

Medidata Coder[®] Cloud-based Enterprise Coding Solution

Medidata Coder streamlines your clinical trials with an easy-to-use, centralized coding environment that works out of the box with Medidata Rave[®] and simplifies dictionary maintenance.

Increased outsourcing and globalization of clinical trial activities make centralized, cloud-based coding critical to geographically distributed research teams. Medidata Coder is an enterprise software-as-a-service (SaaS) solution that delivers:

- A single, consistent, centralized environment serving all coding teams;
- Centralized management of distinct coding segments across therapeutic areas, global and partner teams and regulatory regions; and
- Painless and efficient up-versioning of synonyms and coding decisions.

Centralized, On-demand Coding

Medidata Coder offers clinical professionals on-demand, centralized coding that serves all teams — internal or outsourced — in a secure cloud environment. Multiple coding segments with different workflows, synonym lists and dictionaries can be configured to meet the needs of distinct therapeutic areas. We provide dictionary management and support MedDRA[®], MedDRA/J[®], WHO Drug and J Drug dictionaries. Synonym lists from older coding environments can be easily imported and migrated. As a cloud-based solution, Medidata Coder eliminates the need for dedicated IT resources and for replicated coding environments across multiple workplaces and teams.

The Coding Solution for Medidata Rave

Medidata Coder and Rave provide a superior solution for real-time coding with the ability to reduce coding cycle times, trigger queries and expedite query resolution. Coder works seamlessly with all of a sponsor's Rave studies, with no additional effort or maintenance required.

Centralized, Cloud-based Medical Coding

- Seamless interoperability with Medidata Rave
- Reduce study up-versioning risk prior to study lock and meet internal SLAs by provisioning new dictionary versions within 10 days of vendor release
- Streamlined up-versioning of synonyms and coding decisions to new dictionary versions
- Configurable, role-based workflows
- The ability to code terms and open queries across studies to improve coding productivity
- File-based integration capability with any EDC system
- Reclassification of coding decisions
- Personalized coding task list
- Multiple language support
- Coding audit trail and reports that support coding review processes

Accelerated Dictionary Migration

Traditionally painful dictionary up-versionings have driven sponsors and contract research organizations (CROs) to delay dictionary upgrades, jeopardizing submission timeframes. Medidata Coder provides an intuitive, user-friendly tool with built-in impact analysis that helps resolve potential conflicts prior to up-versioning and provides information on the workload associated with it to help sponsors plan resources accordingly. Verbatim terms that require recoding are automatically added to the coding task list with suggested coding terms. Synonym decisions are made for a single study or across many studies, and new dictionary versions are loaded quietly without service interruptions.

The latest release of Medidata Coder provides new dictionary versions within 10 business days of a vendor's release date. This expedited service enables finishing the process of up-versioning studies to the latest dictionary edition well in advance of the 60-day milestone. The elimination of the time pressure helps ensure the punctual completion of study up-versioning and allows for the allocation of resources to more strategic activities, such as reviewing and approving coding tasks for submission.

Expedited Safety Reporting

Early detection of safety signals and timely reporting and submission of clinical safety data require quick cycle times to collect adverse events from investigative sites, triage pharmacovigilance (PV) cases, code verbatim terms and submit to agencies.

Medidata's Rave Safety Gateway empowers sites to capture safety cases in their primary data entry system — Rave electronic data capture (EDC) — and instantly have them transmitted to PV teams using industry standard E2B files. In conjunction with Medidata Coder's real-time coding and tight EDC integration, this provides a real-time solution to further streamline the safety reporting process and minimize messy reconciliation.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including nearly 850 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 17 of the world's top 25 global pharmaceutical companies and is used by 16 of the top 20 medical device developers—from study design and planning through execution, management and reporting.

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Medidata Clinical Cloud®

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk