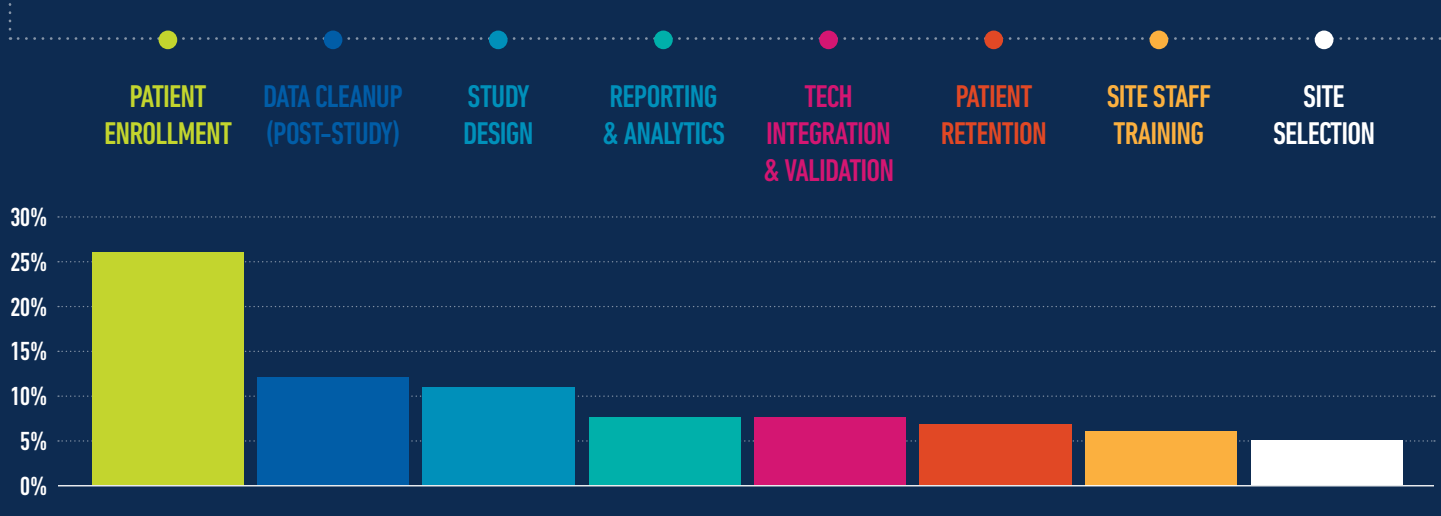
DELIVERING MORE EFFICIENT TRIAL EXECUTION NO MATTER THE STUDY SIZE

Whether it's a start-up of five employees trying to manage resources or an emerging biopharma seeking quick implementation of integrated data solutions for accelerated growth, Medidata understands the unique challenges facing mid-market organizations. Our unified data platform and service offering combine the industry's largest clinical business intelligence repository with user-friendly design, enabling faster study set-up and enhanced success rates. As a premier mid-market partner, we offer more than EDC — we offer end-to-end solutions that scale with your business.

CLINICAL TRIAL PAIN POINTS FOR MID & SMALL PHARMA (REVENUE <$5B)

Q. What are your company's top two challenges or pain points related to the clinical trial process?



CASE STUDIES

NORTH AMERICA

PhaseBio

Clinical-stage biopharmaceutical company committed to developing improved biotherapeutics for the treatment of orphan diseases.

CHALLENGES
- Limited number of affected patients (#1 pain point)
- Limited info available for pre-trial design (#3 pain point)

SOLUTION
- Rave EDC for their first Phase I study

BOTTOM LINE
- Rave's flexible architecture offers scalability to growing companies, providing data management for single- to multi-site studies
- Having all clinical data on one platform reduces the stress of merging data sets that would otherwise require manual effort of the internal team

"Thanks to their robust data management platform, Medidata Rave has the capability to scale with us. We can monitor multiple studies in parallel and potentially merge data sets as needed from these studies in order to support a streamlined development plan leading to approval."

—JOHN LEE, CHIEF MEDICAL OFFICER

EU, MIDDLE EAST, AFRICA

Cancer Research UK

World's largest cancer charity dedicated to saving lives through research.

CHALLENGES
- Randomizing trial subjects (#3 pain point)
- Drug supply management (#7 pain point)

SOLUTION
- Integration of Rave RTSM with Rave EDC enabled seamless monitoring

BOTTOM LINE
- Intuitive user interface led to reduced training time, faster access to data
- Product integration easier than originally thought
- Faster study start-up

"Everything is there in one place. We can filter by site, we can filter by what's been dispensed, and it's really easy for us to track."

—OLIVIA FRANK, CLINICAL RESEARCH ASSOCIATE

NORTH AMERICA

Zosano Pharma

Clinical stage biopharmaceutical company focused on rapid systemic therapeutics' administration.

CHALLENGES
- Increasingly complex regulatory requirements (#3 pain point)
- Siloed document and content management processes (#5 pain point)

SOLUTION
- Edge Quality with SOP implemented in a 6-week timeframe

BOTTOM LINE
- Consolidated documentation environment enables streamlined author-review-approval process
- Greater compliance confidence and inspection readiness
- 62% faster implementation compared to other vendors

"The user interface is extremely intuitive to use, and the mobile app makes reviewing and approving SOPs while traveling so simple."

—HAYLEY LEWIS, VP REGULATORY & COMPLIANCE

NORTH AMERICA

Onconova

Phase III-stage biopharmaceutical company focused on discovery and development of novel small molecule cancer drug candidates.

CHALLENGES
- Difficulty screening patients due to unpredictable eligibility criteria for rare indication qualifications of studies (#1, #6 pain points)

SOLUTION
- Initial selection of Rave EDC and Rave Coder
- Based on success of platform and company growth, Rave RTSM and Edge Targeted SDV introduced

BOTTOM LINE
- Platform offered flexible control over study build and design, allowing Onconova to employ a variety of different models based on available resources and costs
- Reduced costs of contracting third-party builders
- Standardized study build eliminated protocol redundancies and reduced trial start-up time

"A lot of sites were happy to hear we were going over to Medidata."

—PATRICK ZBYSZEWSKI, DIRECTOR OF CLINICAL DATA MANAGEMENT

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