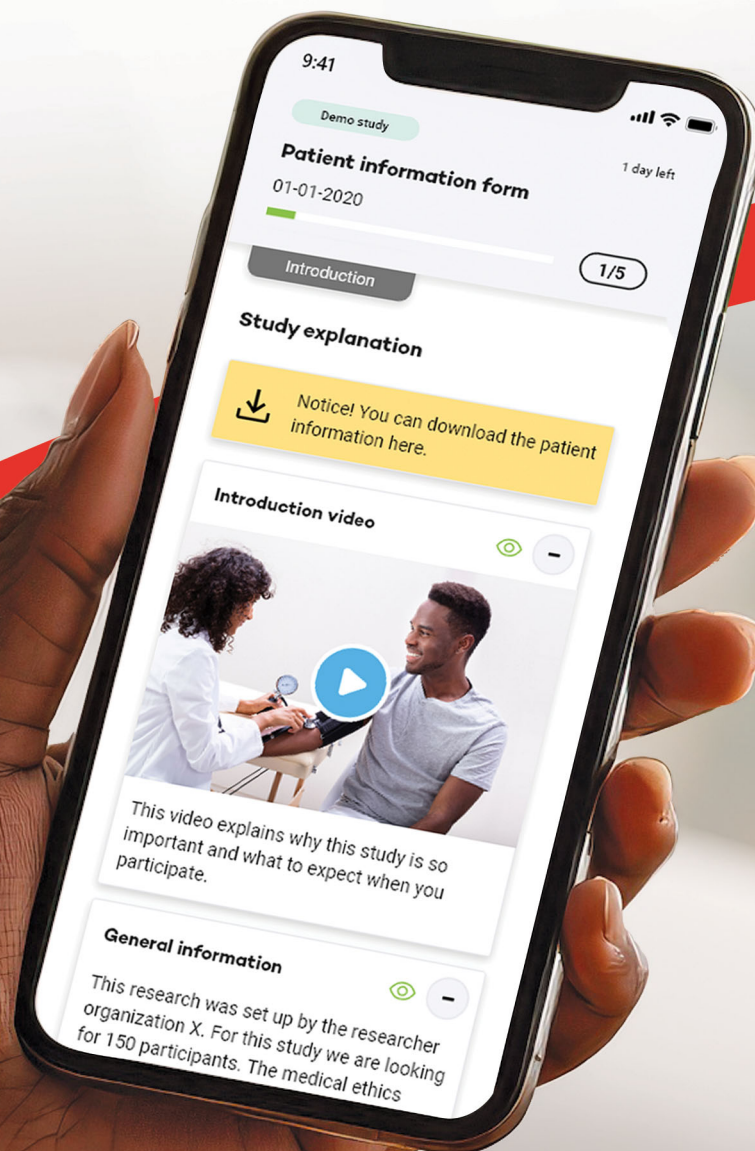


ALMAC TRIAL COORDINATOR™

eConsent

Streamlined, compliant, and participant-focused consent for modern clinical trials.



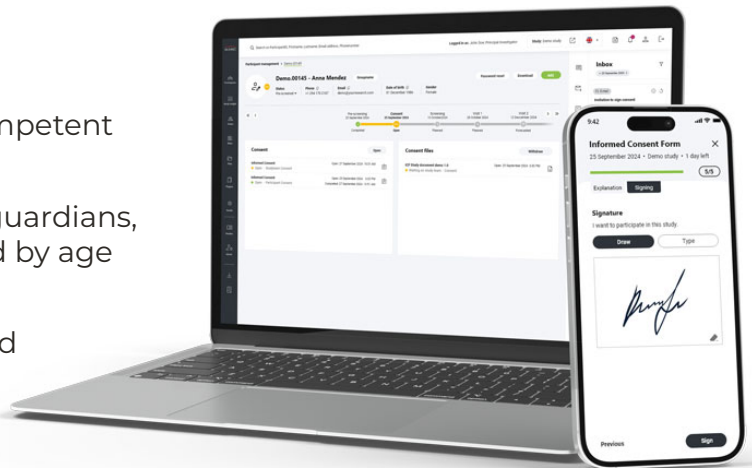
Overview

Almac's eConsent platform streamlines both electronic and paper-based consent for global clinical trials. It ensures regulatory compliance, enhances participant understanding, and reduces the administrative burden for research teams. The platform is flexible, supporting both remote and in-person deployment and can be implemented as a standalone module or as part of the Almac Trial Coordinator™ ecosystem for end-to-end workflow efficiency.

This unified approach provides sponsors with real-time, reliable data and premium services, empowering better decision-making at every stage of the study.

Consent signature options

- **Adults:** standard digital consent for competent adults.
- **Minors/vulnerable adults:** consent via guardians, with optional assent for minors, tailored by age and comprehension.
- **Legal representatives:** consent obtained from a legally designated representative.



Key features



Electronic signatures with audit trails

- Secure, compliant signing with Advanced (AES) or Qualified (QES) Electronic Signatures.
- Full audit trails ensure transparency and meet 21 CFR Part 11 and GDPR requirements.



Real-time consent status monitoring

- Clinician dashboard provides real-time updates on participant consent status, enabling efficient tracking and timely decision-making.



User-friendly interface

- Intuitive design supports seamless navigation for participants of all ages, enhancing engagement and reducing barriers to participation.



Modular & protocol-adaptive configuration

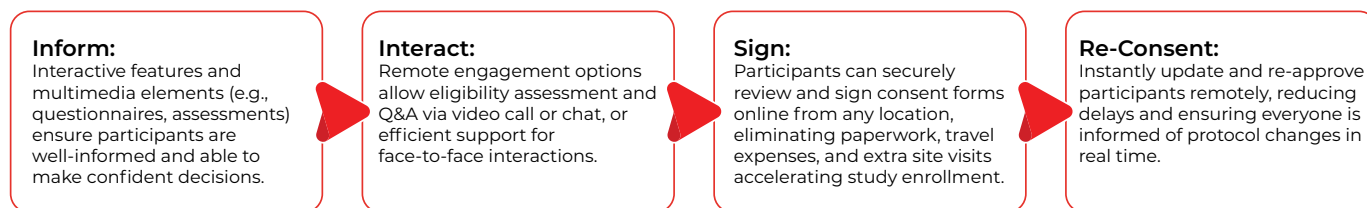
- Customisable to align with study protocols, supporting flexible consent flows and streamlined re-consent processes.



Education module for participant engagement

- Designed to improve participant understanding and engagement during the informed consent process.

Participant experience



Why Almac

Technology alone doesn't deliver outcomes - expert service ensures success at every step.

As a privately owned and independent company, Almac re-invests all profits back into the business, enabling continued innovation and expansion to meet the growing needs of global clients - working in partnership to advance human health.

With 30+ years of experience, Almac delivers intuitive, scalable visit management software backed by trusted global expertise and a deeply integrated technology stack that supports IRT, eCOA, eConsent, CTMS, and beyond.

Proven global delivery

- Supported 100+ trials across 25+ countries and 250+ sites
- Enabled a 42% reduction in missed visits in high-complexity studies
- Achieved 98.3% protocol adherence in a global oncology trial

Compliance & security

- GxP validated
- GDPR and HIPAA compliant
- 21 CFR Part 11 audit trail and e-signature enabled
- ISO 27001 Certified
- Almac Quality Management backed by global audits

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