

EVIDENTIQ ECOA SOLUTION ____

Clinical Outcome Assessments and Patient-Reported Outcomes are being increasingly utilized throughout the industry to demonstrate efficacy and safety for the comparison of treatments in health policy decision-making processes. These instruments provide real-world data throughout all phases of studies with an increased value and understanding of outcomes.

Many sponsors and CROs continue to rely on outdated, error-prone paper diaries for capturing important patient reported outcome (PRO) data that may be injecting unnecessary risk into their clinical trials. Regulatory bodies such as the FDA and EMA recommend that COA data collection methods ensure that data is gathered and reported according to protocol requirements. Unlike paper, eCOA data meets regulatory quality guidelines, meaning they are Attributable, Legible, Contemporaneous, Original and Accurate (ALCOA). Therefore, those who turn to eCOA data capture benefit from improved data quality, regulatory compliance, and accelerated clinical development.

When the success of your organization's work relies on accurate and rapid patient data, why leave the future in the hands of paper?



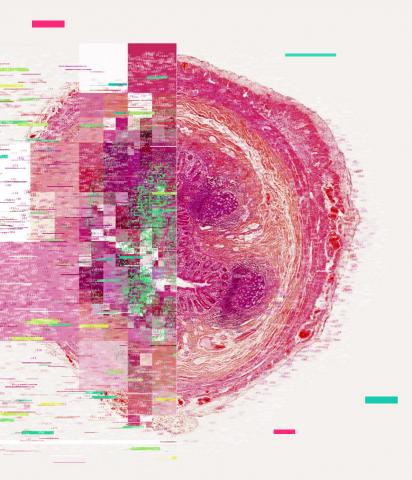
EvidentIQ eCOA solution includes the following services and digital solutions:

- Protocol writing and/or protocol review services
- Standard questionnaire/eDiary selection services
- Custom questionnaire/eDiary build services
- Questionnaire/eDiary validation services
- EvidentIQ eCOA application and mobile device portal technology
- eCOA application technical setup services
- eCOA data analysis services and dataset creation
- Integration with EDC



EVIDENTIQ ECOA CAPABILITIES

With our full eCOA solution, EvidentIQ is bringing together industry-leading data science services with cutting-edge technology. Our customers can benefit from our end-to-end comprehensive eCOA package or create value by selecting certain elements that meet specific requirements. Our solution can be used stand-alone as it is independent of any specific eClinical technologies such as EDC systems, but it can also be integrated into any existing eClinical software landscape. It has been created to collect any patient/clinician/observer reported outcome data in a streamlined, compliant, and efficient way.



EDC Agnostic

The EvidentIQ eCOA solution integrates with multiple EDC providers.

Highly Configurable

Build complex electronic data capture forms for use during in-clinic or virtual visits. EvidentIQ eCOA data capture forms include all standard form fields, text, and scale based-questions, image hotspots, smart notifications, and data checks required for most protocols.

Message Scheduling

Schedule notifications for every important step of your clinical research so as to ensure your endpoints are addressed.

Meets Global Regulatory Standards

EvidentIQ technology meets all regulatory requirements for security and integrity of data in trials.

Multilingual Support

Selectable language for surveys/scales, allowing participants to complete surveys in their native language.

Ensure Data Integrity/Quality

eCOA enables real-time data streams and accurate timestamping and data entries, which improve the quality of the data coming in for a given study. In addition, this data is encrypted and protected, ensuring patient data integrity.

Instant Notification

Instant email notifications can be sent whenever needed to inform the patient about treatment updates or visits.

Device Agnostic

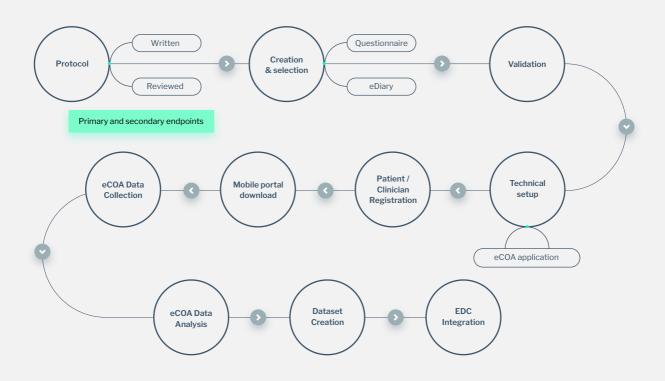
EvidentIQ eCOA is easily accessible from a variety of devices for contributing data and conducting study activities with site team members and participants.



ECOA BENEFITS

eCOA by EvidentIQ

Better, Faster and More Reliable Data.



We aim to build strong partnerships with our clients.

Our teams of project and data managers support small and large pharmaceutical companies, CROs, and sponsor teams throughout the project to deliver a high-quality service that is adapted to client needs and to leverage our 19 years of data management and system expertise. This results in effective and efficient data system integrations. A team of data managers is assigned to each trial to establish the specifications, manage the data throughout the trial, and ensure a clean final database.

We support a bring-your-own-device (BYOD) strategy – **on any device**. We assist our customers with scientific services to review their protocols, proposing standard questionnaires/eDiaries that address their primary and secondary endpoints, or building a custom offer.

We then validate the questionnaires/eDiaries against industry standards and medical requirements, and then set them up in our eCOA application.

After registration, patients/clinicians will receive an automated email with a link to download a portal to their smartphone or tablet. Patients/clinicians can then access the questionnaire/eDiary and enter data. Once the data has been collected, EvidentIQ will analyze the data according to the protocol and deliver the **results in datasets** to our clients. These datasets can then be loaded into the customer's **respective EDC application**.



THE EVIDENTIQ PLATFORM

Our new eCOA offering perfectly demonstrates how we create value for our clients and in doing so build a unique market position for our group.

We empower life science companies of all sizes to transition from outdated, error-prone, paper-based processes to digital data capture and processing.



66

After observing the evolution of the eClinical sector, we decided that now is the right time to develop this solution to better respond to the industry and our clients' needs.

I am proud of our team for responding to this challenge with an exceptional product.

ANDREAS WEBER
EvidentIQ Group CEO

ABOUT US

EvidentIQ is a next-generation technology-amplified data science group championing new standards in value creation and innovation-driven relevance for customers. The EvidentIQ offering brings a pioneering end-to-end eClinical solution that meets increasing customer demand across clinical operations and clinical data management needs, with a suite of applications within a single-integrated cloud platform

By combining its platform with a broad data science service portfolio such as patient recruitment, patient engagement media, and a host of RWE late-phase solutions, EvidentIQ significantly helps customers to optimize HTA submissions, pricing, and reimbursement needs.

EvidentIQ supports 7 of the top 10 pharma companies through novel RWE solutions and 150+ SMB customers in over 20 countries, including the US. Germany, France, the UK, Italy, Japan, and China