ArcheMedX

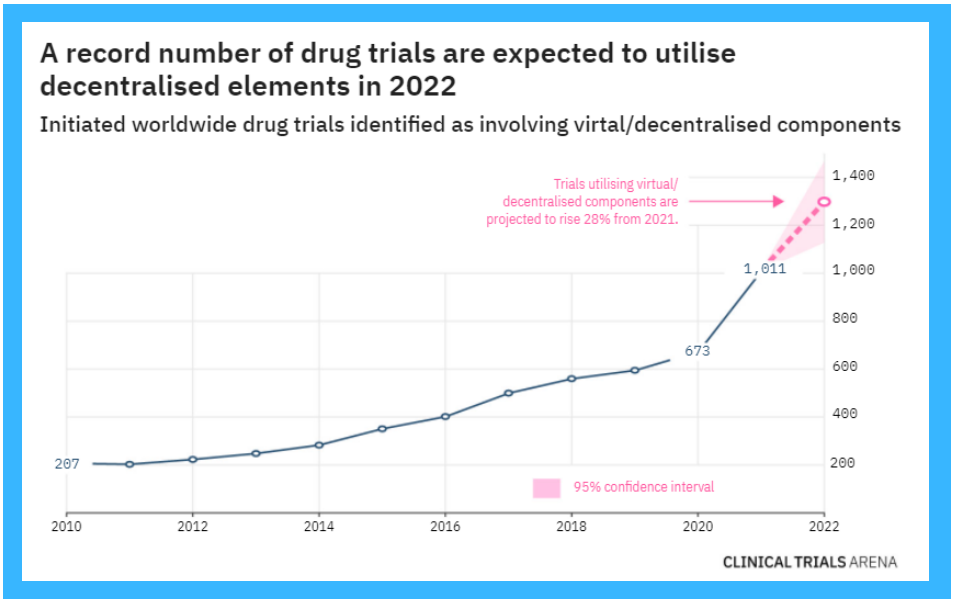
WHITEPAPER

DCTs at Risk, or Ready?
Assessing the Risks and Readiness of your next Clinical Trial

Updated February 2023

INTRODUCTION

It should come as little surprise that the rise in decentralized trials (DCTs) and increase in study complexities have magnified performance demands across clinical trial teams.



And according to a survey by Ernst & Young, **50% of clinical trials will be hybrid or decentralized by 2024**. As these trials move beyond the study site, and into mobile units and patient homes — there are now more far reaching, differentiated tertiary endpoints to manage, monitor, train, and evaluate. And in DCTs where PIs can no longer provide the same level of oversight and environmental control at an approved study site, the risks are magnified as home health staff, caregivers, and patients play more active roles across the study and in data collection.

For sponsors and CROs, preparing traditional sites and decentralized teams in a timely, effectively trained, and measurable manner has become a mission critical and increasingly difficult task. As a result, of the roughly **401,898 globally registered clinical studies** in process last year, more than **90% will miss key milestones** and thousands will ultimately fail to meet primary endpoints due to the operational complexity and costly delays that could have been mitigated and prevented sooner.

58% At Risk

82% Ready

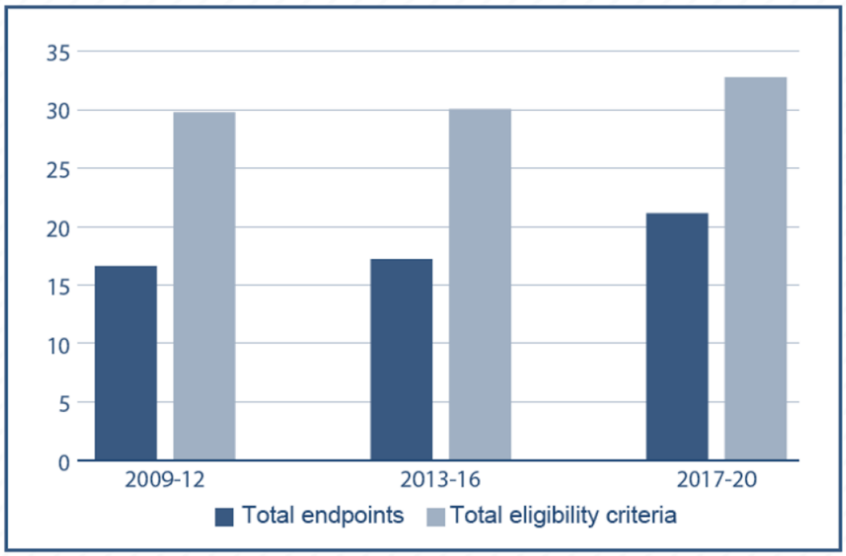
80% Ready

"The greater the trial complexity, the worse the performance - across all measures"

COMPLEXITY ACROSS TRIALS IS AT AN ALL TIME HIGH

According to the Tufts Center for the Study of Drug Development, the greater the trial complexity, the worse the performance - across all measures. And with protocol procedures up 44% since 2009 and study endpoints expanding **to 86% from 2005-2015, trial complexity is already at an all time high and growing.**

Increase in Number of Endpoints and Eligibility Criteria in Phase 2 and Phase 3 Trials



Note: All values are means.

In our podcast interview with Ken Getz - Director of the Tufts Center for the Study of Drug Development - Ken shared the factors that are contributing to increased complexity in clinical trial protocols and why attempting to simplify the design of a study is not the right goal. Rather, Ken explained the benefits complexity provides are greater if study teams can become better equipped at managing the complexity and minimizing the operational risks it creates.

INCREASED COMPLEXITY MAGNIFIES TRIAL RISK

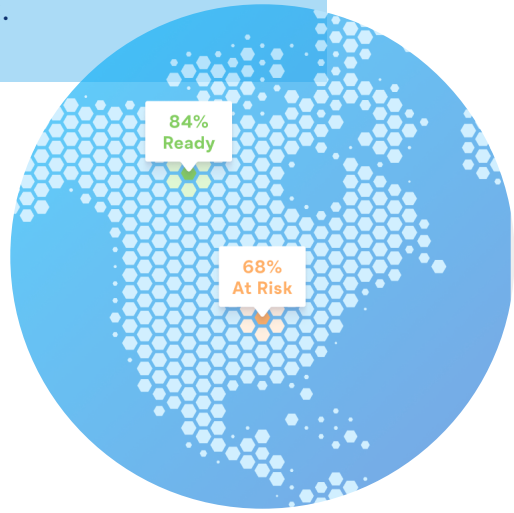
To manage the complexity, trial teams must identify the most likely risk areas before patients are enrolled and implement proactive strategies to address them. While every study shares common operational challenges, each may encounter increasing levels of risk in critical areas. Such as:

- Effectively screening diverse patient populations with more demanding inclusion and exclusion criteria
- Conducting the proper diagnostic tests and procedures safely and effectively at the site, in remote outpatient settings, or at the patient's own home
- Collecting more required data to meet primary, secondary, and tertiary endpoints

When these and many other risk areas are not identified early enough, the result can lead to missed timelines, patient safety concerns, bad data, and increased costs.

In a recent analysis of nearly **43,000+ clinicians** focused on CNS conditions, ArcheMedX found that more than **80% did not demonstrate sufficient proficiency** in clinical areas such as Alzheimer's, Migraine, MDD, MS, and Bipolar/Schizophrenia to formulate a differential diagnosis, develop individualized treatment plans, or navigate the complexity of CNS care teams to provide appropriate treatment.

"The risks are magnified as home health staff, caregivers, and patients play more active roles across the study and in data collection."



A LOSS OF ENVIRONMENTAL CONTROL MAGNIFIES RISK

As decentralized trials increase patient access and diversity, they also magnify the risks inherent in the rising trial complexity Ken Getz referenced earlier. The more distributed a study or the more new operational components, the more likely the operational risk.

This creates greater oversight and operational challenges for trial sponsors particularly as more naive trial participants and new decentralized partners are asked to play increasingly active roles in conducting trial activities and data collection.

These risks can lead to failures that result from an insufficient understanding of how to perform basic clinical research activities, challenges in collecting and reporting data, to reported violations of good clinical practices that require a trial sponsors to shut down some or all of a study.

Potential culprits for the failure might include:

- Poor planning or a misunderstanding of key biological and/or drug development principles
- Growing complexity of dosing regime or improper Dose Selection
- Missing requirements for FDA inspections and regulatory compliance
- Poor communication with patients and non-optimal assessment schedules
- Inappropriate efficacy metrics/markers
- Issues with how data is collected and analyzed

REMOTELY ACTIVATING SITES AND ENROLLING PATIENTS

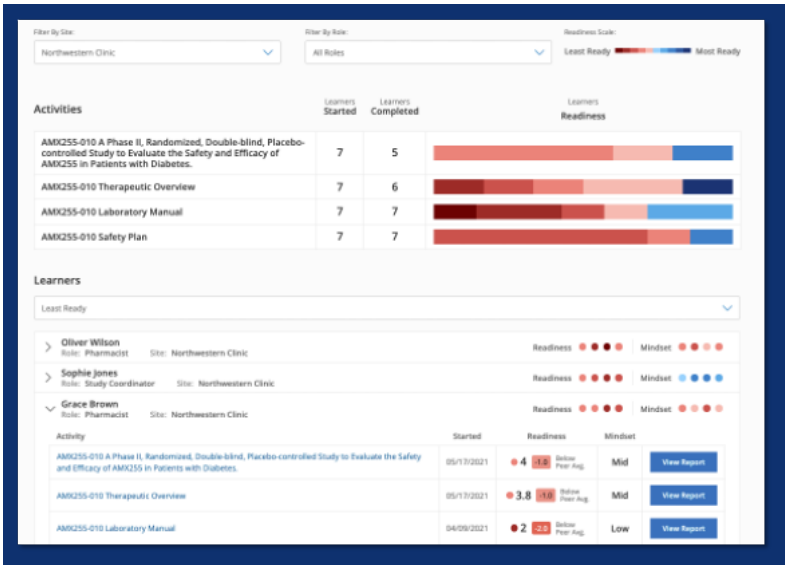
As decentralized trials increase patient access and diversity, they will also encounter increased operational challenges managing remote interactions among study teams, sites, patients, and caregivers. Without more effective remote training, individual trial stakeholder may not be adequately prepared to perform their role, adhere to study requirements, or meet GCP standards. Even worse, without new forms of remote oversight, trial leaders will lack the awareness to proactively address and mitigate these risks.

MITIGATING RISK BY INCREASING PREPARATION AND OVERSIGHT:

We've all seen the recent news of GCP violations at a decentralized site network and the more common statistic - **85% of clinical trials are delayed.** Violations should not occur and trials don't have to be delayed. Many of the unforeseen risks that lead to these issues could be identified far sooner and prevented.

With the expansion of DCTs, there is growing evidence that better remote training and accurate validation of trial team readiness is critical to minimizing risks. Tools that can accurately assess whether trial stakeholders are actually ready to conduct a decentralized study will uncover risks sooner and ensure better preparation that vastly improves trial performance, mitigates risks, and eliminates prolonged delays.

Advances across digital forms of training, cognitive and behavioral assessments, and predictive analytics enable new platforms such as **READY - powered by ArcheMedX** - to reveal precisely which sites, teams, and individuals are sufficiently prepared to conduct a clinical study and to more effectively train and upskill all stakeholders before the first patient is enrolled.



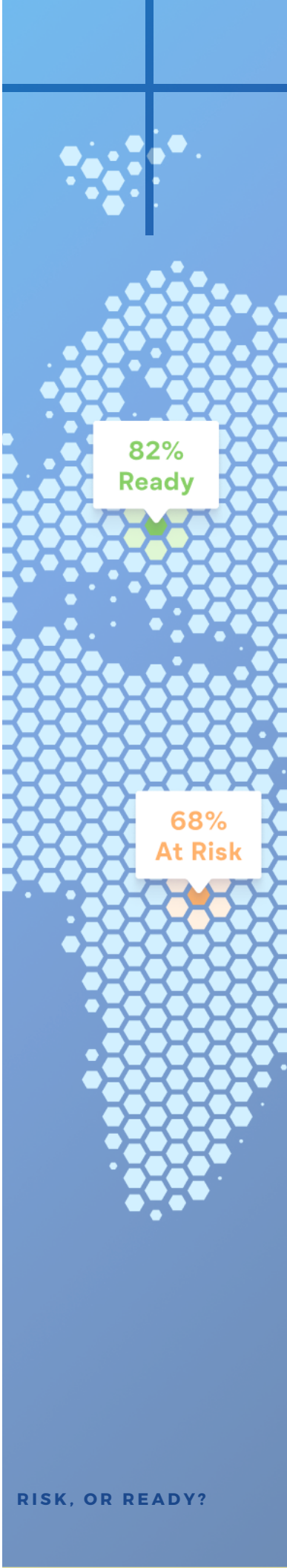
CONCLUSION

The continued rise in study complexity and increased risks in DCTs have magnified performance demands across more diverse clinical trial teams.

Ready provides a smarter way to predict and improve trial performance that overcomes these challenges. The platform empowers trial sponsors to identify risks sooner by transforming how they prepare and assess their sites and extended trial teams to avoid preventable delays.

21 of the top 25 pharmaceutical firms, emerging biotechs, and global CROs rely on Ready to improve clinical performance. For example, the 43,000 CNS clinicians mentioned earlier in this white paper increased their knowledge and confidence about properly screening and diagnosing CNS treatments **by 7x after completing more effective online training** using the Ready platform.

Ready's unique training capabilities and predictive insights enable trial leaders to accelerate enrollment and avoid costly delays. Learn how Ready reveals study risks sooner and delivers more tailored, role specific training at www.archemedx.com/ready.



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Why Do Clinical Trials Fail?

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Estimation of clinical trial success rates and related parameters

BY THE NUMBERS

85%

85% of clinical trials are delayed

"The greater the trial complexity, the worse the performance - across all measures"

90% will miss key milestones

90%

"The risks are magnified as home health staff, caregivers, and patients play more active roles across the study and in data collection."

50%

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