Navigating post-COVID-19: How can clinical trials optimize efficiency and effectiveness during pandemics?

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Abstract

Worldwide, clinical research teams are confronting issues of scale as they seek to develop novel therapies. Emerging complexities such as COVID-19 pandemic, limited resources, technology systems, multiple stakeholders and vendors are some of the recent examples that have challenged clinical trial management. To stay ahead of potential issues in a real-time, sponsors and CROs have opted to remain vigilant on high-value activities, embrace adaptive systems and workflows, as well as embracing the revised ICH E8 (R1) addendum. Attempts to optimize and streamline clinical operations workflows currently remains elusive. Leveraging strategic designs into clinical trial execution has been suggested as a missing link especially during the current pandemic. Strategic design is a procedure used to unpack game-changing insights into clear, concise, and complete actions for execution. It demystifies and illuminates on: the what, where, who, when, why, and how of operations. Due to the Coronavirus disease 2019 (COVID-19) pandemic, clinical trial landscape has evolved rapidly in response to challenges such as quarantines, site closures, travel limitations, study supply chain interruptions, and front line site personnel exposure risk. These challenges may lead to deficiencies in meeting protocol-specified procedures such as investigational product (IP) administration, compliance to protocol-mandated visits, and adherence to laboratory or diagnostic testing. These add a background noise to an environment of growing complexity hence the need for a range of innovative approaches such as streamlining trial designs, virtual visits, patient-centric enrollment, patient's insights, patients-facing techs, analytics-driven feasibility, digitalization of clinical trials, among others. These approaches are designed to quickly evaluate promising therapeutics without rebuilding research infrastructure. However, in an environment with imprecise predictability, managing clinical trials of any size and complexity requires strategic planning and robust execution. The need for strategic design is more pressing now than ever to ensure extensive savings in time and cost.

Key words: COVID-19, Strategic design, Clinical trials, Efficiency, Effectiveness, Optimize

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Introduction

As the Coronavirus diease-19 (COVID-19) keeps evolving [1], strategic designs are providing unique opportunities in maximizing resources and mitigating risks to speed up clinical trial execution [2]. Asking the right questions, sourcing the right data, and consolidating data insights, pathways, processes, and people together can drive potency in decision making and ultimately the successful delivery of a clinical trial. What's more? Digital technology, Artificial Intelligence (AI), real world data, and advanced analytics are recent examples identified as pillars of successful clinical trial in the current COVID-19 pandemic [3].

The situation

In an environment of growing complexity as a consequence of COVID-19 pandemic, navigating clinical trials of any size and complexity requires strategic planning and efficient execution. In March 2010, the Food and Drug Administration (FDA) issued an outline/guidance on safety of trial participants, Good Clinical Practice (GCP) compliance, and minimizing risks to trial integrity. With the FDA guidance, the passage of the ICH E6 R2 addendum (Integrating Risk Management and Oversight), and the introduction of ICH E8 R1 (Infusing Quality by Design/ QbD) [4], the pharma industry needs to re-evaluate their trial designs, regulatory expectations, and project results. With no clear execution map, these clinical trials may fail to demonstrate clear efficacy and safety. Consequently, this may have negative implications on resources and time. The "how" to leverage these new guidance documents during pandemics remains a hypothesis for many sponsors and CROs.

The Challenge

Worldwide, we've witnessed an immediate impact on clinical trials due to challenges coming from the COVID-19 measures taken to "flatten" the curve: travel restrictions, Lockdowns, hospital/clinic visitation restrictions, social distancing precautions, and shifting operations to work remotely on a short notice [5]. These factors have translated into challenges such as operations, milestones, budgets, data integrity, and

monitoring. If not well managed, these challenges may pose as barriers in achieving study protocol-specified procedures such as IP (Investigational Product) administration, compliance or adherence to protocol-mandated visits, and laboratory/ diagnostic testing. To this end, best practices to mitigate risks and adjust clinical operations in these unprecedented times are currently under study to identify potential solutions and optimize the available resources.

The Solution

A new world order in executing clinical trials has emerged during the COVID-19 pandemic. This new paradigm shifts drives innovations, execution, and emerging best practices for planning and implementing high quality clinical trials into the next decade. Through thoughtful approaches to tough industry questions, strategic designs can empower the execution of clinical trials under the new landscape [6]. Encoding strategic design into the new clinical trial ecosystem and services fosters a new paradigm to embrace more risks while avoiding it.

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