Direct-from-Patient Data Capture with eCOA

Create better patient experiences and bring trials to market faster with IQVIA eCOA

IQVIA

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The need for Electronic Clinical Outcomes Assessments (eCOA)

Collecting accurate and timely data from patients plays a vital role throughout the developmental stages of a clinical trial — and the ability to quickly implement technologies to capture this data is essential. The sooner a trial is up and running, the sooner sponsors can recruit patients, collect data, and advance to market approval.

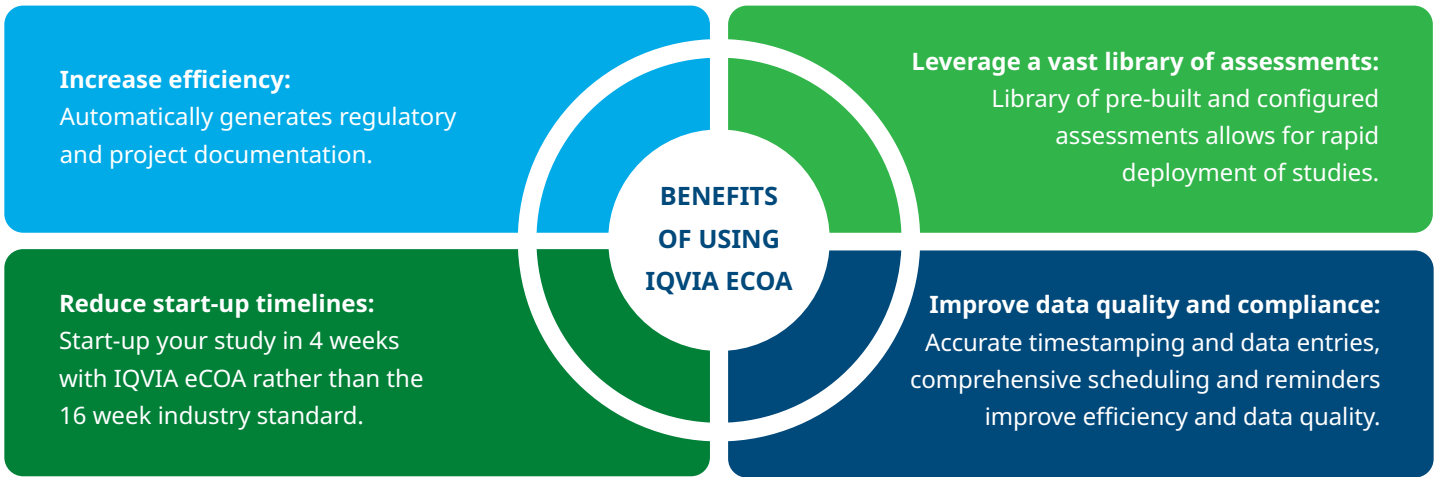
Patient data capture

The rapid start-up and speed to data can shorten a trial and accelerate a drug's path to market. eCOAs capture insights in real time about patient experiences with their disease, a trial and their quality of life on any new treatments. This kind of a tool provides patients a chance to be heard while giving sponsors quantitative and qualitative data to track the efficacy of a treatment.

This real time data that sponsors are able to leverage also allows them to:

- **Adapt to subpopulations of interest.** If sponsors are following an adaptive trial design, eCOA data can help them identify sub-populations who are experiencing better or worse results early in the trial, allowing them to shift course midstream. This early data may drive them to add or drop arms, adapt protocols, or modify inclusion/exclusion criteria to draw those patients most likely to respond to the treatment. That can help them generate the best possible results for their regulatory submissions.
- **Predict potential risks before they become serious.** Early patient recorded outcomes (PRO) data collection allows researchers to monitor patients and detect trends, such as poor sleep or increased pain. Because the data is instantly available for analysis, researchers can identify potential risks sooner so they can respond proactively.
- **Beat competitors to market.** The ability to accelerate start-up and speed to data can potentially shorten the trial and reduce time to market. This not only cuts the cost of the trial, it could help sponsors establish themselves as the first treatment in the market to address an unmet medical need. The impact of that can be huge. First-in-class drugs are more likely to be established as the standard of care, and to have a greater market-share advantage. One study found that when the first mover is a large pharma company, that advantage is worth greater than ten market-share points.
- **Stay connected with remote patients.** The pandemic forced many sponsors to adopt decentralized clinical trials (DCT), using telehealth, home health, and remote data collection. eCOAs gave them the tools to continue to monitor the patient experience, and to provide another conduit for patients to share data and stay engaged in the trial. DCTs are expected to be a permanent part of the trial landscape going forward, making eCOAs an important tool for patient engagement.

89% of respondents in a major study prefer eCOA/ePRO applications over paper diaries



Increase trial efficiencies

CUT OUT THE MIDDLEMEN BY WORKING WITH TRANSLATORS DIRECTLY IN THE ECOA PLATFORM

Our efficient study start-up process is further enhanced by an expedited translation process. Often, studies are conducted in multiple countries, so the assessments need to include multiple languages. We address translations in two ways:

1. Through our library of assessments and
2. Through a partnership with translation vendors.

To further increase efficiency for sponsors, we manage this translation process.

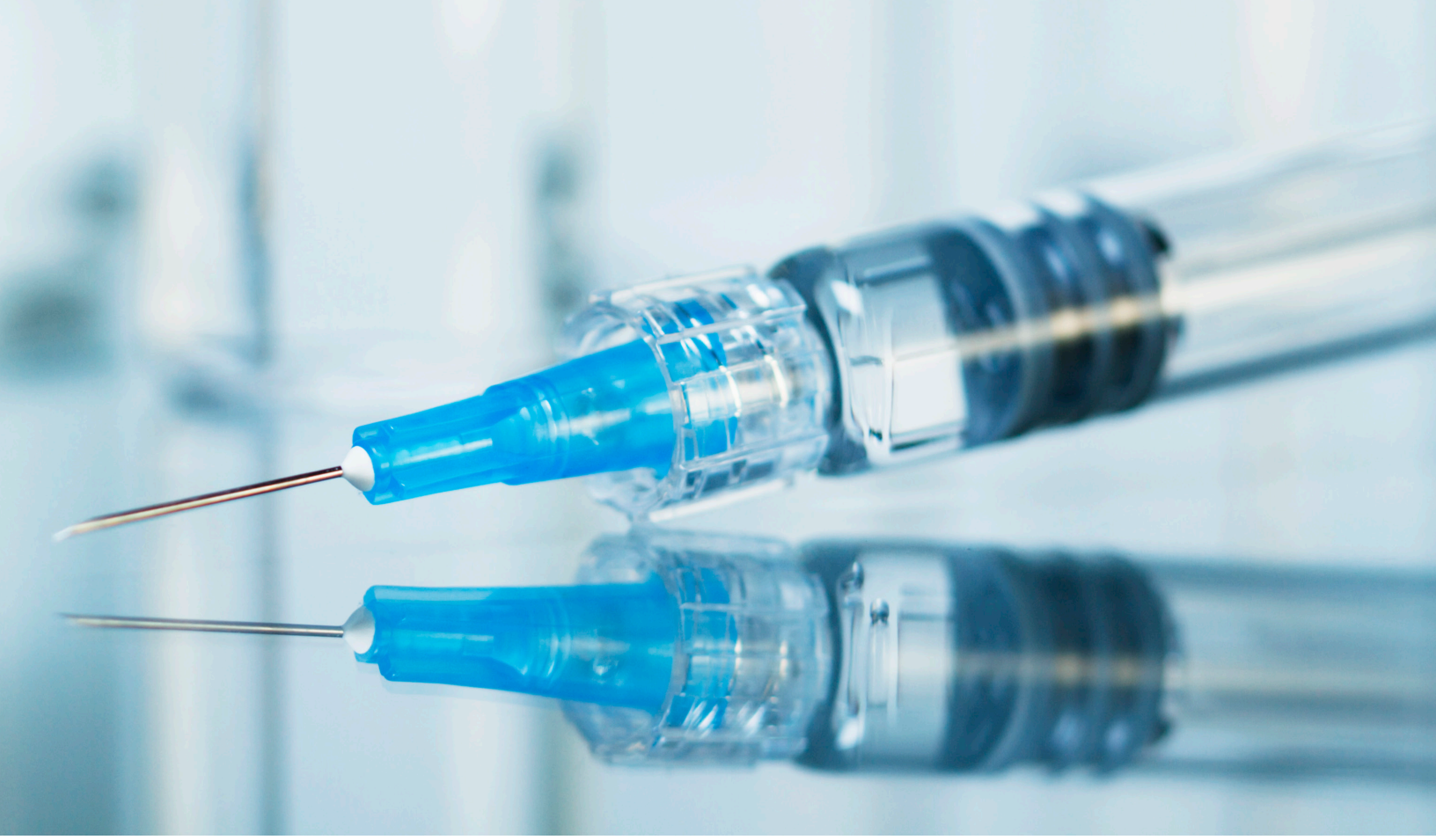
It's still very common for multiple stakeholders to work with a translation vendor through a 20+ step process, which means lots of back-and-forth between the eCOA vendor and the translation vendor.

Our approach is different: we cut out the middlemen and provide our translation vendors with access to our eCOA platform, which allows them to manage the translations themselves based on sponsor needs. This means fewer steps, fewer hand-offs, and fewer mistakes — so ultimately, a faster process. It's like removing players from a game of telephone — a better, clearer result in the end.

SAVE TIME AND REDUCE HUMAN ERROR WITH AUTO GENERATION OF DOCUMENTATION

Documentation is key not only for regulatory bodies, but also for Institutional Review Boards (IRBs) and Ethical Review Boards (ERBs). Collecting screenshots of an assessment, as well as any other user experience data needed, can be incredibly time-consuming if done manually. The hours and days needed to take those screenshots, resize them to fit the pages properly, and put them together in the right order is a tedious process that leaves room for lots of human error.

With IQVIA eCOA, as soon as an assessment is finalized, screenshots are automatically created within the system, and final, submittable documentation is created instantaneously. This documentation is also created for any translated versions. In addition, any time a change is finalized, a new version of the documentation is created automatically. This leads to massive time savings and eliminates human errors.



Efficiency in play: A vaccine use case

MILLIONS OF DATA POINTS

The speed with which study teams can review PROs using the IQVIA eCOA platform is dramatic. In a vaccine trial, by the end of day one, the eCOA already recorded more than 100 entries, giving the study team instant information about the participants' compliance and experiences with the vaccine.

Sponsors can also use automated analytics tools to monitor the data as it flows in to quickly identify important trends related to compliance. Automated analysis is critical in vaccine trials, which often have tens of thousands of participants and millions of pieces of data to analyze.

The instant access and analysis mean sponsors can more rapidly assess the vaccines safety and efficacy, and promptly respond to any potential adverse events that arise. In comparison, using a paper-based PRO approach, they may not capture those events until weeks after they occurred.

Along with faster access to data, eCOAs also provide more controlled results. For example, if an eCOA requires daily reports, participants can only record information about a single day during those 24-hours. If they skip a day, they are unable to go back. This prevents participants from filling in all the diary pages at the last minute and trying to remember what occurred on those days — known as the 'parking lot' effect. Overall, this will reduce the study participants' burden by eliminating the need for multiple office visits and increase the quality of the data.

Because the data is recorded electronically, there is also a lower risk of data getting lost in the transcription process or thrown out due to illegible handwriting. The eCOA systems can also send alerts reminding participants to complete PRO activities, and signal study teams when participants may fall behind.

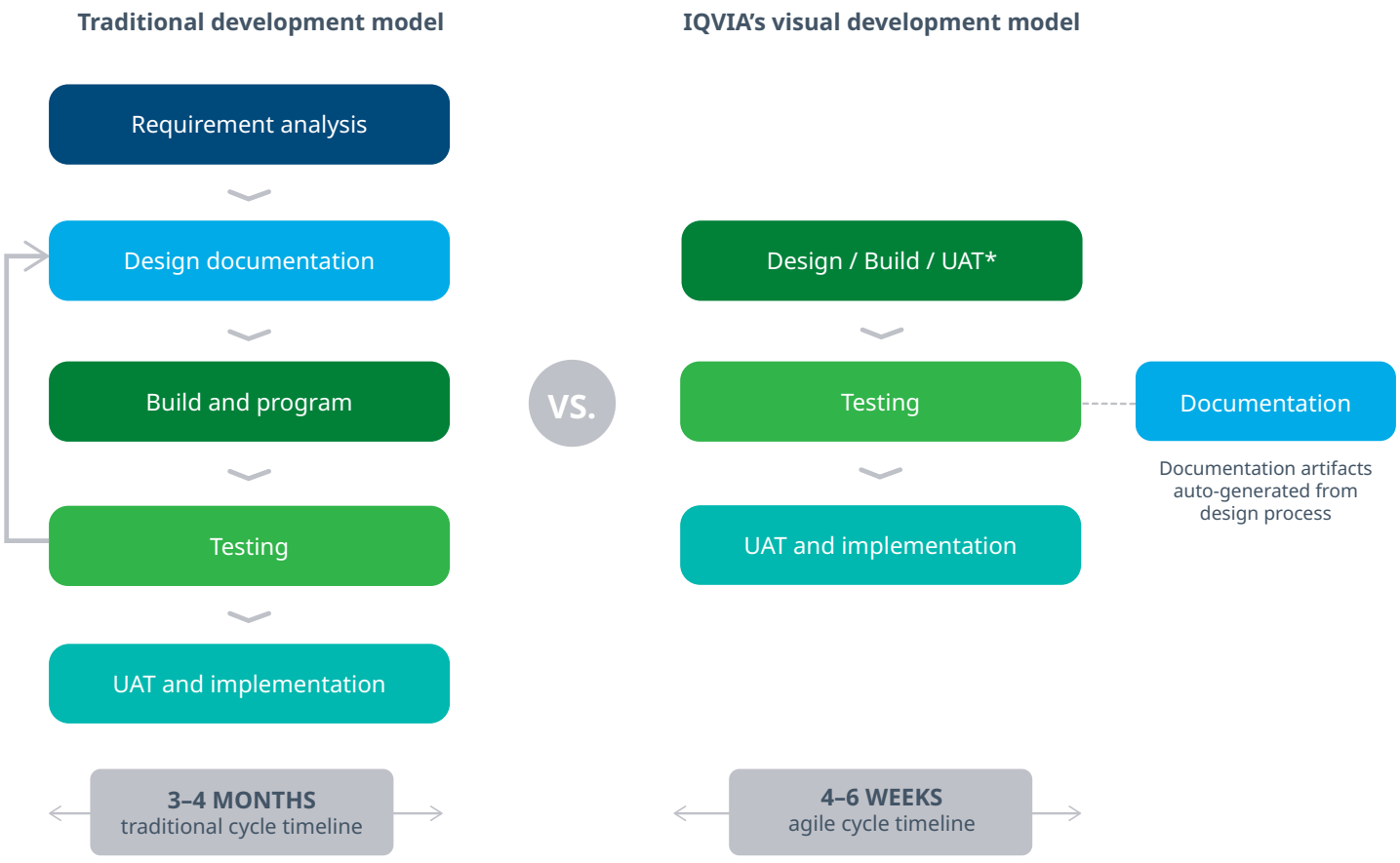
Reduce study start-up timelines

Time is of the essence when you're launching a study. Going back and forth with an eCOA vendor to gather requirements, program, test, and deploy takes unnecessary time. How do we do things differently?

We come to our sponsors with the design in mind and assessments already implemented, so we're not starting from scratch. This saves time and reduces much of the ambiguity in the requirements gathering stage and combines it with the build step. This often reduces the need for change orders down the line since changes are made in real time and clarity is given on the spot.

So how much time can this save? We can have a complete study set up in 4-6 weeks, rather than the industry standard of 3-4 months. With that saved time, sponsors can be flexible about feedback from within their teams or from regulators, Institutional Review Boards (IRBs), and Ethical Review Boards (ERBs), allowing them to make changes at the beginning of the process. So, not only are we getting things done faster, there's also that added level of flexibility to make changes at the beginning based on feedback (see Figure 1).

Figure 1: IQVIA's agile eCOA development model



*Note: This is for illustrative purposes to show that UAT could be conducted during the design/build phase with IQVIA eCOA due to our real-time design capabilities

Focusing on User Acceptance Testing (UAT)

In clinical research, it is less than ideal to wait months for an eCOA provider to build and implement an assessment. Especially when there is typically a lack of transparency throughout and assessment previews are not ready until the end of those few months. UAT is a step in the trial planning process that is often extended when users see the finished product and realize it isn't exactly what they envisioned.

Like most software development projects, eCOAs start with study teams writing a set of specifications envisioning the format and function of the electronic assessment. The development team from the eCOA provider takes the specification and spends weeks or even months building what is described on paper, only to have the team review it during the UAT stage prior to implementation and not have the outcome match what they wanted or expected.

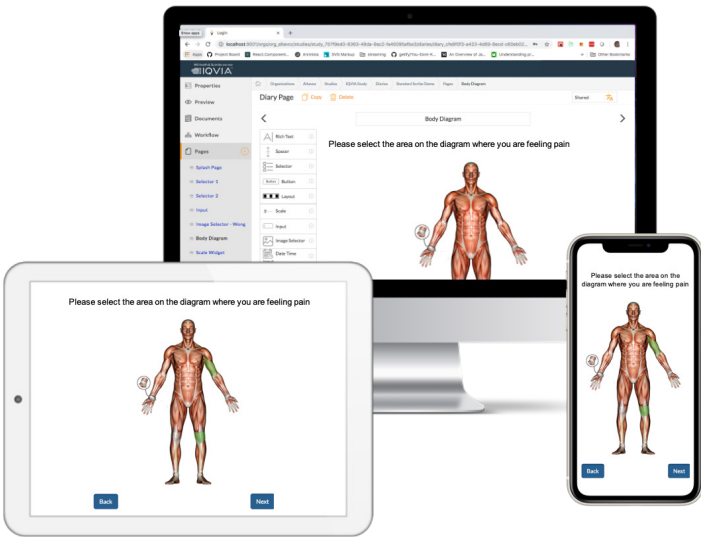
This means developers must tear apart their hard work to redesign the assessment with the exact right colors, button placement, and user experience that the teams had originally envisioned, but weren't able to properly communicate. For example, let's say that an electronic assessment for a trial needed to have a specific background color due to screen sensitivity for a migraine treatment trial. We'll use blue as a simple reference. There are so many different shades of blue and if the developers put in a sky blue and the sponsor team wanted a royal blue, that's a problem. If that isn't perfectly spelled out in the spec and requirement documents, this can be interpreted differently by the study team and developers resulting in late stage changes needed. These changes add cost and time to the process, potentially delaying trial start-up and first-patient-in timelines.

Now imagine if you could avoid this problem by doing UAT in real time — as the assessment is actually being built — to ensure full alignment of the functionality and design within the assessment.

Our eCOA technology enables users to design, build, and preview an assessment all in real-time. And it's not a mock assessment that then has to be developed. As you are designing and building out an assessment within the back-end development tool, IQVIA eCOA Sculptor, all of the development is being configured automatically so the assessment is ready for implementation once design and testing are completed.

Our design team can collaborate directly with sponsors to assemble their eCOA solution together in working design sessions — with the ability to test and preview the assessment at any point. With this capability, sponsors are provided the options to choose the exact right shades for their backdrops, move buttons around the page, and test each step in the patient journey as it is built to ensure a smooth user experience prior to being fully deployed.

This not only makes the eCOA development process easier and less stressful for developers and sponsors, it can make the development process faster and less costly while mitigating any potential risks. In any project, the most expensive time to fix problems is at the end. When an assessment must be rebuilt in response to UAT, it is an added development expense, that is amplified by the delays to trial start-up.



Leverage a vast library of assessments

Creating and validating an electronic COA from scratch for each study is a cumbersome process that can add months to the trial planning process, and even small errors can lead to costly setbacks. Sponsors can spend 12–16 weeks creating a new assessment in an eCOA system, validating it against standards, and qualifying it with regulators.
In many cases, revisions and delays add more weeks to this process, leading to missed deadlines. 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.

In the past, sponsors have repeatedly re-created standard eCOAs for every trial. But what if there was a better way that would reduce costs and timelines, and improve quality?

This is where a library of pre-configured, author approved, and validated assessments plays an important role. A library can shorten the time of implementation down to a matter of days in some cases and ensure consistency in the data being collected. However, for an assessment to be used in a trial, sponsors need to secure approval from the original author of the assessment and validate that the electronic version being used meets their requirements. This is a step that frequently gets overlooked, which creates hidden risks for the sponsor.

Obtaining validation from authors can be as simple as sharing and approving a screenshot review, or it can become very complex if multiple iterations are required and there are communication delays. The process can require several rounds of back and forth as authors verify the version accurately captures the data as intended.

The uncertainty related to this review and approval process means it has the potential to delay trial start-up by weeks. And if sponsors or eCOA vendors fail to complete this step, they put themselves and their trials at risk of copyright infringement, leading to costly fines, punitive damages, and potentially render trial data corrupt or unusable.

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

>1,200

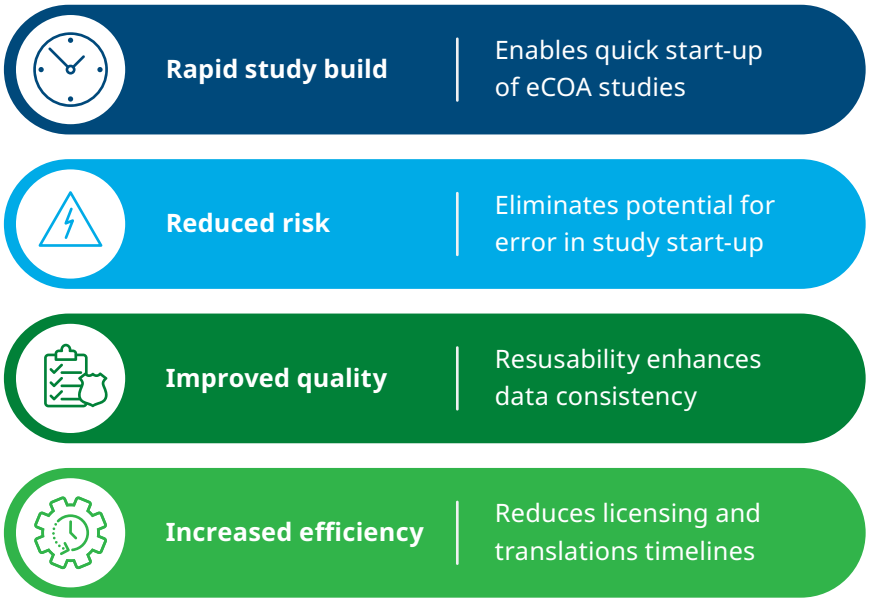
Pre-configured assessments in library and growing

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



Vetted assessments ready-to-go

In order to combat the problem of time delays and copyright infringements when using assessments, IQVIA eCOA has a library ready to go. This provides sponsors with instant access to pre-built electronic assessments to meet their research needs. The eCOA library features more than 1,200 electronic versions of assessments that are pre-configured within the platform. Of these, more than 220 eCOAs have already been validated and approved for use by the original authors, with more approvals being completed every month.

IQVIA follows a rigorous due diligence process, to ensure the copyright holder has fully vetted these assessments in the library. Because there are many existing industry assessments, our team utilizes a weighted scoring system to prioritize approval of the most in-demand assessments for our library. The scoring is based on the following criteria:

- If the assessment is used in studies that are currently recruiting patients and are run in Clinicaltrials.gov
- If the assessment has been used in past/current studies
- If the assessment has been included in any IQVIA proposals within the past year
- If the assessment has been included by IQVIA's clients in eCOA library projects

By analyzing these through our scoring system, the most sought after eCOA assessments are vetted, approved, and ready for use, reducing valuable time spent in the development process. In addition, IQVIA is partnering with many organizations and authors of assessments to foster collaboration that will ultimately help benefit sponsors.

A few examples of fully approved assessments in the IQVIA eCOA library include several PROMIS Measures, Oxford University's Parkinson's Disease Questionnaire (PDQ-39/8), and IQVIA's Treatment Satisfaction Questionnaire for Medication (TSQM).

Having access to these vetted assessments means sponsors do not have to worry about potential delays, 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.

The IQVIA eCOA library provides several key customer benefits including:

- Enables rapid start-up of eCOA studies
- Reduces risk by eliminating potential for errors in study start-up
- Improves data quality by ensuring data consistency
- Increases efficiency by reducing licensing and translation timelines

Improve data quality and compliance

eCOAs transform the paper-based assessment into a real-time digital tool that collects insights directly from the patient about their disease, the trial experience, and the treatment's impact on their quality of life. This brings several immediate benefits.

- **The data is captured electronically.** This eliminates the need to transcribe handwritten data into a digital database — saving site staff hours of manual labor and eliminating the challenge of trying to decipher handwritten notes.
- **The data is collected sooner.** Patients can complete their diaries online or offline, and as soon as they submit their data, it is uploaded to the trial database. This means sites and sponsors get near real-time insights into the patient experience, rather than waiting weeks for diaries to be submitted and entered at the site. This accelerates sponsor's access to data, which can lead to a safer patient environment and faster results.
- **It creates accountability.** IQVIA's eCOA platform sends reminders and alerts prompting patients to complete survey questions on schedule and can let site staff know if patients consistently fail to meet requirements. This creates a culture of accountability for patients to record data as it happens, rather than retrospectively in the moments before an appointment.

Bring Your Own Device (BYOD) encourages compliance

Replacing paper with an eCOA aligns more naturally with the patient's life, creating a patient-centric data collection experience. To amplify these benefits, many sponsors are embracing a BYOD approach to their eCOA practice.

Many sponsors assume they need to provide specialized medical devices to patients in order to complete these assessments in a safe and regulated manner. However, we have found that allowing patients to use their own devices to complete eCOAs increases patient engagement with the process, while meeting all data safety requirements.

When sponsors adopt BYOD, patients can start recording data as soon as they download the app. Because they are rarely away from their phones, the eCOA is woven into their daily lives, giving them the flexibility to complete assessments anywhere. It also makes it harder to ignore reminders and alerts because their personal device is usually by their side.

The eCOA apps are password protected, and the data is uploaded as soon as they submit it, which means even if a patient loses their phone, as soon as they replace it, they can download the app and continue where they left off. It's a safe, cost-effective and patient-centric approach that makes trial participation easier for everyone involved.

Conclusion

Life sciences companies are often wary of introducing new technologies to their clinical research workflow, but the payoff of using an eCOA can't be ignored. Patient-centricity has become a priority for trial leaders, and patients expect their trial experiences to be as seamless as their consumer interactions. eCOAs offer that ease of use, adding value for everyone involved.

Regulators and patients expect the patient's perspective to be represented in clinical research. eCOAs give sponsors a way to capture that perspective quickly and concisely, while accelerating their ability to make decisions about the benefits of the therapy. The speed and agility eCOAs provide benefits to everyone in the clinical landscape, making them an essential part of the future of clinical research.

To learn more about how to use an eCOA in your next clinical trial, reach out to an IQVIA eCOA expert at **ecoa@iqvia.com**.

About the authors

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As vice president and global head of eCOA at IQVIA, Kris Gustafson leads a global team responsible for the strategic oversight, delivery and project services associated with 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 several leadership positions within the company across both service and technology delivery 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.

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As senior director of eCOA operations at IQVIA, Anthony Mikulaschek manages all operations, data management, quality management, training and eCOA project work associated with IQVIA eCOA. Anthony has extensive experience in validated system implementation, systems integration, business process re-engineering, IT operations, and consulting. He has successfully led the development, delivery, and management of technology solutions for over 30 years, including 26 years in the Pharmaceutical sector.

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As the eCOA Library Manager 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.

J.C. WILSON
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As the product manager of IQVIA eCOA, J.C. Wilson leads a team that is responsible for the product delivery and execution of the IQVIA eCOA solution.

With more than 20 years of industry experience, J.C. has successfully led a variety of product management initiatives within the healthcare industry. Prior to joining IQVIA in 2018, J.C. led product teams at Bioclinica and ICON. J.C. holds a Bachelor's degree from Baldwin Wallace University and a Master's degree from New York University.

FREDERIC SIBEAUD
eCOA Data Management Director

As eCOA DM Director Fred leads a team of Data Managers involved in all eCOA projects. He is also involved in many support activities related to processes and data management aspects within eCOA area.

Frederic has more than 23 years of experience in clinical research, with 20 years spent in the data management sector of IQVIA. Frederic has gained a wild range of knowledge and expertise in clinical research and team management thanks to his extensive experience in global customer account management and team management over the last two decades.

Fred has a master's degree in biology and a master's degree in project management.

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