medidata

EMERGING BIOPHARMA

DECISIONS THAT WILL ACCELERATE YOUR STUDY SUCCESS

64% of FDA-approved drugs in 2018 originated from Emerging Biopharma (EBPs)[1]

73% of late-stage research are managed by EBPs[1]

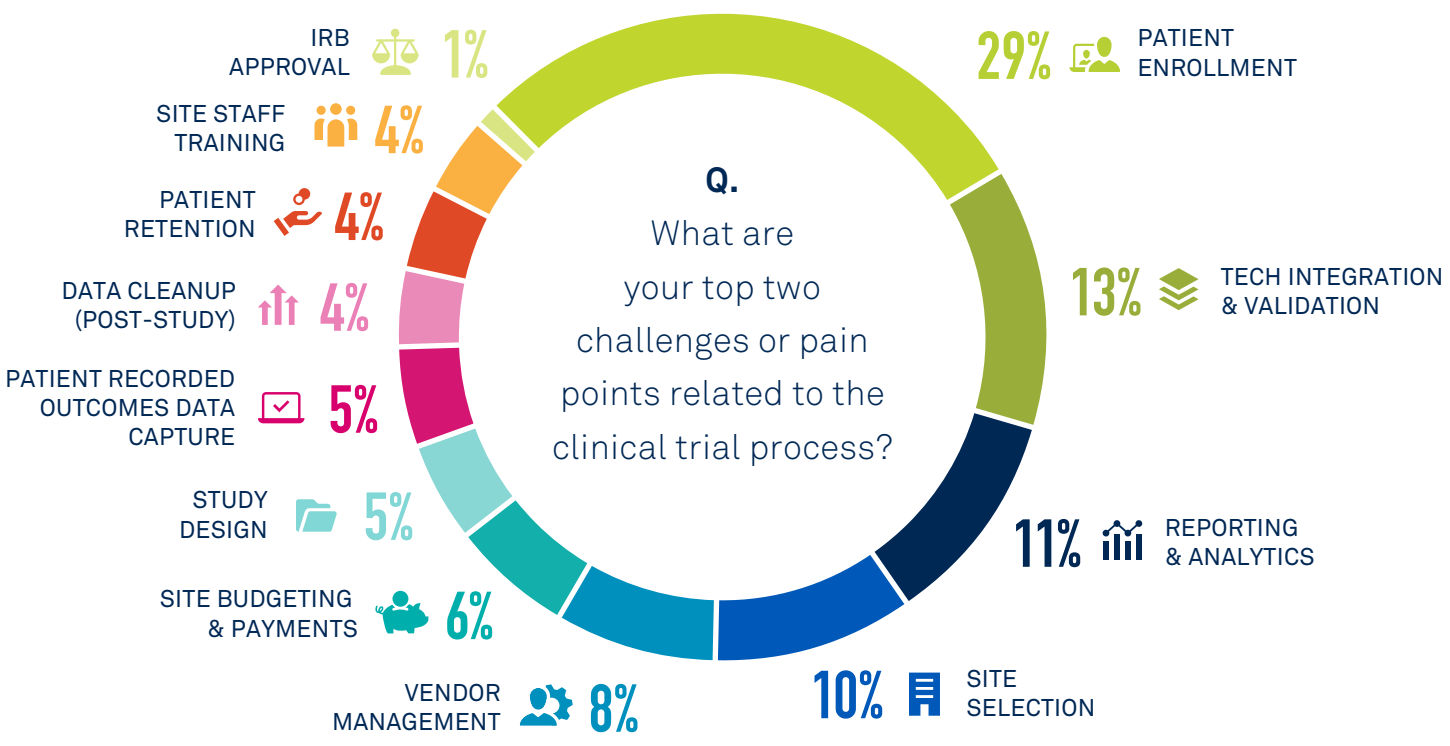
65% of all 2018 clinical trials were ran by EBPs, more than larger companies across all phases[2]

Emerging Biopharma drives 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**.[2]

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

CLINICAL TRIAL PAIN POINTS FOR SMALL & MID PHARMA

(Revenue <$5B)



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.

WHAT OUR EBP CUSTOMERS EXPERIENCED

NORTH AMERICA

PHASEBio

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

> "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

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

EU, MIDDLE EAST, AFRICA

CANCER RESEARCH UK

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

> "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, CANCER RESEARCH UK

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

NORTH AMERICA

ZOSANO PHARMA

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

> "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, ZOSANO PHARMA

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

EU, MIDDLE EAST, AFRICA

ONCONOVA THERAPEUTICS

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

> "A lot of sites were happy to hear we were going over to Medidata."
>
> **PATRICK ZBYSZEWSKI**
> DIRECTOR OF CLINICAL DATA MANAGEMENT, ONCONOVA THERAPEUTICS

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

WHY MEDIDATA FOR EBPs

+3,000 Phase 1 Studies

+2,600 Single Site Studies

+1,200 Small and Emerging Biopharma Sponsors Globally

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

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