

Medidata Rave Coder Cloud-based Enterprise Coding Solution

Rave Coder streamlines your clinical trials with an easy-to-use, centralized coding environment that works out of the box with Medidata Rave EDC and simplifies dictionary maintenance which allows for mapping between terms entered in EDC forms to describe adverse events and concomitant medications and specific terms in industry standard dictionaries such as MedDRA and WhoDrug. The dictionaries provide a unique and special code number that is associated with the verbatim term. This precise and accurate coding allows detailed analysis of data collected across a clinical study.

Increased outsourcing and globalization of clinical trial activities make centralized, cloud-based coding critical to geographically distributed research teams. Rave Coder provides 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;
- Capability to build and use synonym lists for consistency and efficiency.

Centralized, On-demand Coding

Rave Coder is built on the Rave Clinical Cloud's unified data platform, which enables a single source of truth for all study-related data across your entire portfolio. This ensures that the right code numbers are associated consistently to the verbatim terms real-time enabling for faster data review and elimination of reconciliation. This can be accomplished because once data is entered, the platform masters and populates it throughout the end-to-end suite of Rave applications. The power of the platform offers clinical professionals on-demand, centralized coding that serves all teams.

Multiple coding segments with different work flows, 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, Rave Coder eliminates the need for dedicated IT resources and for replicated coding environments across multiple workplaces and teams.

The Coding Solution for Medidata Rave EDC

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

A Complete Clinical Trial Solution

- Seamless interoperability with Medidata Rave EDC and file-based integration capability with any EDC system
- 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
- Multiple language support
- Coding audit trail and reports that support coding review processes

The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords and excel sheets, you are now on a truly unified platform.

Accelerated Dictionary Migration

Traditionally painful dictionary up-versionings have driven sponsors and contract research organizations (CROs) to delay dictionary upgrades, jeopardizing submission time frames. Rave 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 Rave 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.

Rave Coder works directly with Rave Safety Gateway to empower sites to capture safety cases in their primary data entry system — Rave EDC— and instantly have coded data transmitted to PV teams using industry standard E2B files. In conjunction with Rave 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 Us

Medidata is leading the digital transformation of life sciences, with the world's most used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by the #1 ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve more than 1,200 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life sciences:

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Medidata Rave Clinical Cloud

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