

POWER THE DECISIONS THAT WILL ACCELERATE YOUR STUDY SUCCESS

Emerging Biopharma and Biotech (EBPs) drive the majority of trials and innovation in life sciences. However, median time for EBPs to launch new drugs is estimated to be **16.6 years, over 30% slower than other segments.**¹

A key success factor to address critical pain points is to assess the value and potential of clinical trial technologies.



64% of FDA-approved drugs in 2018 originated from Emerging Biopharma (EBPs)²

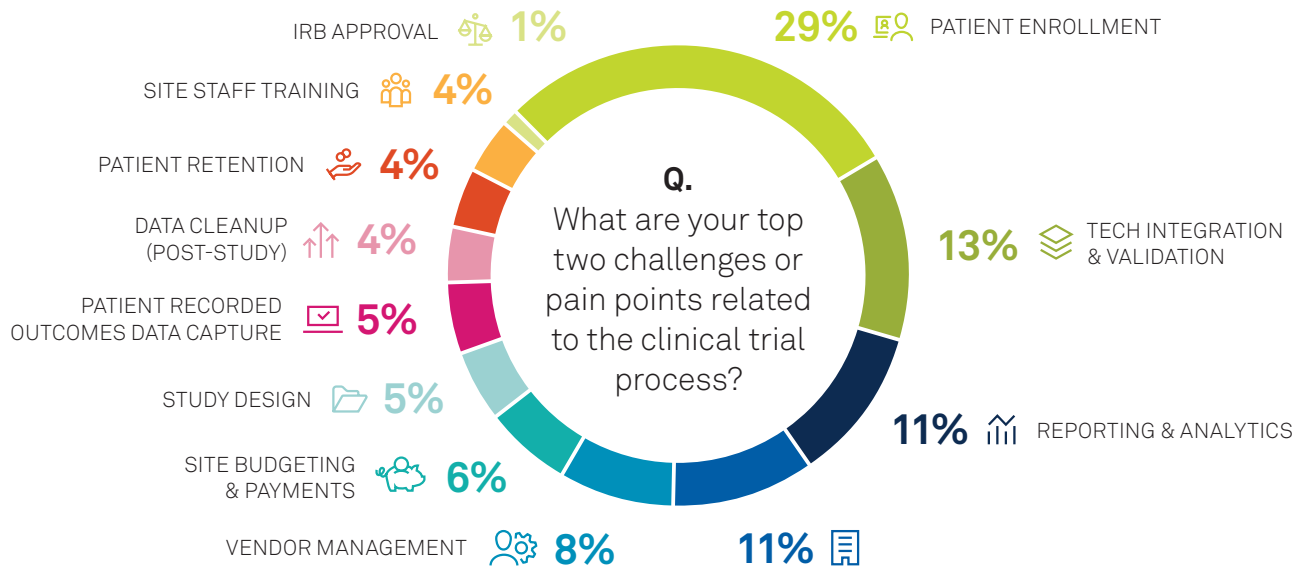


73% of late-stage research are managed by EBPs²



65% of all clinical trials were run by EBPs, more than larger companies across all phases¹

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



WHY MEDIDATA FOR EBPs

+3,000

Phase 1 Studies

+2,600

Single Studies

+1,200

Small and EBP Sponsors Globally



What our Medidata EBP customers experience

Medidata optimizes your patient enrollment, risk-proofs your data management, and gives you the agility to pivot your study, while meeting regulatory and compliance requirements.



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

PATRICK ZBYSZEWSKI, DIRECTOR OF CLINICAL DATA MANAGEMENT

⚠️ CHALLENGE

- 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



“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

⚠️ CHALLENGE

- 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 and faster access to data
- Product integration easier than originally thought
- Faster study start-up



“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, PHASEBIO

⚠️ CHALLENGE

- 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

¹IQVIA Institute, Emerging Biopharma’s Contribution to Innovation, June 2019

²Biotechs getting bigger in late-stage R&D, leaving Big Pharmas behind: report Fierce Biotech, April 2019