Complexity and Specialization: AN INEVITABLE DANCE

Contributed By:

DONALD A. DEIESO, PH.D.
Chairman and CEO
WIRB-Copernicus Group

For decades, general practitioners successfully managed the healthcare needs of entire families. From treating the common cold to addressing urgent injuries, from delivering babies to providing geriatric care, the family doctor was there to see us through all walks and phases of life. Today, although many of us reflect on that period in time with some nostalgia, we also understand how unsustainable that model was due to the natural evolution of increasing medical knowledge.

With so many recent advances in the underlying science — the half-life of what clinicians know has been shortened considerably. This has challenged their ability to provide exceptional care across the growing range of therapeutic areas. For this reason, general practitioners rely on the expert advice of specialists and subspecialists in the delivery of care. We have come to embrace a model of healthcare delivery in which hyper-focused professionals provide deep care across increasingly specialized domains.

THE BIOPHARMA INDUSTRY, SUPPORTED BY THE FDA, HAS RECOGNIZED THE NEED TO CHANGE THE ONE-SIZE-FITS-ALL APPROACHES TO CLINICAL TRIAL DESIGN AND MANAGEMENT.

Creating a Specialized Approach

Why should the management of clinical trials not also favor specialization? The biopharmaceutical industry, supported by the FDA, has recognized the need to change the one-size-fits-all approaches to clinical trial design and management. As an example, with the advancements of personalized medicine, our industry is tackling more orphan and rare diseases requiring different approaches to conducting clinical research. Those involved in the management of clinical trials must adapt conventional approaches to reflect these changes. New models of collaboration among sponsors, CROs, clinical service organizations, sites and regulators are required to meet the growing demand for efficacy and quality — these models must favor specialization in the performance of each trial component. Reductions in clinical trial time can be achieved by eliminating needless administrative delays and frictions among the many parties involved in the trial.

SPONSORS AND CROS WOULD BE BETTER SERVED BY IMAGINATIVE AND RESPONSIVE NEW APPROACHES TO CLINICAL SERVICES.

Consider the significant challenge of improving the timeline of the clinical trial activation process. To maximize efficiency, sponsors and CROs must first select supporting service partners that possess the specialized knowledge and technology to optimize these activities. Trial optimization begins at site feasibility. Choosing the right sites for a specific trial can determine the overall success of a trial. By using detailed site performance characteristics, the probability of sites meeting expectations can increase dramatically. For example, a top 10 pharmaceutical company was able to eliminate more than one month from its site feasibility process using a highly specialized, proprietary feasibility solution — one that produced a 45% higher response rate than the industry average.

Every sponsor and CRO is mindful of the delays that result from negotiating clinical trial contracts and budgets with the participating sites. Challenging, too, is assuring that the sites receive timely site payments. Global clinical studies provide an even greater complexity in this regard — specifically the negotiator should understand local laws, customs, and regulations and be able to communicate fluently with sites and doctors in local languages. If not properly managed, these tasks can expose clinical trial sponsors and CROs to unnecessary risk.

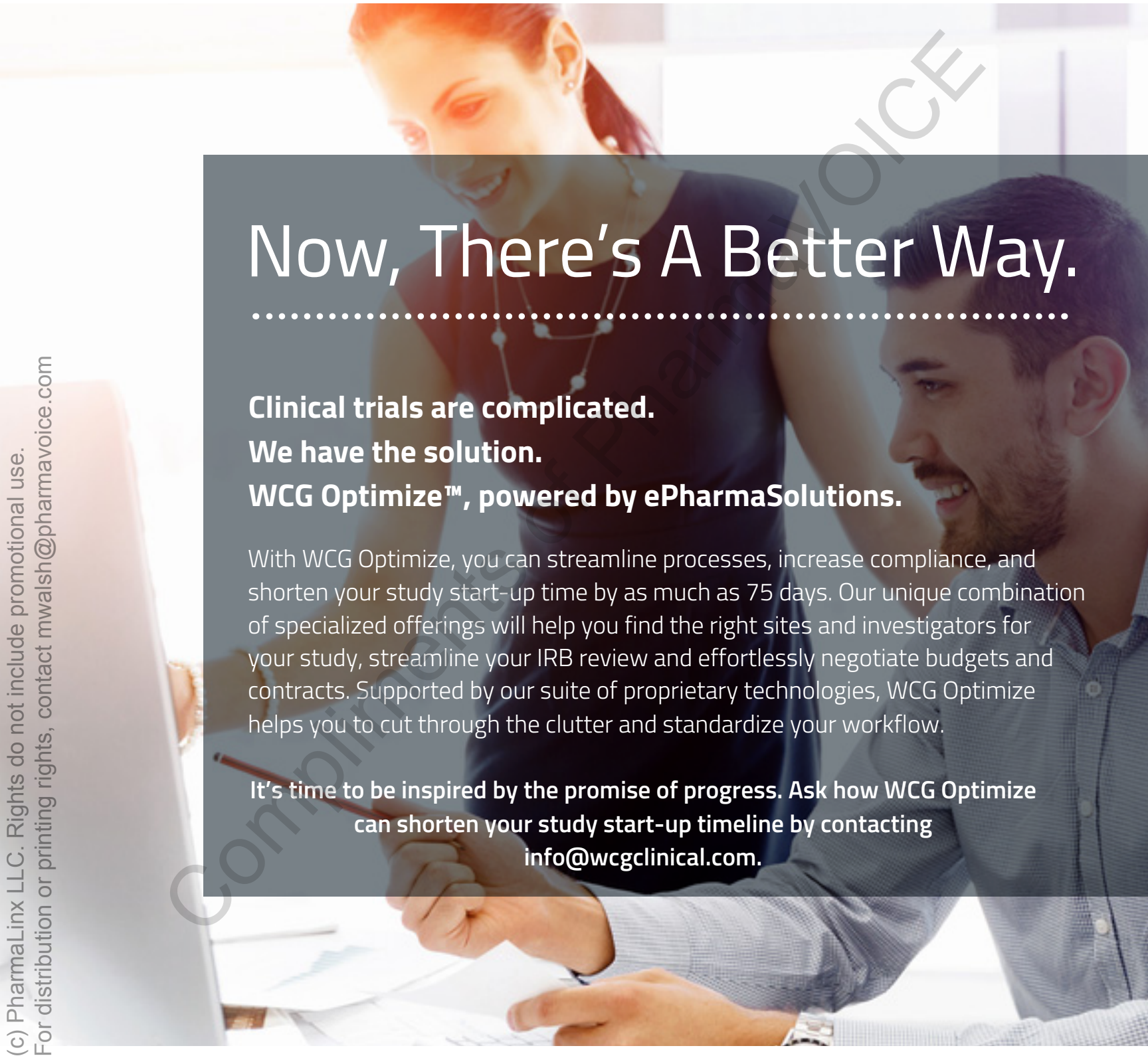
The introduction of new trial designs, increasingly complex protocols, and companion diagnostics have made the ethical and regulatory oversight of clinical research more challenging than ever. IRBs must be current with the latest science and technology, especially in rapidly advancing therapeutic areas like oncology and gene therapy.

Best-of-breed clinical trial solutions can yield powerful results individually. However, the results can be synergistic when used in combination. That's why end-to-end clinical trial activation solutions that address the most time-consuming elements of the start-up process — capable of producing a four- to five-month reduction in the study start-up timeline — are necessary.

Sponsors and CROs would be better served by imaginative and responsive new approaches to clinical services. Much like the savvy general practitioner, clinical trial partners that have evolved to better meet the specialized needs of their clients can look forward to continuing the inevitable dance of progress as the future ushers in new and ever promising advances in clinical research.

wcg Optimize™

powered by ePharmaSolutions®



Now, There's A Better Way.

Clinical trials are complicated.
We have the solution.
WCG Optimize™, powered by ePharmaSolutions.

With WCG Optimize, you can streamline processes, increase compliance, and shorten your study start-up time by as much as 75 days. Our unique combination of specialized offerings will help you find the right sites and investigators for your study, streamline your IRB review and effortlessly negotiate budgets and contracts. Supported by our suite of proprietary technologies, WCG Optimize helps you to cut through the clutter and standardize your workflow.

It's time to be inspired by the promise of progress. Ask how WCG Optimize can shorten your study start-up timeline by contacting info@wcgclinical.com.

www.wcgclinical.com

WIRB-COPERNICUS GROUP.
Powered by change.