

# From Signatures to Success: How Digital Consent Accelerates Trials, Enhances Compliance, and Engages Patients

*PharmaPhorum: By Vinita Navadgi, Senior Director, Product Management, IQVIA*

Informed consent is a foundational element of every clinical trial. Yet, the traditional paper-based process has long been associated with delays, documentation errors, and disengaged participants. As the clinical research landscape continues to evolve, digital consent is emerging as a powerful enabler of faster study start-up, greater regulatory alignment, and more meaningful patient engagement.



While consent has always been a compliance-driven activity, today's digital tools demonstrate that regulatory rigour and patient-centred design are not mutually exclusive. Digital consent is reshaping how trials begin, how they are monitored, and how participants experience their journey by streamlining the consent process for sites and patients alike, while simultaneously reducing administrative burden and improving operational efficiency.

## Accelerating study start-up

For clinical operations teams, speed matters. Every day of delay in study start-up not only increases costs, but also slows the path to data collection. One often overlooked contributor to those delays is the manual process of preparing, distributing, and reviewing Informed Consent Forms (ICFs). Digital consent

addresses this bottleneck by enabling rapid deployment of centrally approved, site-specific consent documents, allowing teams to move forward without the logistical challenges of printing and distributing hard copies.

Rather than printing, shipping, and double-checking physical documents, teams can electronically push updated, localised versions to sites. This minimises versioning errors, eliminates shipping delays, and provides ethics committees with a consistent format that supports faster approvals. Additionally, digital platforms simplify tracking document status across all participating sites, providing real-time visibility into which locations have received, reviewed, and approved consent materials. With digital consent, study teams can launch trials with greater agility and ensure that no site is left waiting for paperwork.

## Ensuring regulatory compliance

In clinical research, like every aspect of healthcare, compliance is paramount. This is not groundbreaking, but what is evolving in the industry are the industry standards and requirements to meet and exceed compliance expectations. Both the U.S. Food and Drug Administration ([FDA](#)) and European Medicines Agency ([EMA](#)) have issued guidance supporting the use of electronic informed consent, provided it includes key safeguards. These include identity verification, secure storage, version control, and a complete audit trail.

Digital consent solutions provide these safeguards by design. Qualified electronic Signatures (QeS), supported by certified identity providers, ensure that each signature is attributable and time-stamped. Every interaction with the consent form is recorded, enabling sponsors, monitors, and regulators to reconstruct the process in detail. This auditability reduces the risk of protocol deviations and protects the integrity of the study.

In the EU, QeS are the only type of electronic signature recognised as having the same legal standing as a handwritten signature under eIDAS regulation. Compliance with QeS requirements — including use of a Qualified Trust Service Provider (QTSP), multi-factor identity authentication, and secure signature creation devices — is therefore essential for sponsors conducting studies in EU member states. Digital consent platforms that support QeS help ensure full alignment with EU regulatory expectations.

Importantly, digital consent also supports remote re-consenting when protocol amendments occur, ensuring participants are always operating under the most current information. These tools give sponsors confidence that their studies are not only compliant, but also inspection-ready at every stage.

## Engaging patients from the start

Every healthcare solution, strategy, and innovation must be designed with the patient at the centre. Today's patients expect more than just a signature line — they want to understand what they are signing up for and feel confident in their decisions. Traditional consent forms — dense, lengthy, and complex — often fall short.



Education systems recognise that each student learns differently, so, they offer many avenues for individualised approaches, targeting the most effective learning styles for each student. Why should learning about your own health be any different? It shouldn't.

Digital consent platforms address this by incorporating interactive, multimedia content tailored to diverse learning styles. Videos, visual aids, and glossary features help demystify medical jargon, improving comprehension and recall. Patients can access the information at their convenience, revisit it with family or caregivers, and ask questions through integrated communication features. This new technology has brought forth a new sense of ownership for patients in their decision-making process.

By making the consent process more flexible and transparent, digital solutions build trust and reduce early drop-out rates. [Studies](#) have shown that better consent comprehension is associated with higher retention. A well-informed patient is more likely to stay engaged and adhere to trial protocols.

## A measurable difference

The benefits of digital consent aren't just theoretical. Trials that have implemented digital consent have seen measurable improvements, including shorter site activation timelines, fewer consent-related deviations,

and improved patient randomisation rates. By combining patient-centric design with built-in compliance controls, digital consent transforms an administrative necessity into a strategic advantage.

As clinical trials become more decentralised, global, and data-driven, the case for digital consent continues to strengthen. Sponsors and sites looking to future-proof their operations should consider how modern consent technologies can accelerate timelines, ensure compliance and, most importantly, improve the participant experience.

In the end, informed consent isn't just a regulatory requirement — it's a moment of trust between the researcher and participant. With digital consent, that trust begins with clarity, continues with compliance, and culminates in a better clinical trial for everyone involved. The goal is to make the consent process more accessible, transparent, and efficient. By redefining how trials are conducted and how patients engage, digital consent is laying the groundwork for more successful and patient-friendly clinical research.

## About the author



### VINITA NAVADGI

Senior Director, Product Management, IQVIA

Vinita Navadgi is senior director of product management, digital products and solutions at IQVIA., a technology leader focused on innovation in clinical research and advancement of drugs. With over 25 years of technology expertise, she is passionate about accelerating clinical research and the patient consenting process by leveraging digitally transformative technologies while offering intuitive user experiences.