queries generated.

**Tip**

For your next study, consider whether eCOA can provide more scientific “power” to resolve discrepancies and prove efficacy. Research has found that a reduction in data variability with eCOA translates into an increase in study/statistical power or a reduction in the required number of patients required to reach study power.

DOWNLOAD THIS CASE STUDY TO LEARN HOW ONE PHARMA ELIMINATED THE BURDEN OF 80 CLINICAL INTERVIEWS PER SITE WITH eCOA.
Enables real-time data transmission

eCOA supports frequent and reliable data transmission for real-time upload to your study database. Seamless (and secure) data transmissions can reduce the need for data clarification forms and decrease the time from last patient, last visit (LPLV) to final data transfer.

Streamlines the submission process

With eCOA, you can provide documentation that meets regulatory requirements, including a complete archive for each site and one with de-identified data for sponsors. Archives must be in the required PDF-submissible format and contain all data and documentation necessary to recreate any trial for regulators.

DOWNLOAD THIS CASE STUDY TO LEARN HOW ONE PHARMA REACHED 95% STUDY POWER WITH FEWER THAN HALF THE PATIENTS USING eCOA.
5 REASONS TO IMPLEMENT ELECTRONIC DATA COLLECTION IN YOUR NEXT CLINICAL TRIAL

REDUCE STUDY DEVELOPMENT COSTS

Some sponsors and CROs are reluctant to convert from paper studies because of the misperception that eCOA studies are more expensive and cost-prohibitive to implement, especially for smaller and mid-sized organizations who may lack expert internal resources to guide the process. This is not the case! Here are some ways eCOA can help you save money by cutting development costs.

No hidden costs

There are many hidden expenses associated with paper-based studies. For example, data transcription and data entry can introduce errors, poor-quality data, and, ultimately, incur greater costs. The additional site staff and administrative costs required to manually monitor study performance, reconcile issues, resolve data queries and physically archive paper-based data adds up to great expense. When all the hidden costs of paper are revealed, eCOA often emerges as the less risky, more cost-effective solution.

Electronic system validation
Since eDiaries and questionnaires are recognized as actual source documents, no manual source document verification (SDV) is required. Given the data volumes represented by eDiaries, the replacement of SDV by electronic system validation saves weeks of time and travel, and 30-50% of the cost of a trial. Additionally, final data analysis sets can be provided within days of a trial’s conclusion.

Dramatically reduce provisioning logistics and expenses
If a Bring-Your-Own-Device, or BYOD, strategy is used, overall cost savings are further magnified. The BYOD approach substantially reduces the number of provisioned devices required. Instead, patients can use their own mobile phone, tablet or computer to record outcomes. This brings the added benefit of familiarity, as patients are typically more comfortable reporting outcomes on devices already familiar to them — and that they usually have with them in their daily lives.

Tip
Consider all your trial needs at the onset and order any required provisioned devices accordingly to keep your trial budgets and timelines on track. Costs add up quickly when eCOA devices must be shipped urgently overnight, so have adequate devices when and where they are needed, especially to keep high-performing sites fully stocked. Consider regional depots for additional devices that may be required in countries with challenging import regulations.

30-50% savings in overall trial costs when validating eDiaries electronically

DOWNLOAD THIS CASE STUDY TO LEARN HOW eCOA SAVED CELGENE $13 MILLION IN OVERALL TRIAL COSTS.

INCREASE PATIENT ENGAGEMENT AND COMPLIANCE

Compliance tends to increase and study drop-out levels fall when patients are more engaged with the clinical trial. When patients are attentive and inputting data when they’re supposed to according to the trial protocol, compliance can reach well over 90%, compared to just 11% with paper. Here are some of the ways patient engagement and compliance are higher with eCOA than with paper diaries.

**Electronic reminders and dynamic messaging**

Patients are more likely to take scheduled medicine and dosages — and complete diaries at the correct time — with the help of electronic reminders/alerts. Animated compliance feedback and dynamic, context-sensitive messaging increase eDiary compliance, keeping patients motivated and personally engaged.


Configurable workflow with validated controls and checks

eCOA allows you to configure workflows specific to your unique protocol. Patients are actively guided by the device logic, remaining engaged in prescribed activities. Validated controls and edit checks prevent what’s known colloquially as “Parking Lot Syndrome,” where patients backfill multiple diary entries just before their appointment, or fill out data in advance. As patients complete diary entries at times specified by the study protocol, authorized clinical site personnel can see the timestamp of each patient’s entry.

Enables reporting of sensitive, personal patient information

Research shows that patients are more willing to provide complete data when given the opportunity to record symptoms and other feedback without embarrassment. In a study of patients with breast cancer, there was a higher response rate for an item on satisfaction with current sex life among those who responded on an electronic tablet compared to paper. eCOA gives patients confidence that caregivers and family don’t have access to their personal information.

**Collect data from diverse patient populations**
You can easily collect data from diverse patient populations with eCOA’s BYOD multi-modality capabilities, regardless of sociodemographic factors. Using their own mobile phone, tablet or computer, patients can use the device most familiar to them to record outcomes.

**Consistent, standardized assessments**
Screen features and functions that are familiar to patients facilitate consistent and predictable data collection, avoiding study bias. You can further increase compliance rates and standardize the use of any required devices or instruments by providing instructions, standardized scoring, rater training and gating on the correct use of required instruments or devices.

**Tip**
To minimize the impact of patient fatigue, order questionnaires by importance of secondary endpoints, so the first questionnaire patients see is the key questionnaire needed.

**DOWNLOAD THIS CASE STUDY TO LEARN HOW GILEAD EXPERIENCED 98% COMPLIANCE WITH eDIARIES.**
**7 EASILY INTEGRATE WITH DIFFERENT DATA SOURCES**

Stop manually collecting and collating patient data from different sources. With eCOA, you can save time and study costs by integrating with multiple data sources, including medical devices, wearables, EDC systems and IVR. Here’s how eCOA eases integration with other systems.

**Collects objective data in addition to ePRO**

Wireless integration with medical devices such as spirometers, glucometers and activity meters allows you to collect objective data in addition to PRO. All eCOA devices must be validated for accuracy and safety, and must store and transfer data privately and safely within a tamper-proof eCOA data collection and storage system. eCOA collections work synergistically with integrated measures to provide more granular endpoint data for your study.
Simplifies data transmission
By integrating with, for example, medical devices and wearables, wireless transmission of data to the study database is simple and secure. This automation further increases overall data quality and offers real-time visibility for sites and study teams.

Accounts for data management needs
While ePRO, eClinRO, eObsRO and ePerfO are eSource data, integrations with objective measures from devices, labs and perhaps images and electronic medical records (EMRs) may also contain primary and secondary endpoints required for the protocol analyses. Additional endpoint integrations can increase the complexity of each trial and require data cleaning and reconciliation.

Tip
The volume of eCOA data for any study can be very high. As eCOA data may stream from multiple medical devices, centralized labs, clinicians, observers/caregivers and patients, your data management team should anticipate and plan for this volume. Make sure your clinical trial management system (CTMS) is able to integrate disparate data sources from different systems. In the long run, this will save considerable time and money, plus reduce IT burden and cost.
ACCELERATE YOUR RESEARCH AND PROTECT YOUR TRIAL FROM RISK

ECoA adoption will continue to expand as the benefits of electronic data collection are quantified. ECoA administration is an efficient use of time and resources—and is preferred by patients over paper-based assessments. Additionally, leveraging familiar modalities such as smartphones, tablets, and browsers enables patients to complete COAs easily and effectively without the costs and potential for errors typically seen in paper-based studies.

Technologies that reduce researchers’ time while reducing the risk for data errors invariably benefit the patient. Implementing eCOA is not a complicated or burdensome process when planned for and executed using best practices. The far-reaching benefits of eCOA significantly outweigh any perceived issues, which is why it is expected that technology adoption will quickly prevail over the reluctance of some sites and clinical teams to migrate from paper to electronic methods.

7 REASONS TO IMPLEMENT ECOA:

1. Generate high-quality data
2. Provide real-time insights into patient safety
3. Provide real-time insights into study performance
4. Enable shorter study timelines
5. Reduce study development costs
6. Increase patient engagement and compliance
7. Easily integrate with different data sources
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.