Fact Sheet

Reduce Regulatory Risk in Global Trials with Qualified eSignature (QES)

Ensure eConsent compliance across regions, study types and regulatory requirements

Clinical trial sponsors must navigate complex and evolving eSignature regulations across regions, study type, and risk profile. Failure to meet these requirements can delay approvals, increase audit risk, and limit the ability to support decentralized or remote consent.

IQVIA Complete Consent provides flexible, compliant eSignature options — including QES — to meet the highest regulatory and legal standards while maintaining a seamless participant experience.

What is QES ?

QES represents the highest level of electronic signature assurance under EU eIDAS regulation. It enables secure, identity-verified, and legally recognized signing for clinical trial consent.

QES ensures:

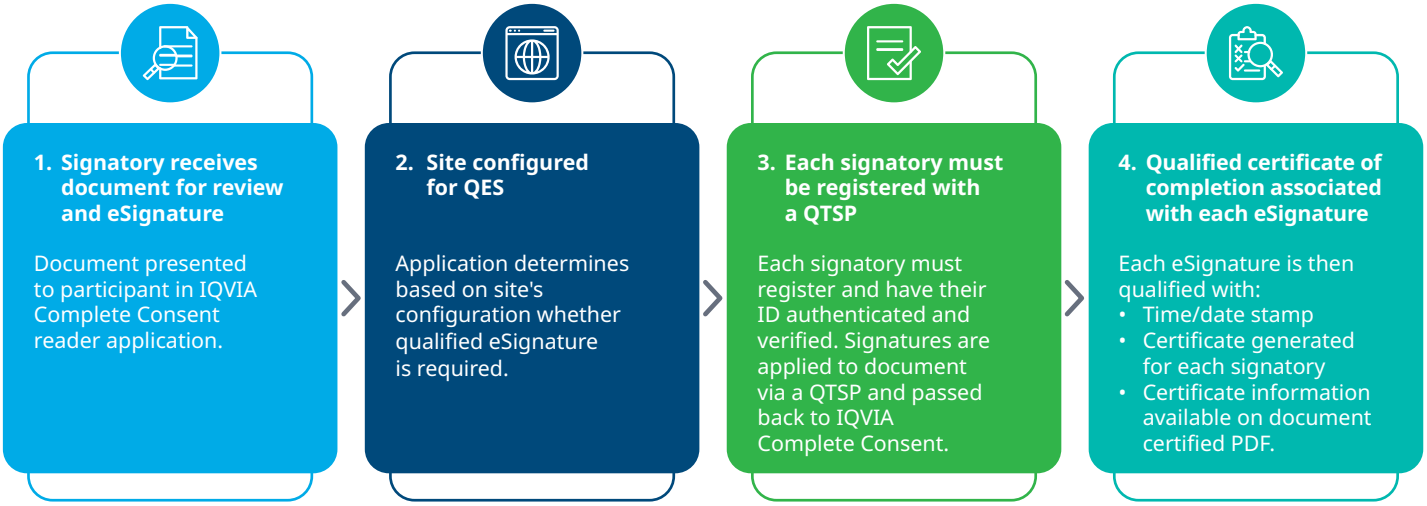
- Verified identity of all signatories
- Signature created under the signer's sole control
- Signed documents protected against tampering or modification

When is QES needed?

- EU-regulated studies requiring the highest level of legal assurance
- Decentralized or remote trials requiring strong identity verification
- High-risk or sensitive protocols with increased regulatory scrutiny
- Studies where audit readiness and legal enforceability are critical

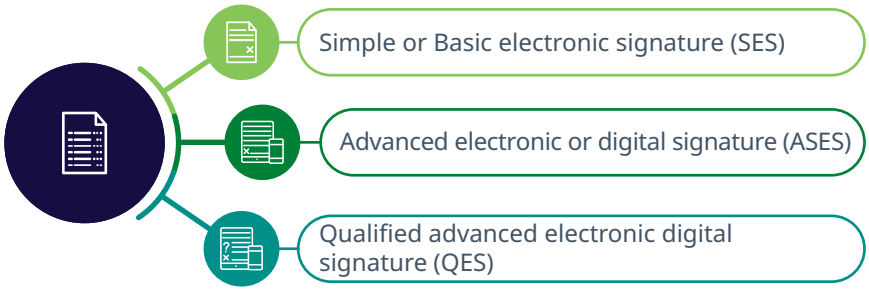
How QES works in IQVIA Complete Consent

QES is enabled through integration with Qualified Trust Service Providers (QTSPs) in alignment with EU eIDAS requirements, allowing sponsors to securely verify participant identity, enable certificate-based electronic signatures, and ensure compliance with regional regulatory standards.



Flexible eSignature approaches for global trials

Not all studies require the same level of signature assurance. IQVIA Complete Consent supports multiple eSignature types:



SIGNATURE TYPE	BEST FIT
Advanced Electronic Signature (AES)	Most global studies with standard compliance needs
Qualified Electronic Signatures (QES)	EU or high-risk studies requiring the highest legal assurance

IQVIA Complete Consent typically uses AES, with QES available when required by regulatory or study-specific needs.

Proven compliance at global scale

IQVIA Complete Consent helps sponsors navigate evolving global eSignature requirements, including the EU eIDAS framework, with flexible, compliant workflows designed for studies of all types and sizes. Backed by a global delivery organization, the platform enables rapid deployment, integration with trusted identity providers, and secure electronic consenting across geographies. Explore how IQVIA Complete Consent can support your next trial at www.iqvia.com/econsent.

IQVIA TECHNOLOGIES

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