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Data-driven Site Selection ACCELERATING YOUR TRIALS THROUGH PREDICTIVE SITE MODELING

Accelerated study start-up is the universally acknowledged holy grail of streamlining clinical trial operations. While advancements like central IRB review, adaptive trial designs, and the implementation of electronic systems have led to increased efficiencies across the clinical trial enterprise, the overall start-up phase of a clinical trial continues to be the primary source of trial delays. The persistent application of 20th century thinking and practices in study start-up lie at the root of the biopharmaceutical industry's failure to streamline study activation. The most egregious cause of study delays occurs in site selection at the very beginning of a trial. It is well documented that antiquated practices in site selection leads to wasteful trials. Notably, in many indications, more than 50% of sites fail to enroll a single subject — a factor that unnecessarily extends enrollment timelines by over 75%. Consequently, many trials fail not based on science, but due to poor operational strategy and execution. Though avoidable, this costly reality is largely ignored by many biopharmaceutical companies.

Predictive Modeling

The emergence of big data sets, sophisticated data mining techniques, natural language processing, and machine learning has created enormous opportunities to solve inaccurate, inefficient, and misinformed site selection practices through predictive modeling. Predictive modeling is the process of creating, testing, and validating a model to best predict the probability of an outcome. While predictive modeling solutions for site selection are readily available to biopharmaceutical companies, the greatest obstacle to realizing their value remains in overcoming lagging adoption curves. Many of the biopharmaceutical companies that could benefit most from these solutions are not taking advantage of them. The overwhelming majority of biopharmaceutical companies continue to engage in imprecise, subjective, and entirely human-driven site selection practices. Predictive and sophisticated site selection techniques are often resisted and not implemented by operational leadership and study teams. As such, historical problems persist even when far more effective solutions are available.

THE PERSISTENT APPLICATION OF 20TH CENTURY THINKING AND PRACTICES IN STUDY START-UP LIE AT THE ROOT OF THE BIOPHARMACEUTICAL INDUSTRY'S FAILURE TO STREAMLINE STUDY ACTIVATION.

THE PRESSURE ON CLINICAL OPERATIONS LEADERSHIP AND STUDY TEAMS TO OVERHAUL THEIR CLINICAL TRIAL OPERATIONS BY HARNESSING THE POWER OF DATA HAS REACHED A TIPPING POINT. IT IS NO LONGER SUFFICIENT TO SIMPLY CONSIDER PREDICTIVE MODELING; BIOPHARMACEUTICAL COMPANIES MUST IMPLEMENT THESE SYSTEMS NOW.

Companies that fail to implement predictive modeling solutions in site selection do so at their own peril. In examining the most competitive drug development indications, our research at WCG demonstrates that companies that apply predictive modeling in site selection achieve downstream efficiencies of up to seven months, on average. These companies require fewer sites to achieve patient enrollment targets and do so 50% faster than their competitors in the same indications. Clearly, applying predictive modeling can mean the difference between winning and losing a drug development race.

Highly competitive indications like non-small cell lung cancer (NSCLC) demonstrate the stakes of applying antiquated models of site selection. Of the 50 biopharmaceutical companies jostling to bring their respective therapies to market in NSCLC, average enrollment cycles for Phase III trials are in excess of 20 months. Alternatively, those companies using predictive modeling achieve enrollment completion in 10 months, or 100% faster than their competition. In the face of skyrocketing R&D failure rates, mounting costs to the healthcare system, and the hundreds of millions of dollars of waste that could be avoided through predictive modeling, it stands to reason that biopharmaceutical companies have an obligation to employ such techniques.

The Tipping Point

The pressure on clinical operations leadership and study teams to overhaul their clinical trial operations by harnessing the power of data has reached a tipping point. It is no longer sufficient to simply consider predictive modeling; biopharmaceutical companies must implement these systems now. When science is equal, the biopharmaceutical companies that utilize predictive modeling in site selection will win drug approval races. In so doing, they will create advantages for their organizations, patients, and the larger healthcare ecosystem. PV

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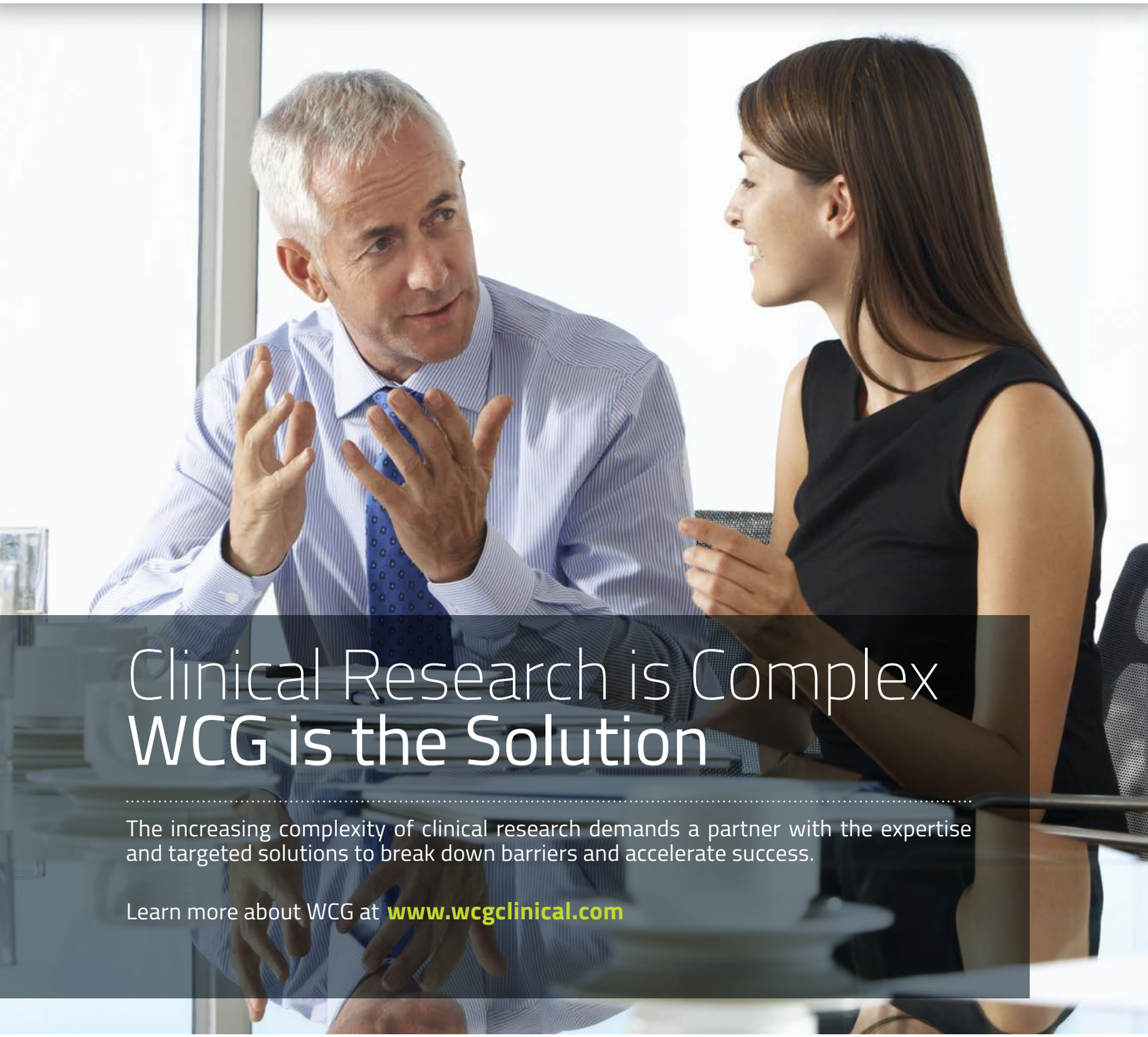

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