Captivate® VDC: eConsent

Flexible,Web-BasedElectronicInformedConsent for Modern Clinical Studies

Product Overview

Captivate VDC eConsent is a secure, participant-centric electronic informed consent solution designed to streamline the consent experience while maintaining rigorous compliance and audit readiness.

Built for sponsors, CROs, and clinical data managers, Captivate VDC eConsent supports flexible presentation of consent materials, robust documentation of participant decisions, and integration with the Captivate platform to unify consent and clinical data.

Captivate VDC eConsent is delivered through a responsive web interface that works across desktops, tablets, and mobile devices, reducing technical friction for participants and study teams alike.

Structured Consent Experiences That Reflect Your Protocol

Captivate VDC eConsent enables study teams to design electronic informed consent materials that reflect their protocol, study population, and regulatory requirements.

Key capabilities include:

- Support for rich content including embedded video, images, and formatted text
- Configurable staged consent and consent grouping for complex protocols
- Multi-language support for global study populations
- Inline comprehension checks and dynamic content based on participant responses

Participant-Friendly Consent That Drives Understanding

Captivate VDC eConsent is designed to support participant engagement and comprehension at every stage of the consent process.

Key capabilities include:

- Simple navigation and clear presentation of consent elements
- Built-in accessibility support for diverse participant needs
- Ability to pause and resume consent flows without losing context

Web-Based and Device-Agnostic Access

Participants can review and sign consent forms from their own devices without requiring a native application. The interface adapts to screen size and device type while preserving security and accessibility.

Key capabilities include:

- Responsive web interface accessible from desktop, tablet, and smartphone
- Secure, role-appropriate access for participants and site staff
- Support for in-clinic, remote, and hybrid consent workflows

Secure Documentation and Auditability

Ensuring a complete, accurate, and compliant record of consent interactions is central to Captivate VDC eConsent.

Key capabilities include:

- Complete audit trails of consent presentation and decisions
- Time-stamped eSignatures aligned with applicable regulations
- Secure storage of signed consent documents alongside study data
- Support for re-consent and version tracking for amended consent forms

Unified Consent Data with the Captivate Clinical Data Platform

Captivate VDC eConsent is fully integrated with Captivate EDC and other VDC modules, supporting unified workflows and data visibility for study teams.

Key capabilities include:

- Centralized access to consent status within Captivate study dashboards
- Shared audit trails for consent and clinical data events
- Consistent data availability for review, monitoring, and reporting
- Simplified downstream exports that include consent metadata

Security, Compliance, and Inspection Readiness

Captivate VDC eConsent is built to meet global regulatory and privacy expectations while supporting audit and inspection readiness without operational complexity.

Key capabilities include:

- Compliance with 21 CFR Part 11, Annex 11, GDPR, and applicable privacy regulations
- Secure delivery and storage of consent materials and signatures
- Role-based access controls and detailed access logs
- PHI and PII protections aligned with HIPAA and related standards

A Practical Alternative to Legacy Consent Models

Captivate VDC eConsent avoids the limitations of paper-based and rigid platform consent approaches.

- More flexible and engaging than static PDF or paper workflows

- More integrated and traceable than standalone eConsent tools
- Designed to scale from single-site studies to global, multi-phase programs

Who Uses Captivate VDC eConsent

Captivate VDC eConsent is used by sponsors, CROs, academic research organizations, and medical device and diagnostics companies that require compliant, participant-friendly electronic consent solutions.

Common use cases include:

- Interventional clinical trials Hybrid and fully decentralized
- studies Longitudinal observational research requiring re-
- consent Studies with multimedia or staged consent
- requirements

Why Study Teams Choose Captivate VDC eConsent

- Flexible configuration that supports complex consent requirements
- Participant-centric experiences that enhance understanding
- Unified consent and clinical data for streamlined workflows
- Built-in compliance and inspection readiness
- Secure, device-agnostic access for global study populations