WHITE PAPER

IQVIA TECHNOLOGIES

eCOA Technology Guide

Seven recommendations to consider when vetting eCOA technology solutions

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Planning your platform

When sponsors and sites initially embrace decentralized clinical trial (DCT) models, electronic clinical outcome assessments (eCOAs) are among the first tools they adopt.

These platforms intelligently automate collection of the patient's experiences through robust and reliable electronic measures, providing real-time quantitative and qualitative insights that inform trial progress and demonstrate results. eCOAs also make it easier for patients and caregivers to share information in real-time about the treatment experience without the added burden of constant site visits.

But, as with any technology used in clinical research, choosing the right vendor, solution and deployment model are critical for success.

eCOAs may seem like simple enough tools to deploy in a trial setting, but this isn't a one size fits all solution that can be rolled out the day a trial goes live. Every application must be customized to the needs of the sponsors, the site staff and the patients, with features and options designed to ensure data can be securely collected and reviewed with minimal disruption to users.

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Because this technology is still relatively novel, many sponsors aren't certain what they need to look for in an eCOA platform, how to align features with the needs of the study, and what training, support and review steps are required to create a seamless user experience. Without proper planning and the right vendor, it's easy to make choices that lead to unexpected start-up delays, disgruntled patients, frustrated staff and a lot of hidden costs that could have been avoided.

eCOAs for a modern world

Consumers love technology that is easy to use, remembers what they like and can be seamlessly woven into the flow of their life. Their expectations for eCOAs are no different. If sponsors want patients and site staff to interact with these platforms every day, they need to be sure the technology is intuitive, easy to use and protects the data it collects.

These end users will determine whether the eCOA platform is embraced and used as intended, yet they are rarely involved in the selection process. That means the teams who choose the eCOA platform have to be their champions.

ADVOCATE FOR PATIENTS

Every patient population is different, which means every eCOA will require customization to meet the unique needs and abilities of that population. Before vetting any eCOA technology, the sponsor's team first needs to figure out what those needs are.

Patients will not be at the table when the technology is tested, so the team selecting the eCOA technology needs to know what they want, and what will make their experience better. That means using real-world data to define the patients' experience with the disease and treatment, then asking questions about how that experience will affect the way they use the eCOA.

Do these patients have small motor skill issues that will make typing long narrative answers on a small device difficult? Are they struggling with memory problems or neurological issues that will interfere with their ability to complete assessments? Do they suffer from light sensitivity or nausea that will make reading a brightly lit or flickering screen excruciating? These questions should shape the technology vetting process including how the platform's interface, features, color schemes and usability can be adapted to meet their needs.

Sponsors also need to consider whether patients will be open to carrying a new device and learning how to use it. If patients will complete an assessment multiple times a day, giving them the option to use their own smartphones may be a better alternative to asking them to lug an extra piece of equipment everywhere they go.

When considering a bring your own device (BYOD) option, sponsors should also determine whether patients will have the infrastructure, such as Wi-Fi and storage capacity, to run another app on their smartphones or tablets and whether they will trust the sponsors enough to give them access to their devices to upload that data.

If sponsors fail to align their platform choice with the needs of the patient, it can negatively impact retention and compliance. But when sponsors take the time to consider their patients' physical and emotional needs as part of the technology selection process, they will choose a solution that can be customized to their needs, which benefits everyone. The happier the patient is, the more likely they are to stay engaged.

SIMPLIFY WORK FOR SITE STAFF

Site staff needs also need to be considered when vetting eCOA technology. Site staff will be expected to constantly review assessment results, verify completion rates, and transfer data to study databases. This is time they spend away from patients, so the technology has to be simple and easy to access with few barriers. Ideally, an investigator will be able to drop into the platform, look at the data, make decisions and get out within minutes.

The best eCOA platforms are defined by how little site staff must interact with them. So, when vetting whether an eCOA platform is right for site staff, decision-makers should focus on the speed and simplicity of workflows. How much time does it take to create a new patient profile? How easy is it to monitor the status of individuals or groups of patients in the study? Can investigators see compliance rates at a glance, or do they need to dig 10 layers deep to find that information? The goal should be for the investigator and site team to spend as little time as possible learning to use the platform and interacting with it in their day-to-day work.

Remember, their job is not to spend time in your data ecosystem. Their job is to treat patients and work their way through the protocol.

PROTECT THE DATA

Data does not spend its entire life on an eCOA platform. Rather it is a starting point for the data is captured and sent to another database where it can be analyzed and prepared for regulatory review.

When choosing eCOA technology, sponsors need to verify that they can get the data out of the platform quickly, securely and with little effort. That means vetting how data security and privacy is maintained at every touchpoint, and what steps are required to move the data through the system.

Ideally, the data transfer process will occur through APIs that pull data from one application and send it downstream to another without any humans involved. Once these APIs are set up, the data should show up in the destination system without any additional logins or interactions with the platform. Such seamless integrations free site staff from having to deal with technical data tasks they are likely not trained for and ensure fast and consistent delivery of data while adhering to data privacy rules.

Best Practices for vetting eCOA tech

Factoring the needs of patients, site staff and data into the eCOA technology vetting process is the key to choosing the best eCOA platform for any trial. Though that isn't all that sponsors need to consider. Timing, testing and vendor support will all impact successful deployment.

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Depending on the technology, the assessment and the need for customization and training, rolling out an eCOA platform can add weeks to the trial timeline. Planning ahead and talking to vendors about how they can accelerate those timelines will help sponsors speed deployment and ensure a seamless user experience from day one.

Don't delay

The weeks leading up to the trial launch can feel overwhelming, especially for smaller sponsors with limited resources. Having an eCOA system already in place and working with a trusted technology vendor frees study teams to focus on other tasks critical to study start-up and ensures patients' first interactions with trial technology will set the stage for an excellent trial experience.

Here are 7 best practices to help sponsors make the best eCOA technology decision:

1. **Determine whether the platform meets all regulatory requirements for data privacy and security.**
   This is especially important if the trial will be global, as every country has unique rules governing how data is collected, transmitted, shared and stored.

2. **Choose a platform that integrates with your existing trial systems.**
   Ideally, the eCOA will work seamlessly within the clinical trial technology network. This reduces the number of systems site staff need to use and accelerates sponsors' access to data.

3. **Ask site staff what to look for.**
   If they have used eCOAs in the past, they will have a list of things they love and hate about these platforms. Use that list when vetting your vendors.

4. **Build in time for validation user acceptance testing (UAT).**
   Any assessment used in an eCOA has to be proven to perform as expected on all potential operating systems and show that the intent of the assessment is met through every interaction. Some vendors have pre-built APIs and libraries of pre-validated assessments that can be deployed overnight while others build and test each model separately, which can add many weeks to the deployment process.

5. **Make sure sponsors maintain complete control over the data.**
   Sponsors need control over their data in order to pull it whenever they want or need it for their study.

6. **Meet your point of contact.**
   A dedicated project manager is the most important person on the eCOA team. Your vendor should assign a point of contact who will be available to solve problems, answer questions and make sure the technology works as expected.

7. **Review training materials.**
   Site staff and patients have little patience for extensive user training or a platform that requires frequent training updates. When reviewing training materials, consider how accessible it is, how long it takes and whether a single course will give end users everything they need to confidently use the technology.

Fast, flexible and proven, IQVIA eCOA runs on devices patients already know and use to collect direct-from-patient data that is clean and ready to use in real time across clinical workflows.

As an agile solution, IQVIA eCOA accelerates trials and enhances the patient experience so you can bring new medicines to market faster. Are you interested in learning more about how IQVIA eCOA could work in your next trial?

Visit us at **iqvia.com/ecoa** for more information or reach out to us at **ecoa@iqvia.com**

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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.

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