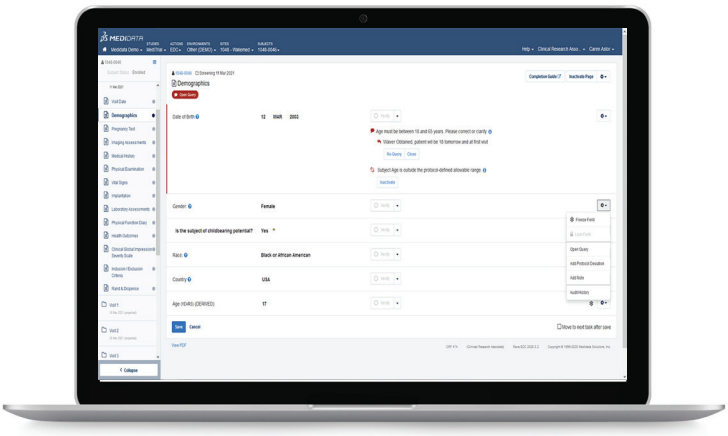
Rave EDC for Phase I Clinical Trials

Rave EDC delivers tailored, flexible and cost-effective solutions for Phase I clinical trials. Medidata has supported over 8,800 Phase I studies for over 980 clients.



Benefits of Rave EDC for Phase I Trials

In a 2020 survey[1], 42% said Rave EDC was their first-choice preference for Phase I and II studies, here's why:

Pricing and Speed to Match Your Budget and Timelines

- Pricing is scaled appropriately for the smaller size and budget of Phase I studies
- Phase I studies are built quickly and accurately using a pre-configured, pre-validated and accelerated EDC implementation service

Scalable Continuity into Phase II-IV Studies When You Need It

- Rave EDC is the preferred choice across all study phases according to a 2020 survey[1]: "First-choice preference for Medidata was fairly aligned across R&D segments, ranging from 33–42% of respondents – perhaps **evidence of a provider that has carved out a 'one size fits all application'"**
- Rave EDC scales from a few sites and healthy volunteers to mega-trials with thousands of sites and tens of thousands of patients

Flexibility for Mid-Study Changes

- Protocol amendments and incremental changes are implemented with no system downtime
- For adaptive trials, the management tool allows granular control over extensive study design changes, by configuring and testing the changes before deployment, with a full audit trail
- Multiple versions of a protocol are managed across subjects and sites based on IRB approvals etc. with the ability to move subjects from one version to another

Additional, Unified Capabilities to Meet Your Study Needs

- Rave EDC is built on the Medidata Clinical Cloud®, the unified platform that delivers streamlined workflows and common data views across multiple clinical development applications including:
  - eConsent: Provides patients with the option to consent in person or remotely using eConsent that automatically populates Rave EDC with the consented patient data
  - eCOA: Captures patient diaries and questionnaire responses via mobile devices or a web browser and directly feed that data into the EDC system
  - RTSM: Drives randomization, dispensation and supply inventory management from your EDC interface and eCRF data

1 EDC Market Dynamics and Service Provider Performance (4th Edition), Industry Standard Research, December 2020.

Features of Rave EDC

Centralized Administration

Manage users, roles, studies and sites across all Rave EDC (and other products on the Medidata Clinical Cloud) studies through Cloud Administration.

Intelligent Coding

Code verbatim terms automatically or manually with coding suggestions through Rave Coder.

Real-time Data Validation

Ensure data is correct at the time of entry. Validation is performed when data is entered into each field, not when a complete form is saved.

Reporting and Analytics

Make informed decisions with real-time study insights through dashboards and standard/ad-hoc reports, and one-click access from reports to relevant forms.

Bulk Actions

Eliminate repetitive clicking to set data statuses, speeding up data entry and verification by Data and Study Managers.

Interoperability

Ingest data from or extract data to any external system using sophisticated and secure integrations.

980+
PHASE I CUSTOMERS

8,800+
PHASE I STUDIES

The Medidata Advantage

The world's leading biopharmaceutical and clinical research organizations choose Medidata because they trust our unparalleled experience and expertise in providing clinical trial technologies to over 29,000 studies with over 8 million patients and healthy volunteers.

From Phase I to IV studies and across all therapeutic areas, our Rave EDC customers are enabled to:

- Execute with agility: Rapid deployments and upgrades, reduced study build times and faster database lock
- Work with the cleanest data: Real-time data validation and coding accuracy
- Manage complexity and scale: From the simplest to most complex protocols and adaptive trials; and from small patient populations in rare disease studies to mega-trials