

Captivate® Coder

Integrated, Accurate Medical Coding for Clinical Studies

Product Overview

Captivate Coder is a flexible, integrated medical coding solution designed to help sponsors, CROs, and clinical data managers standardize adverse events, concomitant medications, and medical history terms using recognized medical dictionaries.

Built to work within the Captivate clinical data platform, Captivate Coder provides structured, traceable, and compliant coding workflows that support data quality, analysis readiness, and regulatory expectations.

By combining intuitive workflows with configurable automation and quality controls, Captivate Coder helps teams reduce manual effort, improve consistency, and maintain full audit-ability throughout the coding lifecycle.

Flexible, Standards-Aligned Coding Workflows

Captivate Coder supports systematic application of medical dictionaries to clinical terms captured in EDC and other sources, while enabling teams to define rules that align with their operational and quality expectations.

Key capabilities include:

- Support for widely adopted medical dictionaries including MedDRA, WHO-Drug, ICD, and CTCAE
- Configurable dictionary versions based on study requirements
- Term mapping for adverse events, medications, medical history, and other coded fields
- Support for hierarchical term structures to preserve context and consistency

Intelligent Automation and Human Review

Captivate Coder balances automated suggestions with structured human review to support both efficiency and accuracy.

Key capabilities include:

Automated suggestion of coded terms for review

- Dictionary-aware pattern matching to improve first-pass accuracy
- Support for custom coding rules to surface preferred term suggestions
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- Real-time feedback loops for coding specialists during review

Automation is configurable, enabling teams to adjust the balance of machine-assisted suggestions and manual control to match their quality requirements.

Controlled Review and Quality Oversight

Captivate Coder supports structured review and adjudication to maintain coding integrity and traceability throughout the study lifecycle.

Key capabilities include:

- Role-based review and approval workflows
- Version history and change tracking for coded terms
- Commenting and rationale capture to support adjudication
- Searchable audit trails tied to coding activities

Seamless Integration With Captivate EDC

Captivate Coder is integrated with the Captivate EDC environment, enabling teams to manage clinical data and coded terms within a unified ecosystem.

Key capabilities include:

- Direct access to CRF terms requiring coding without data export
- Shared subject and event context between clinical entries and coded outputs
- Unified reporting that includes both source and coded data
- Simplified exports for analysis and regulatory submission readiness

Security, Compliance, and Traceability

Captivate Coder is designed to meet regulatory expectations and support disciplined quality processes without unnecessary complexity.

Key capabilities include:

- Compliance with 21 CFR Part 11, Annex 11, GDPR, and applicable privacy standards
 - Secure, role-based system access tied to study permissions
 - Detailed audit trails for coding decisions and workflows
 - Configurable dictionary versioning to support transparency across coding activities
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A Practical Alternative to Standalone Coding Tools

Captivate Coder delivers robust, standards-aligned medical coding without requiring standalone software or disruptive integrations.

- More integrated than disconnected coding spreadsheets or manual workflows
 - More structured and traceable than point solutions lacking audit and dictionary management
 - Designed to support studies of varying size and complexity without unnecessary overhead
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Who Uses Captivate Coder

Captivate Coder is used by study sponsors, CROs, and clinical data management teams who need consistent, efficient medical coding to support clinical data review and analysis.

Common use cases include:

- Coding adverse events across Phase I–IV studies
 - Standardizing concomitant medications and medical history entries
 - Supporting pooled safety analyses across programs
 - Preparing coded outputs for regulatory submissions and safety reporting
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Why Study Teams Choose Captivate Coder

- Standards-aligned application of medical dictionaries
- Balanced automation with controlled human review
- Integrated workflows with Captivate EDC
- Traceable review and audit histories for quality oversight
- Configurable dictionary versions and coding rules to support diverse protocols