IQVIA Complete Consent

The proven, global electronic informed consent platform

IQVIA TECHNOLOGIES

Deliver eConsent to sites and patients around the world with confidence

IQVIA Complete Consent is the user-friendly, feature-rich electronic consent solution designed to support diverse protocols at a global scale. Proven through more than 300 studies with over 400,000 participants and 10,000 sites in 60-plus countries, we offer complete flexibility to meet your trial needs while delivering more convenience for sites and a better experience for patients. IQVIA Complete Consent supports all trial types and business models, from decentralized clinical trials to site-based trials, from full-service solutions to self-managed product licensing – and every combination in between.

TRANSFORM AN OUTDATED PROCESS INTO AN INTERACTIVE DIGITAL EXPERIENCE

Historically, patient consent is a complicated and slow paper-based process. The move to digital is transforming clinical trials and patient consent, but these changes can be challenging. IQVIA is paving a path forward, with over 15 years of experience developing and deploying clinical technology solutions.

IQVIA Complete Consent provides an easy, secure way to **deliver highly engaging, regulatory compliant electronic consent** for trials of all types so you can optimize enrollment and engagement, while realizing efficiencies to achieve better outcomes across the entire study lifecycle.

IQVIA has fine-tuned our flexible eConsent product to better support:

Site satisfaction

- **Ultimate flexibility** around document collections, and workflows to consent, reconsent, or withdraw from the first document version through the final amendment
- **Single sign-on available** for all non-patient users

Sponsor oversight

- **Robust data on patient behavior** down to the document and section levels
- **Access controls for remote monitoring** or site visits that ensure patient information is fully protected
- **Peerless data quality** regardless of location or language

Study operations

- **Faster amendments** with document workflow flexibility
- **New tools for quality control** and regulatory submission
- **Flexible study and site configurations** to meet diverse local requirements

IQVIA Complete Consent empowers patients to make truly informed decisions about clinical trial participation, while providing sites and sponsors with greater oversight and compliance.

What is Complete Consent?

A feature-rich system to improve participant discussions and the overall quality of the informed consent process

Multimedia patient-facing features

Digitized ICF | Video | Pictures | Narration | Glossary terms/ definitions | Question flags | Global compliant signature modalities | ICF preview from home | On site or remote Consent

Optimize study team workflows

Internet enabled device agnostic | Audit trail notes to file | Simplified reconsenting | Enables efficient on site and remote monitoring | Automatic staff training | System integrations | Global privacy and security compliance

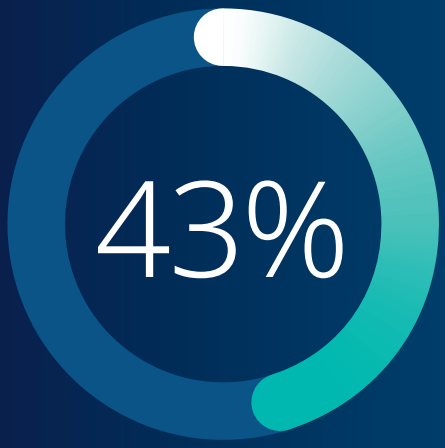
Functionality to support global delivery

Fully configurable global documents | Fully configurable signature workflows (including legal representatives) | Cohort and pre-screening design enabling features | Pediatric design enabling features | Biosample attribute tracking | SaaS ICF authoring | Start up enabling technology

- An engaging, interactive experience
- A fully validated electronic system
- Empowers participants and caregivers to make informed decisions
- Increases the quality and efficiency of clinical trials
- Provides valuable consent analytics
- Improves data integrity

Reduce protocol deviations

In a review of nearly 100 trials across IQVIA that used eConsent, compared to paper, consent-related major and critical protocol deviations were reduced from an average of 14% to only 6%. This entailed a combination of both electronic signature and print-to-sign modalities.



Reduction in consent-related protocol deviations compared to paper-based options

MEET PATIENTS RIGHT WHERE THEY ARE

Clinical trial participants are a precious resource. Complete Consent equips investigators and sponsors to engage patients outside of the site – at home or in the hospital, from urban to rural areas around the world – and still maintain an irrefutable audit trail.

Sponsors can expand their global reach with confidence by leveraging IQVIA's deep experience in technology-enabled solutions for clinical trials. IQVIA Complete Consent makes it easy and seamless to execute trials of all sizes and types – from traditional site-based models to decentralized clinical trials requiring remote consent.

Complete Consent incorporates proven learning approaches and flexible features to embrace the diversity of patient populations. And with access to education and technology as varied as site locations and regulatory environments, only IQVIA has the depth and breadth of resources needed to make global eConsent adoption a reality.

FLEXIBLE SIGNATURE CONFIGURATIONS TO MAXIMIZE BENEFITS

Complete Consent is not limited by e-signature regulations. With print-to-sign options, you can deploy a consistent eConsent solution to every site in every country and maximize the benefits everywhere.

SECURE AUDIT TRAIL FOR REMOTE MONITORING

Monitors can access a reliable, unalterable record of all consent-related activities:

- Start of consent visit
- Document version read by the patient
- Study staff involved in consent visit
- Question areas and glossary terms accessed
- Elapsed time to read informed consent and mark all sections as “understood”
- Electronically signed documents
- Time/date stamps of signed documents viewed, printed, and emailed and by whom

FUTURE-READY ARCHITECTURE FOR EFFICIENCY, SPEED AND SCALE

- Rebuilt authoring and study management tools
- More powerful, faster, scalable, reliant hardware infrastructure for faster load times and secure connections
- Flexible configurations to digitize and automate the informed consent process, delivering benefits to every stakeholder
- Helpdesk support

IQVIA TECHNOLOGIES IS DEDICATED TO YOUR SUCCESS

Meeting the demands for diverse and complex clinical trials requires a technology partner that advises, supports, and delivers every step of the way. IQVIA Technologies works in tandem with your team to accelerate site activation and first patient visit, ensuring you can demonstrate compliance with informed consent documentation consistently across languages and regulatory environments, especially through protocol amendments and re-consents.

Our world-class eConsent team includes pioneers in electronic patient consent and regulatory strategy, the most experienced global operations and integration team in the industry, and a physical presence around the world to support your success.

LEARN MORE

IQVIA Complete Consent is part of the Patient Engagement Suite of patient-facing clinical trial products from IQVIA Technologies. To learn more visit **IQVIA.com/PatientSuite.**

CONTACT US

IQVIA.com/econsent

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