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Today's Feasibility Challenge: Harnessing Data to Deliver Patients into Clinical Trials

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With research pipelines continuing to grow, drug developers must address two critical challenges: recruiting greater numbers of study patients in an increasingly crowded research space; and reducing today's unsustainable research costs. Solutions to both challenges lie in accessing and applying growing volumes and types of health data. Data-driven feasibility assessment is at the heart of the emerging evidence-based clinical trial process.

Current startup practices are limited by constraints on accuracy, timeliness and transparency of the processes, particularly in site selection and patient recruitment. Traditional approaches still rely on manual processes and ad-hoc tools that are time and resource intensive and have a high degree of inaccuracy. Traditional site selection focuses primarily on sponsor and CRO experience and site surveys. These methods can lead to a high level of non-enrolling and under-enrolling sites, driving up costs and time overruns.

Accurate, reliable feasibility assessment has the power to dramatically improve the

predictability of site performance and patient recruitment. New data-driven approaches to feasibility that integrate disparate data sources that map potentially eligible patients to sites, research expertise and sophisticated modeling and simulation are the keys to improving decision-making and performance predictability.

With so much data available today, it is not only the ability to access this data, but moving from simply knowing that eligible patients exist, to actually bringing them into study sites for screening and enrollment. To meet this "last mile" challenge, companies need to connect the most relevant patient, site and investigator data with analytic tools and targeted processes to ensure efficient, cost-effective startup operations. Strategic assessment of a trial's specific challenges provides insights to mitigate risks before startup activities begin. At the end of the feasibility engagement, this holistic, data-driven methodology delivers the right combination of study sites, enabling sponsors to navigate the complex startup ecosystem with greater confidence and efficiency.



Gaurav Bhatnagar leads the strategic vision and development of PPD's feasibility services. In that role, he manages the implementation of analyses of external and internal data sources and drives innovation across strategic feasibility services. Prior to PPD, he held leadership positions in global data and safety monitoring, clinical development productivity and quality, product development and strategic planning for innovation.