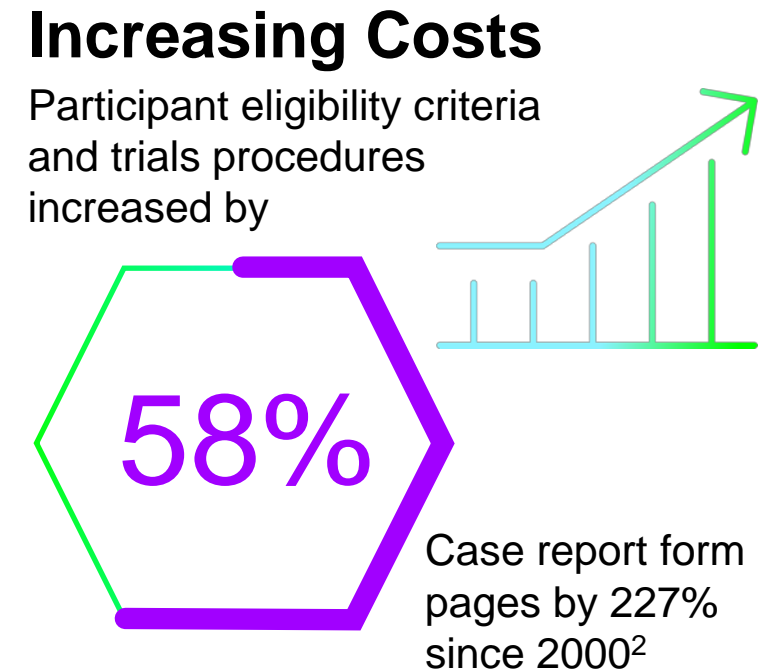
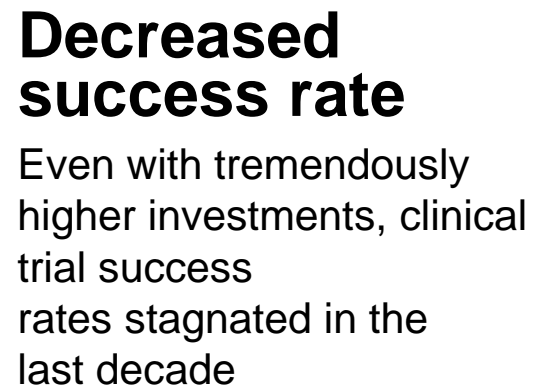
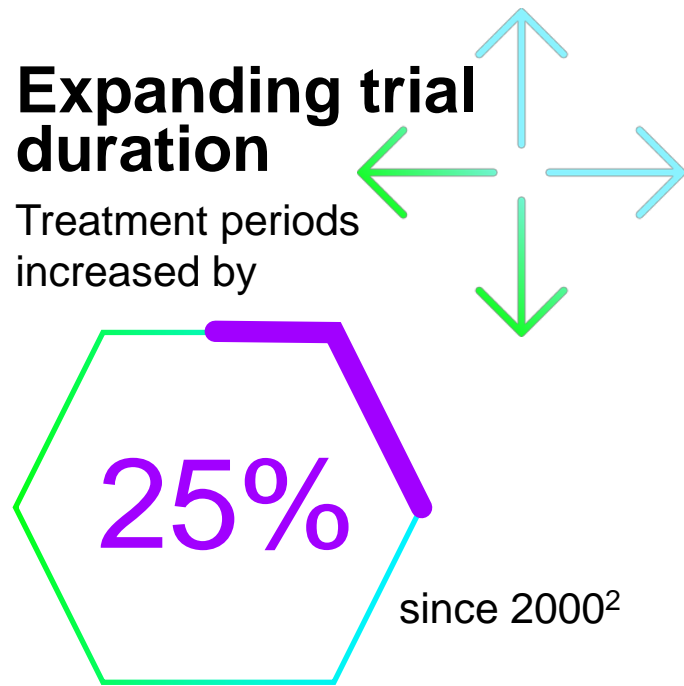


THE DIGITAL CLINICAL TRIAL: PLACING THE RIGHT BETS



TODAY'S INDUSTRY CHALLENGES REQUIRE FOCUS ON INNOVATION AND PATIENT OUTCOMES



DIGITAL CAPABILITIES ARE CREATING SPONSOR AND PATIENT VALUE

1 TRIAL DESIGN

Real world evidence, adaptive trial design, and inclusion of patient perspectives to enhance clinical trial design



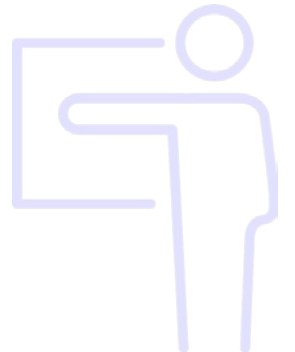
2 TRIAL START-UP

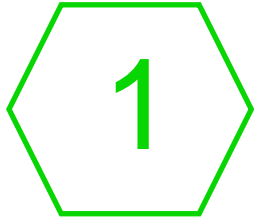
Analytics and digital learning platforms for site selection and engagement



3 TRIAL CONDUCT & CLOSEOUT

Digital tools to enhance patient recruitment and trial adherence while speeding time to database close





Real world evidence, adaptive trial design, and inclusion of patient perspectives to enhance clinical trial design



TRIAL DESIGN



CURRENT CHALLENGES

- One- dimensional trial design
- Rigid trial protocols
- Significant patient burden



DIGITAL ENABLER

- RWE and RWD to leverage previous trial success and failure
- Adaptive trial design and digital simulation of trial scenarios
- Patient and caregiver involvement via digital platforms



KEY OUTCOMES

- Decrease protocol complexity
- Increase ability to predict protocol outcomes
- Reduce trial delays and non-value added activities
- Improve patient experience and outcomes

2

Analytics and digital learning platforms for site selection and engagement



TRIAL START-UP



CURRENT CHALLENGES

- Ineffective site selection
- High site related costs
 - Recruitment, retention and monitoring account for ~30% of trial costs³
- Low patient recruiting rate
 - ~50% of all trials fail to achieve planned patient enrollment targets⁴



ACTION

- Site identification using analytics and aggregated databases
- Electronic health records (EHR) to model patient populations and inform about an investigator's ability to recruit
- Automation of process through Artificial Intelligence (AI) for site selection
- Digital media for training and communication



KEY OUTCOMES

- Improve site experience
- Enhance ability to focus on the high recruiting sites
- Reduce cost (up to 10%³) with remote management and training of sites
- Improve site engagement with digital training for staff



Digital tools to enhance patient recruitment and trial adherence while speeding time to database close



TRIAL CONDUCT AND CLOSEOUT



CURRENT CHALLENGES

- Significant (~ 200%) delays in recruiting timelines³
- Clinical staff engagement critical, not under control of sponsor
- Significant patient drop out rate
- Lack of patient adherence



ACTION

- Automated and digital tools for patient screening and engagement
- Adherence control by remote digital systems
- Direct data capture via wearables and mobile networks



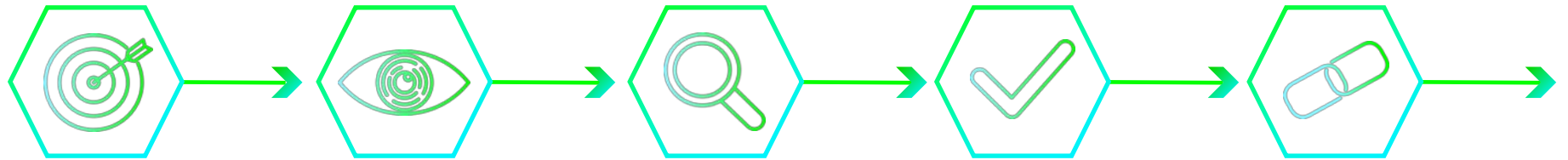
KEY OUTCOMES

- Improve patient experiences
- Reduce timelines from first patient first visit to last patient first visit
- Enable precise data collection and real-time analysis
- Decrease time from data collection to data clean/ database close

RETHINKING CLINICAL TRIAL CONDUCT AND A MINDSET SHIFT WILL DRIVE DIGITALIZATION BENEFITS

To fully embrace digital and help enable end-to-end transformation, companies need to scale these capabilities to the enterprise level

Next steps for realizing value through adoption of digital capabilities:



Determine the needs of all clinical trial stakeholders (e.g., sponsors, sites, patients) to inform a digital clinical trial strategy

Define and implement a digital clinical trial strategy and plan aligned to a broader R&D digital strategy

Evaluate and incorporate the ongoing and planned digital pilots into the digital clinical trial strategy

Confirm top-level management alignment to set and communicate the digital clinical agenda, structure and culture within the development organization

Embed and test selected digital capabilities; document success / failures to continue scaling the right tools at the right time to new products or therapeutic areas



SPONSORS NEED NOT— AND SHOULD NOT— WAIT FOR 'PERFECT' DIGITAL TOOLS OR SOLUTIONS

Sponsors will be able to reimagine how they conduct the critical activities of product development, which would measurably improve patient experiences and outcomes

By looking at patients and diseases holistically and interacting with patients differently, the digitalization of clinical trials would help:

- Feed insights back into research and early development to improve disease targeting and protect future patients a burdensome trial or therapy experience
- Find the patients that benefit the most from a selected therapy and enroll in high performing sites
- Reduce the risk for all stakeholders by identifying issues in real-time, or better yet, predicting them before they occur

Sponsors who “get in the game” and begin to place their digitalization bets will find themselves in the best position to be leaders in the future of clinical trials.

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