Insight Brief

Accelerating Study Start Up Through An Electronic Clinical Outcome Assessment (eCOA) Library

IQVIA's global library of pre-built assessments gives sponsors instant access to validated tools that capture the patient's perspective in a given study.

KRIS GUSTAFSON, Vice President, Global Head Patient Centered Technologies, IQVIA
PIERO BINDI, Associate Director, eCOA Library, IQVIA

Table of contents

Introduction

As the pharmaceutical industry continues to move towards a more comprehensive picture of treatment benefits for new drugs in development, patient reported outcomes have become a new benchmark for regulators and payers to measure the quality of a drug or therapy. This shift has made Clinical Outcome Assessments (COAs) an increasingly necessary and often required tool in the clinical research landscape.

COAs offer a direct line to patients, capturing insights about experiences with their disease, the trial, and its impact on their quality of life. And now electronic COAs, or eCOAs, are enabling this in real time. These insights give patients a chance to be heard while providing sponsors with patient-relevant endpoints to better understand the impact and efficacy of a treatment. Capturing insights directly from patients helps researchers design trials around their needs, while increasing the likelihood of drug approval and reimbursement.

However, creating and validating a COA in an electronic format adds months to the trial planning process. Sponsors can spend 12–16 weeks at a minimum building an assessment in an eCOA system, validating it against standards, qualifying it with relevant approvers, and adjusting/translating the tool as necessary. In many cases, revision and approval delays cause this planning step to extend well beyond the deadline, delaying first-patient- in milestones, which can drag the entire schedule off track.

This adds time and cost to the trial. It also increases the risk that the questions they ask will vary from assessment-to-assessment, making it more difficult to compare results across trials or patient populations.

Historically, sponsors have repeatedly re-created standard eCOAs for every trial, but what if they didn't have to? The industry has enough experience in eCOA development and validation that sponsors could leverage existing assessments in new trials with minimal or no modifications.

IQVIA has created a standardized library of assessments, pre-built for use in a range of trials to meet patient-reported outcome goals. Sponsors can instantly deploy the eCOA tools in the library as part of their trial process.

>1,550

PRE-CONFIGURED ASSESSMENTS IN THE IQVIA LIBRARY AND GROWING

To fill this need, IQVIA has created a standardized library of assessments with more than 1,550 eCOAs that have been pre-built for use in a range of trials to meet patient reported outcome goals. The library is a one-stop-shop for eCOA tools, which sponsors can instantly deploy as part of their trial process. This collection of industry validated assets promises to accelerate trial delivery while ensuring every assessment captures the right data at the right time.

The evolution of COAs

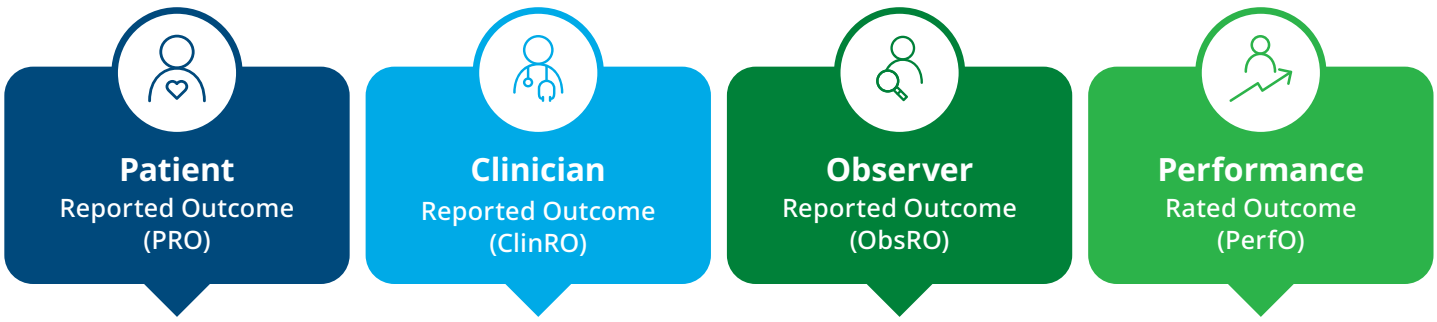
When a patient is ill and receiving treatment, their primary goal is to feel better. It's a simple idea but one that isn't always adequately captured in clinical or real world settings. Historically, endpoints have focused on clinical indicators such as tumor size, delayed disease progression, and absence of side effects. While these are excellent measures of a treatment's impact, they don't measure how these changes make patients feel or function.

Do they have more energy? Can they walk up stairs? Are they in pain? Do they experience nausea? These feeling- and function-measures are more meaningful for patients than tumor size or biomarker measures, and can only be captured through the patients' point-of-view.

COAs provide those insights in a regulated format that can be easily reviewed and monitored. When sponsors adopt COAs in trial planning and design, it provides a means to better understand the patient experience, which is fundamental to demonstrating that a drug is safe, effective, and ready for market.

According to the FDA, a COA is a "well-defined and reliable assessment of a specified concept of interest for use in adequate and well-controlled studies in a specified context of use."[i] Simply put, a COA is "a measure that describes or reflects how a patient feels, functions, or survives."[ii] COAs must measure a specific concept that can be clearly interpreted as part of regulatory decision-making, and that the data is reliable enough to support conclusions about the stated context of use.

Measuring the patient experience



COAs — Clinical Outcome Assessments

eCOA platforms intelligently automate capturing patients' experiences through robust and reliable electronic measures, providing **real-time insights** that inform trial progress and demonstrate results.

i https://www.fda.gov/drugs/drug-development-tool-qualification-programs/clinical-outcome-assessment coa-qualification-program
ii https://www.fda.gov/about-fda/clinical-outcome-assessments-coa-frequently-asked-questions#COADefinition

COA is a broad term that encompasses the following: patient reported outcome (PRO), clinician reported outcome (ClinRO), observer reported outcome (ObsRO), and performance outcome (PerfO).

For example, these can include questionnaires that evaluate a patient's perception of pain (PRO), clinician's evaluation of the severity and extent of psoriasis (ClinRO), or a caregiver's report of a patient's ability to perform activities of daily living (ObsRo). PerfO measures the patient's performance on a specific task as measured by a healthcare provider such as a 6-minute walk test. It's important to understand that all COAs can reflect the patient's experience. In other words, we can understand what a patient is going through by obtaining patient-centered information from clinicians, parents/caregivers, performance on specific tasks, and the patients themselves.

Simply put, a COA is "a measure that describes or reflects how a patient feels, functions, or survives."

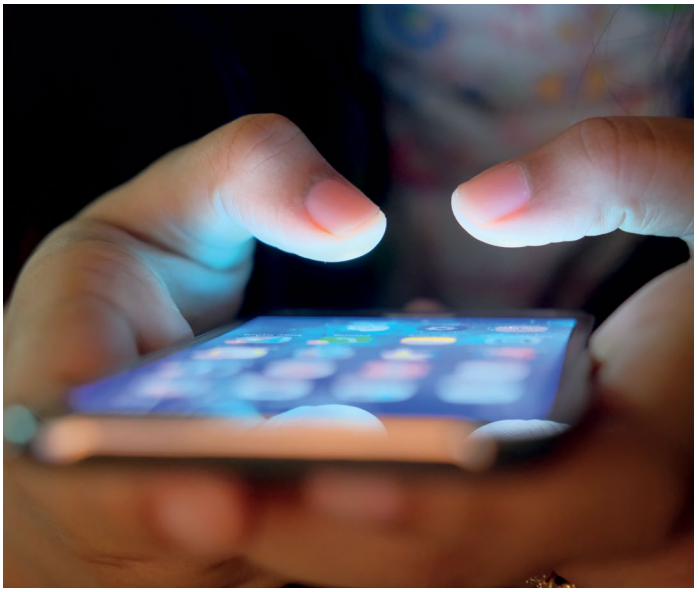
COAs go digital

COAs were originally paper-based, however, the evolution to eCOAs have made them more valuable and reliable.

Paper-based assessments led to opportunities for inadvertent fraud, for example, when patients complete a month of diary entries in the parking lot before an appointment. Paper formats are also easily lost or damaged, can be filled out incorrectly, and have to be transcribed, which adds time and risk of transcription error to the data collection process.

eCOAs eliminate many of these risks by intelligently automating the capture of the patient's experience. These electronic measures collect and share data in real time, which eliminates the 'parking lot effect', reduces the risk of transcription error, and ensures all data is captured in the same format for easier review. eCOAs can also include alerts reminding patients to complete the assessment on a schedule, and validation rules that prevent them from recording data in the wrong field or format.

All of the benefits of a digital format make it easier to capture accurate data, identify adverse event risks, and demonstrate value and efficacy from a patient perspective.



eCOAs on demand

Trial sponsors develop new eCOAs for trials based on the data they want to collect, the questions they want to ask, and the format that best meets the needs of patients. It generally takes three-to-four months to build and review a new electronic assessment and have it approved by relevant stakeholders. Sponsors are sometimes able to re-use standard industry assessments in a trial, but historically, they had to redevelop the same eCOA for each use, adding time and cost to the process, along with the potential for error.

In clinical research there are rarely shortcuts. However, when it comes to eCOA, we have a solution that reduces this process from months down to potentially less than a day.

IQVIA's library of assessments: a one-stop-shop for eCOA tools

>1,550

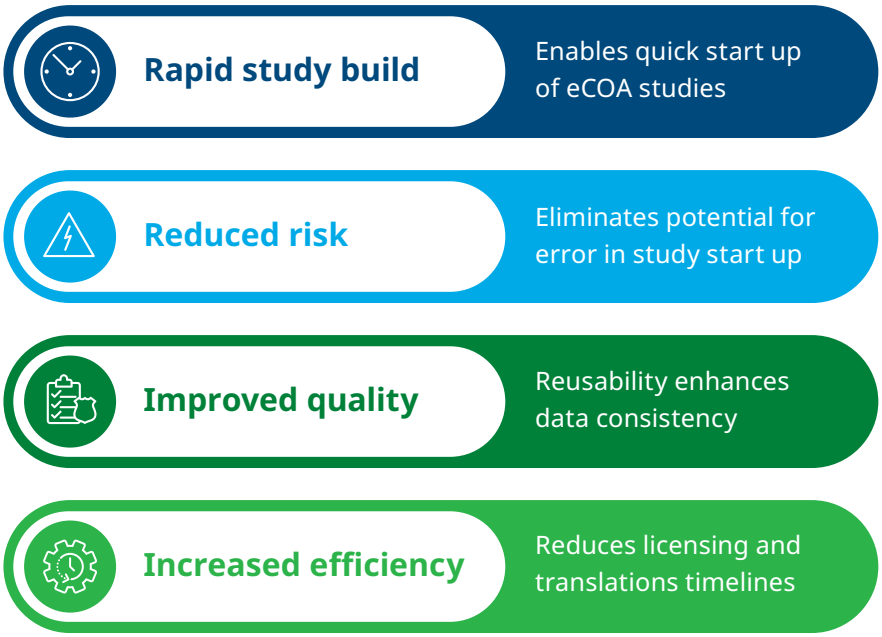
Pre-configured assessments in library and growing

Assessments in the library can be

- Author approved
- System validated
- Available for all devices
- Available in multiple languages

Ability to build a customer specific library, which ensures customer standards are met

Key customer benefits:



With IQVIA's eCOA solution, we have an opportunity to capture those best practices and share them with our clients. Our team of assessment experts reviewed thousands of eCOAs and interviewed hundreds of medics to identify the surveys, questionnaires, and standardized tasks most commonly used in trials. We selected the top instruments, which are now available on-demand from the IQVIA eCOA library of assessments. There are currently more than 1,550 assessments available in the library for our clients and we will continue to expand.

For example, IQVIA's Treatment Satisfaction Questionnaire for Medication (TSQM) is available within the library, which is a popular industry instrument that conceptually and psychometrically evaluates a patient's experience of a medication's effectiveness, side effects, convenience, and satisfaction, enabling comparisons across medication types and diseases.[iii] Other examples of approved industry assessments in the IQVIA eCOA library include several PROMIS Measures and Oxford University's Parkinson's Disease Questionnaire (PDQ-39/8).

Each assessment can be validated against approved standards, translated to relevant languages, and scientifically validated so that it is ready for use immediately.

Having access to these vetted assessments means sponsors do not have to worry about potential delays from this process, which provides valuable flexibility in the event that late changes need to be made to the eCOA strategy for a trial. This ensures confidence that the selected assessments will capture the real-time insights needed to inform trial progress and demonstrate results, potentially speeding the journey to market.

iii https://www.iqvia.com/landing/treatment-satisfaction-questionnaire-for-medication-tsqm

Conclusion

Since the launch of the IQVIA eCOA solution, clients have been amazed by the ease of use and time savings the library of assessments brings to their planning process. After a quick review, they are finding and deploying eCOAs quickly, eliminating the risk of delays, and speeding their ability to begin recruiting.

This library is an exciting next step in the quest to create a more agile, and patient-centric clinical research environment. We look forward to sharing this library with clients, and plan to keep adding new eCOAs to our platform to expand its value for users.

Contact us today for more information or to schedule a demo: ecoa@iqvia.com

About the authors

KRIS GUSTAFSON
Vice President,
Global Head of eCOA, IQVIA

As vice president and head of eCOA at IQVIA, Kris Gustafson leads a global team responsible for the strategic oversight and delivery of the IQVIA eCOA solution.

A biopharmaceutical industry veteran with more than 25 years of leadership experience in data management, information technology and clinical research, Kris has successfully led the integration, delivery, and management of technology solutions to meet customer needs. Kris joined IQVIA in 2012 and has held a number of leadership positions within the company, including the IT organization and was responsible for the delivery of multiple technology platforms. Prior to joining IQVIA, Kris founded a clinical technology company that developed IVR, IWR and ePRO products for clinical trials. Kris holds a Bachelor of Science degree in mechanical engineering from Washington State University.

PIERO BINDI
Associate Director,
eCOA Library, IQVIA

As Associate Director, eCOA Library, at IQVIA, Piero Bindi leads the eCOA Library project and is responsible for the management of collaborations with authors and copyright holders of assessments.

With more than 10 years of industry experience, Piero has developed extensive expertise in authorship, linguistic validation, licensing and electronic implementation of COAs. Piero joined IQVIA in 2020 and holds a BTS Management of Small and Medium-sized Firms from GRETA Lyon.

CONTACT US
iqvia.com/ecoa
ecoa@iqvia.com