Meet the Late Phase Challenge

In a regulatory and safety conscious environment where post-marketing commitments and studies are becoming ever more routine, biopharmaceutical and medical device companies increasingly turn to technology to drive efficiencies and optimize collaboration in their post-approval studies and registries.

The Medidata Clinical Cloud™ delivers instantaneous global access to advanced technology, data and analytics to transform clinical research. Study conduct from planning to execution is streamlined and accelerated, dramatically reducing trial timelines, costs and risk.

Part of the Medidata Clinical Cloud, Medidata Rave®—the industry-leading system for clinical research data capture, management and reporting—helps life science companies optimize their research investments. Rave maximizes utilization by investigators, reduces risk and redundancies in the clinical study process and dynamically provides trending data to help streamline and enhance studies.

Medidata brings over 10 years of proven experience in providing globally accessible electronic data capture (EDC) and data management solutions. With its modular approach and standards-based integration capabilities, Rave provides flexibility and scalability to meet any specific late phase study or registry requirements.

Easy to Use and Access Anywhere

Medidata Rave is cloud-based, meaning its accessible from any Internet-ready computer without the need for special software. An intuitive interface puts data entry, study management and reporting into the hands of prescribers regardless of their computer skills. Integrated eLearning modules help to quickly train even first-time investigators as they work.

Rave is exceptionally well-suited for late phase studies that involve investigators around the globe. Multi-language studies are handled within a single system, with translations occurring transparently. Users enter data in their local language; all data is immediately available for reporting in any study language.

Data can be entered into Rave from multiple sources—directly via browser, from paper (double data entry) or with easily integrated electronic sources, such as safety systems. With real-time quality checks, data is immediately available for analysis and trending from a single unified database.

Making the Right EDC Choice

The industry-leading system for rapid capturing, managing and reporting clinical research and post-marketing data, Medidata Rave is designed to help life science companies optimize their research investments by streamlining the clinical trial and post-marketing study process. A user-friendly interface, simple web-based access and real-time communication capabilities facilitate recruiting access and retention of investigator sites.

Combining innovative technology and expert global professional support,Medidata offers a scalable, low-risk alternative throughout the study life, even for extremely large long-duration studies. Rave is:

- Easy to deploy, train and use,
- FDA, 21 CFR Part 11 compliant,
- Efficient in handling mid-study changes, including visit structure and enrollments,
- Cost-effective with a low total cost of ownership, and
- Capable of integrating with investigator or patient portals and other third-party applications such as web-based patient reported outcomes (PROs).
Real-Time Data Analysis and Reports
Because Medidata Rave is a single system for EDC and clinical data management (CDM), data entered is immediately available to study management. Sophisticated reports for analysis and trending can be created without programming skills, providing immediate insight in patient and site performance and ultimately helping improve time-to-market opportunities.

Flexible Study Design and Mid-Study Change Services
Medidata’s experienced services team or a sponsor’s own internal team can quickly create data capture forms and workflows adapted to the unique needs of specific studies. If the protocol changes (a frequent occurrence in long-duration studies), researchers can change forms or workplans without threatening data integrity or study continuity. Sites and patients can be added in any language and data capture forms can be updated without losing collected data or critical study time.

Partnerships Expand Sponsors’ Implementation Options
Medidata trains and accredits select service providers ranging from small, niche consultancies to global contract research organizations (CROs) to deliver Medidata technology along with their project and data management expertise. Sponsors enjoy the flexibility to outsource aspects of their clinical research process or the complete implementation of their late phase study. Medidata also partners with best-of-breed clinical technology providers, taking advantage of Rave’s extensive interoperability tools to support rapid data sharing with other systems, such as web-based patient reported outcomes (PROs), safety reporting, electronic trial master file (eTMF) and clinical data repository/analysis systems.
Case Studies

Global Patient Registry
A major pharmaceutical company had relied on an internally developed, fragmented system to collect data on tens of thousands of patients receiving treatment in an open-ended patient registry. Inconsistent collection and storage made it difficult to obtain global data views, which hampered study usefulness. The company adopted Medidata Rave, which enabled:

- Building and maintaining an electronic system for the capture, management and reporting of data on more than 100,000 patients,
- Migration of patients and previously collected information into Rave,
- Access from 3,000 sites in 70+ countries, and
- Creation of management reports on study and non-study patients.

Multinational Phase IV Study
A global biopharmaceutical company designed a post-approval study to gather additional data on the safety and efficacy of an oncology drug. This multi-year investigation involved 3,000 patients in 18 countries across Europe. The sponsor decided that Medidata Rave was the best choice to help recruit and retain a broad participant base. The sponsor valued Rave’s ability to support a range of investigators through features including:

- Easy-to-use interface,
- Multi-language capability that accommodated the nine languages used by researchers, and
- Double-data entry support.

About Medidata
Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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