EMERGING BIOPHARMA & BIOTECH

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]

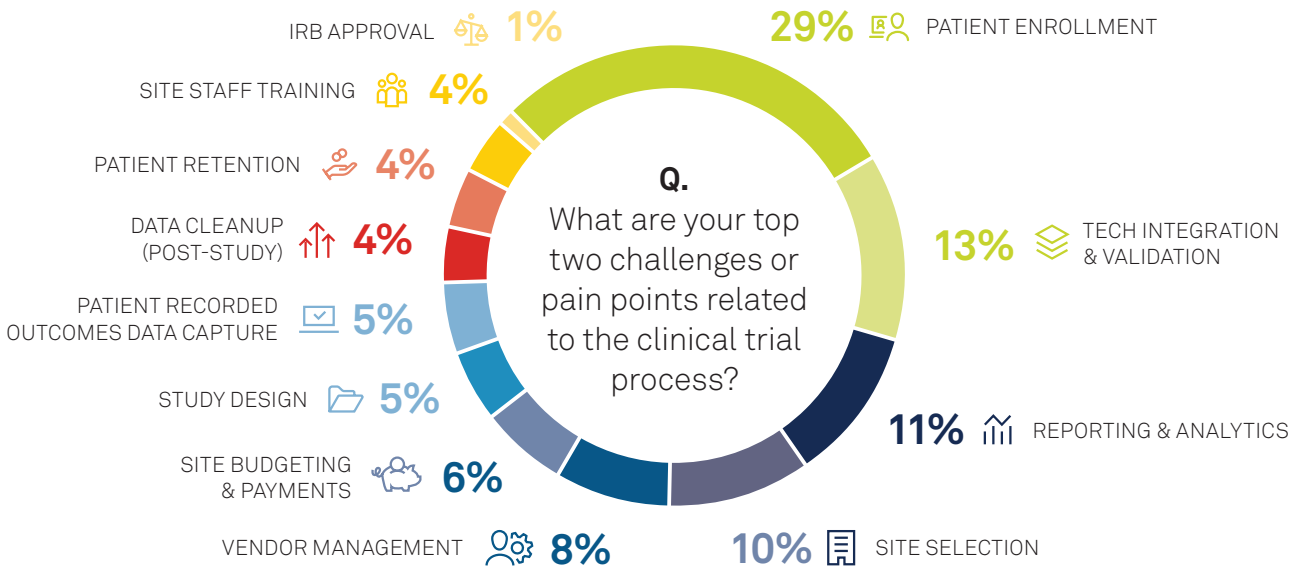
A key success factor to address critical pain points is to assess the value and potential of clinical trial technologies.

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

73% of late-stage research
are managed by EBPs[2]

65% of all clinical trials
were run by EBPs, more than larger companies across all phases[1]

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

Visit medidata.com/en/emerging/ to learn more.

MEDIDATA

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.

ONCONOVA THERAPEUTICS

"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 Rave 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

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CANCER RESEARCH UK

"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

PHASE Bio

"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

[1]IQVIA Institute, Emerging Biopharma's Contribution to Innovation, June 2019

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

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