

# Designing & Implementing Studies Using Medidata Rave's Unified Clinical Trial Platform

## Study Building & Data Processing

As a Medidata partner, Westat uses a full suite of Rave solutions offered on a single unified study platform. Our clients benefit from the process efficiencies of this approach and have peace of mind that Westat data services adhere to the highest industry standards.

### INTEROPERABLE RAVE SOLUTIONS

- Electronic data capture (EDC)
- Randomization & trial supply management (RTSM)
- Coder
- Rave Safety Gateway
- Clinical Trial Management System (CTMS)
- eTMF

### Who We Are

Westat is a leading professional services organization providing end-to-end support for Phase 1 through 4 clinical trials. Westat is accredited in Medidata Rave study builder and our expert teams work directly with clients on the configuration of a wide range of Rave data capture and management solutions.

Our data services staff support the full trial life-cycle and all aspects of documentation and reporting needed to ensure audit readiness, and accessibility to data and documentation needed for communicating with key stakeholders and regulatory authorities.

Westat's integrated approach to data service offerings can fulfill your organization's research goals by providing real-time data and documentation to answer specific clinical and regulatory objectives.



## What We Do

- Engage sponsors early to identify Medidata tools and solutions that will enhance trial design and conduct.
- Streamline traditional processes on the unified Rave study platform, such as:
  - Design and build CDISC-compliant databases and analytic datasets in a 21 CFR part 11 compliant environment.
  - Subject randomization leverages the interoperability of the Rave EDC and RTSM system, eliminating delays and the burden of reconciliation.
  - As variables with an assigned dictionary are populated within Rave EDC, the embedded coding tool triggers auto-encoding or sends a notification for manual encoding.
  - Serious Adverse Event (SAE) data captured in EDC is directly transmitted to external safety systems via Rave Safety Gateway using E2B specifications.
  - Regulatory documents automatically filed, upon approval, to the eTMF for faster eSubmissions.

Photos are for illustrative purposes only. Any person depicted in the photos is a model.

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