Insight Brief

What Makes a Qualified E-Signature for Electronic Consent Systems?

AIMEE PASQUARIELLO, Director, Product Operations, IQVIA
SONIA FISCHER, Director, Product Management, IQVIA

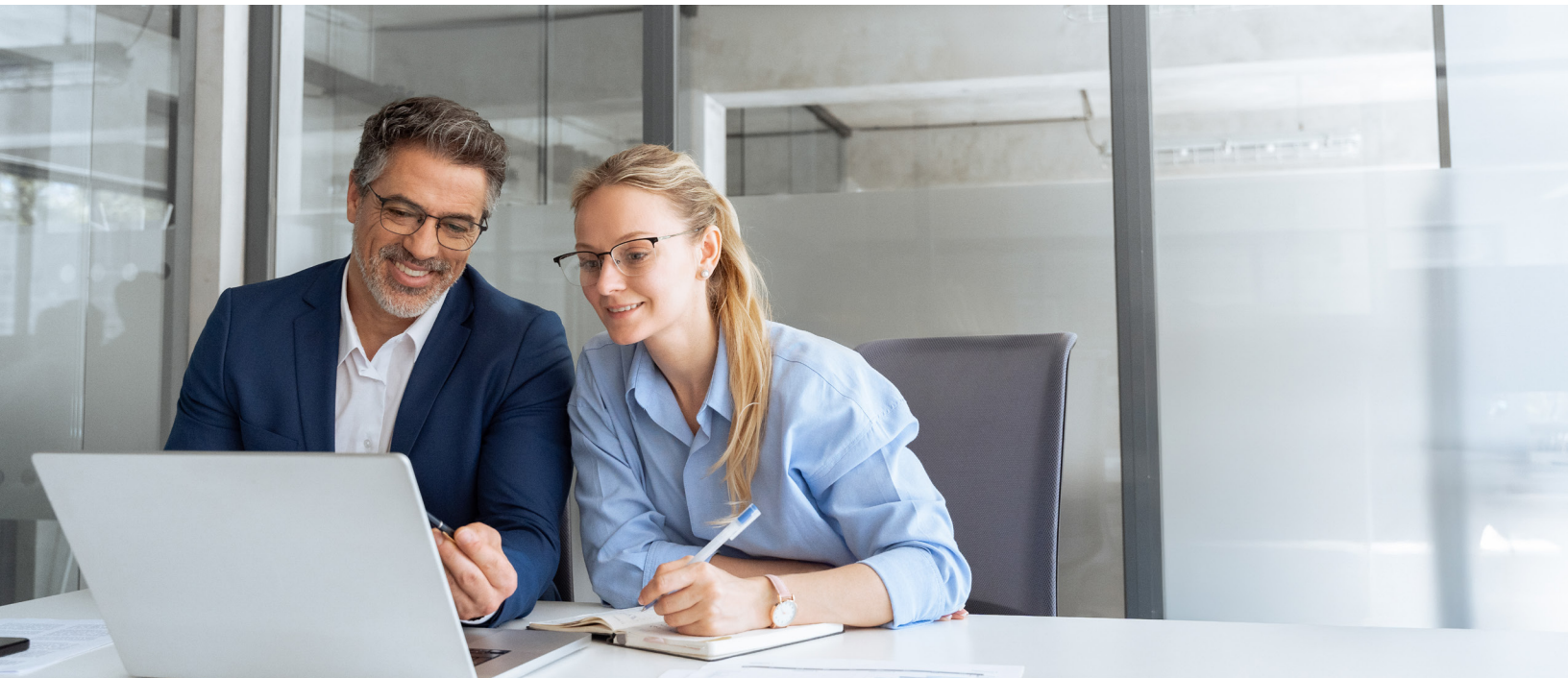
As clinical trials become more decentralized and digitally enabled, electronic consent (e-consent) systems and digital signatures are playing a growing role in how participant consent is captured and managed. While these technologies can improve efficiency, compliance, and participant understanding, they also introduce new considerations, particularly for global studies navigating varying regulatory expectations and signature standards.

In a recent discussion, experts from IQVIA explained how electronic consent platforms and Qualified Electronic Signatures (QES) are shaping the future of clinical trial consent, alongside what sponsors and study teams should consider when implementing them.

IQVIA's experts included:

- **SONIA FISCHER**, Director of Product Management at IQVIA
- **AIMEE PASQUARIELLO**, Director of Client Services, Project Management, Patient and Site Delivery

In the following Q&A, Fischer and Pasquariello discuss the range of consent signature approaches used in clinical trials, from traditional wet-ink signatures to hybrid models and fully electronic signatures captured within e-consent platforms. The pair also outline the differences between Simple Electronic Signatures (SES), Advanced Electronic Signatures (AES), and QES, which provides the highest level of identity verification and legal assurance in certain jurisdictions. Fischer and Pasquariello likewise address questions about the operational realities of global trials, where regulatory requirements can vary significantly by country, as well as operational trade-offs and best practices for implementing e-consent and electronic signature strategies in clinical research.



When is a Qualified Electronic Signature (QeS) actually required — and when is AES sufficient?

PASQUARIELLO: AES is compliant with CFR Part 11 and sufficient for most use cases in the U.S. However, some sponsors or studies may require QES depending on regulatory expectations or the level of study risk.

Globally, requirements vary. Health Canada permits electronic signatures within eConsent if they meet Good Clinical Practice standards. In Asia-Pacific, countries such as Australia and Japan allow multiple signature types with appropriate oversight. In Latin America, adoption is evolving, with local regulators and ethics committees typically determining which signature modalities are acceptable.

What do you see as the biggest operational trade-off when a study has to support both QES and non-QES consenting methods?

PASQUARIELLO: The primary trade-off is flexibility versus complexity. Supporting multiple signature types allows alignment with regional requirements and participant needs, but it increases oversight, training, and monitoring effort. Selecting a platform with clear rules and visibility is critical to managing this complexity.

FISCHER: The platform needs to support all signature modalities within a single environment, including wet ink, AES, and QES. It should allow signature types to be assigned at the country or site level and guide both site staff and participants through the process in an intuitive way. Clear workflows and upfront identity verification for QES are essential so that signatures can be applied smoothly without introducing delays or confusion.

You mentioned several Qualified Trust Services Providers (QTSP) providers during your presentation. Are all of those integrated into your platform?

FISCHER: There are multiple QTSP vendors. At this point, we have integrated one QTSP vendor after very, very careful evaluation. This vendor provides services across multiple countries, which was a critical component of our evaluation. In addition, we ensured that their security measures and encryption standards met our global requirements from a regulatory, security, and technology perspective.

We have built the technology to be scalable so that additional QTSPs can be onboarded if needed. If we feel that a country requires a better or more widely accepted QTSP, we have the capability to integrate that in the future. But at this point, we have only one QTSP integrated within our IQVIA Complete Consent solution.

How is participant identity verified for QeS, and what does that experience look like for the participant?

PASQUARIELLO: There is some additional setup required, as participants must register with the QTSP provider. However, that initial effort enables the use of electronic signatures in regions where QES is required, removing the need for print-and-sign workflows.

Once participants are registered, they can reuse their credentials across documents and for re-consent. This makes subsequent interactions much faster and more familiar. Over the full lifecycle of a study, the upfront effort is generally offset by increased efficiency later on.

FISCHER: To use a QTSP, participants must register using valid identification documents such as a passport, residence permit, or other approved identification. This is completed through a secure mobile application, where documents are uploaded and verified as part of the registration process. Once registered, participants can sign informed consent forms within Complete Consent by applying their signature through the QTSP application on their device.

For a document to meet QES requirements, all signatories must sign through the QES process. This means that any required countersigners, including site staff, must also be registered and verified in advance. All signatures on the document must meet QES standards. In practice, some studies take a hybrid approach.

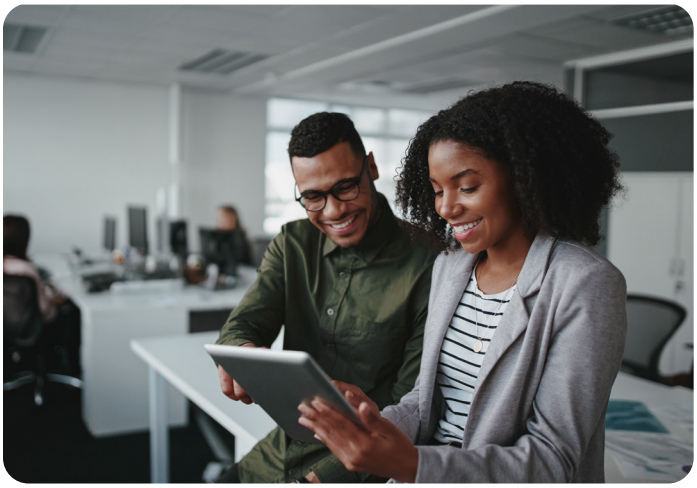
This model is particularly beneficial for decentralized trials. Participants can Complete Consent remotely without returning to the clinic, and once registered, they can reuse their QTSP credentials not only within the study but for other secure signing needs as well.

How is participant PII protected when using QeS and QTSP?

PASQUARIELLO: Protecting participant PII is critical in any clinical trial. In the QeS process, PII used for identity verification is collected within our platform but never stored. Participants self-register directly with the QTSP and agree to the provider's privacy policy. Once transmitted, the data is deleted from our system.

Digital signatures issued by the QTSP are embedded in the signed PDF and stored in encrypted form. Data is secured both in transit and at rest using industry standards (TLS 1.2 and AES 256) across both IQVIA and QTSP environments.

To support GDPR and regional data privacy requirements, data is stored within designated regional data centers (U.S., EU, and APAC), ensuring it is not transferred outside its geographic boundary. Additional safeguards include client-specific encryption keys, regional data fencing, and strict tenant isolation, with identity data securely maintained within the QTSP environment.



AES also ensures no changes can be made after signature, doesn't it? That's not exclusive to QES.

FISCHER: Absolutely. Yes, and AES also ensures that the signer is verified and the document is tamper-proof after signing. What a QES does is, it involves a third party like a QTSP to ensure that the signatures are verified by a third party, which adds that additional level of security and compliance. So, it is a notch up from the AES, and it adds an additional layer of security validation, which is not just done at the site but also by a third-party partner like a qualified trust service provider. That's why an AES is accepted in many countries, although there are still some countries that mandate QES. In these situations, we recommend AES, which we believe is adequate for clinical trial informed consent. However, there are certain regulations in some countries or certain types of trials where a QES is mandated, and we are positioned to support those in the future.

What do you think is the greatest barrier in sites adopting e-consent technology?

PASQUARIELLO: We track this on all our trials, and across studies, one of the most common barriers is a continued preference for paper and hesitation around adopting new technology. It is important for sponsors to recognize that adoption takes time and to ensure that sites receive the training, support, and engagement needed to understand how the system works and why it is being implemented. While there may be initial resistance, sites typically become more comfortable with continued use and begin to recognize the operational efficiencies and benefits over time.

Are there any limitations for registration for QES for caregiver studies like limited cognition participants or underage participants, or what is the alternative process?

FISCHER: We do not recommend QES for vulnerable or pediatric populations or for anyone with cognitive disabilities. There are also times when a passport is required, which some participants may not have. In all these scenarios, we recommend vetting signatures on paper, which can then be uploaded onto our platform. Site staff can use the system to track all participants and consent documents, regardless of whether signatures were obtained electronically with the QES or through signed paper documents uploaded into the platform. Everything is maintained in one central location.

How can e-consent help lower patient dropout rates?

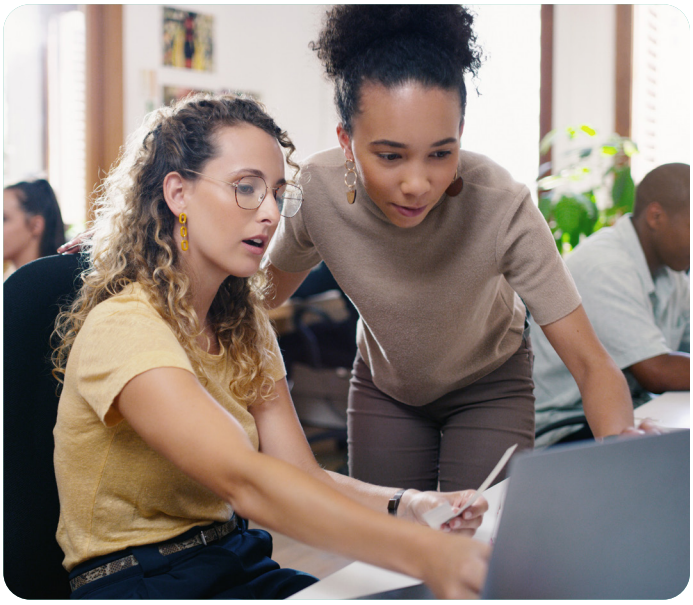
PASQUARIELLO: I think it goes back to empowering the participant and ensuring that they're properly informed and giving them those additional tools and resources just helps their understanding. E-consent can improve their understanding of what's expected of them throughout the lifecycle of the trial. If you hand a participant a 30-page document, it's a lot for them to read and digest, particularly if they're facing critical situations. By utilizing an electronic system and integrating educational components and glossary terms that highlight and explain unfamiliar terms, Participants can better understand what they're agreeing to, which is where we see those lower dropout rates coming from.

How much additional effort is it for a user to set up their QES credentials versus having to simply e-sign in the current state? And does QES facilitate avoiding having to use additional devices for e-consent?

PASQUARIELLO: There is some upfront effort required to register with the QTSP. However, once that step is completed, participants can reuse their credentials across documents and re-consent processes, which improves efficiency over time. In regions where QES is required, this also removes the need for print-and-sign workflows, simplifying the overall experience.

How does QeS support audit readiness and inspection confidence in multi-regional trials?

FISCHER: The audit trail provides a detailed, unalterable record of all participant activity in the eConsent system, ensuring reliability and supporting audits. IQVIA Complete Consent also enables remote audit capabilities and uses role-based access controls to ensure only authorized users can interact with the system. The platform is designed with intuitive workflows, making it easy for sites to operationalize eConsent with support from local delivery teams. These teams assist with uploading IRB-approved ICFs, managing amendments, and providing ongoing site support.



Training sessions and online guides help site staff quickly get up to speed, minimizing the learning curve. Formal User Acceptance Testing (UAT) is not required, reducing operational burden and accelerating adoption. Additional capabilities, including reporting, automated email notifications, and ICF version tracking, enable sites and sponsors to monitor consent activities, maintain compliance, and respond efficiently to regulatory changes.

To explore the full capabilities of our system and see how it can be tailored to your specific needs, please go to iqvia.com/econsent

Source: IQVIA

About the authors

AIMEE PASQUARIELLO
Director, Product Operations, IQVIA

Aimee Pasquariello is a seasoned leader in digital clinical solutions with deep expertise in eConsent strategy and delivery. As Director of Product Operations, Aimee has driven global initiatives to optimize patient engagement and streamline consent processes, ensuring compliance and operational excellence across diverse markets. Aimee's work spans governance, integration, and client success, making eConsent a cornerstone of modern clinical trials.

SONIA FISCHER
Director, Product Management, IQVIA

Sonia Fischer is Director of Product Management at IQVIA and a recognized leader in healthcare technology. She specializes in bringing together cross-functional teams to deliver innovative solutions that support clinical research, clinical care and patient engagement. With a background spanning health information systems, electronic health records, and digital health technologies, she focuses on turning complex healthcare challenges into practical, scalable solutions.

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