Integrated Study-specific eClinical Solutions: THE MOST EFFICIENT PATH FORWARD AND HIGHEST QUALITY RESULTS

Contributed by:

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While other industries decrease their operational timelines and increase efficiencies by implementing the newest technologies, the pharmaceutical industry is at a stand-still, plagued by unnecessary redundancies and administrative burdens imposed by inflexible, enterprise eClinical solutions. Promising consistency and integration, too often these solutions require extensive customization and necessitate layer upon layer of internal deliberation and review.

IT'S TIME TO MOVE AWAY FROM A ONE-SIZE-FITS-ALL APPROACH AND TOWARD SIMPLER, MORE FLEXIBLE, STUDY-SPECIFIC TECHNOLOGY THAT BETTER MEETS THE NEEDS OF THE INDIVIDUAL TRIAL.

Single Study Versus Enterprisewide Solutions

As anyone who has lived through it knows, it takes years to implement an enterprise eClinical solution. This prolonged timeline is inconsistent with the biopharmaceutical business model, which is increasingly dynamic in nature. If research organizations want to remain as responsive as the drugs and biologics they create, they cannot afford to hamper their processes with one-size-fits-all technology. It is unrealistic to think that one solution — implemented across an entire global research organization – could be flexible enough to adapt to changing regulatory demands, new and innovative study designs, and individual workflows.

Ideally, the trial's operations would mirror its design in innovation, flexibility and adaptability. In an era of precision medicine, agile, single-study eClinical solutions hold more promise than their enterprise counterparts in being able to meet the unique demands of each trial.

For example, a study-by-study eClinical solution, empowers clinical teams to make more informed decisions about every element of their trial – from executing the confidentiality agreements to collecting participant data – while easily integrating with existing technologies for expedited deployment. This type of solution ensures excellent data quality and regulatory compliance, while facilitating accelerated timelines.

To understand the value of the single-study solution, let's examine its positive impact on the site selection process, which is integral to the conduct of a successful study. Historically, sites have been chosen based on conversations with trusted sources. However, a much more effective site selection process is one that is technology-enabled and data-driven, based not only on historical performance but also on real-time site-specific qualifications. By being able to analyze study-specific criteria and historical performance data as well as real-time feasibility responses, sponsors and their CRO partners can create a tailored pool of sites to participate in each study.

In addition to delivering real-time data to better inform the site selection process, a single-study solution helps to increase investigator engagement and reduce site burdens. With a single, study-specific end-to-end solution, investigators only need to remit one user name and password to access all electronic study tasks. Rather than waste time logging onto disparate systems, investigators can spend their time reviewing important study information, such as interactive study and compound-specific training modules.

Employing Nimble Solutions

As study compounds increase in complexity, and researchers learn more about their mechanisms of action, the need for investigator training also grows significantly. In addition to standard Good Clinical Practice (GCP) training, today's learning management solutions must be nimble enough to provide study-specific content to investigators and their teams. More than that, they must accommodate the needs and schedules of busy research professionals. A solution that is purpose built can accommodate the deployment of a full library of standard GCP training, as well as just-in-time, compound-specific modules for each study. This type of learning management solution is flexible enough to meet the needs of the study, while facilitating Part 11 compliance across the organization. And with interactive elements and quizzes, it is engaging enough to meet the needs of an adult learner. Using a learning management solution that is specifically designed to deploy both standard GCP modules and compound-specific interactive modules not only increases investigators' understanding but also their engagement in the study.

Sponsors should spend as much time choosing the right eClinical solution as they do developing their dynamic trials. It is time to move away from a one-size-fits-all approach and toward simpler, more flexible, study-specific technology that better meets the needs of the individual trial. PV

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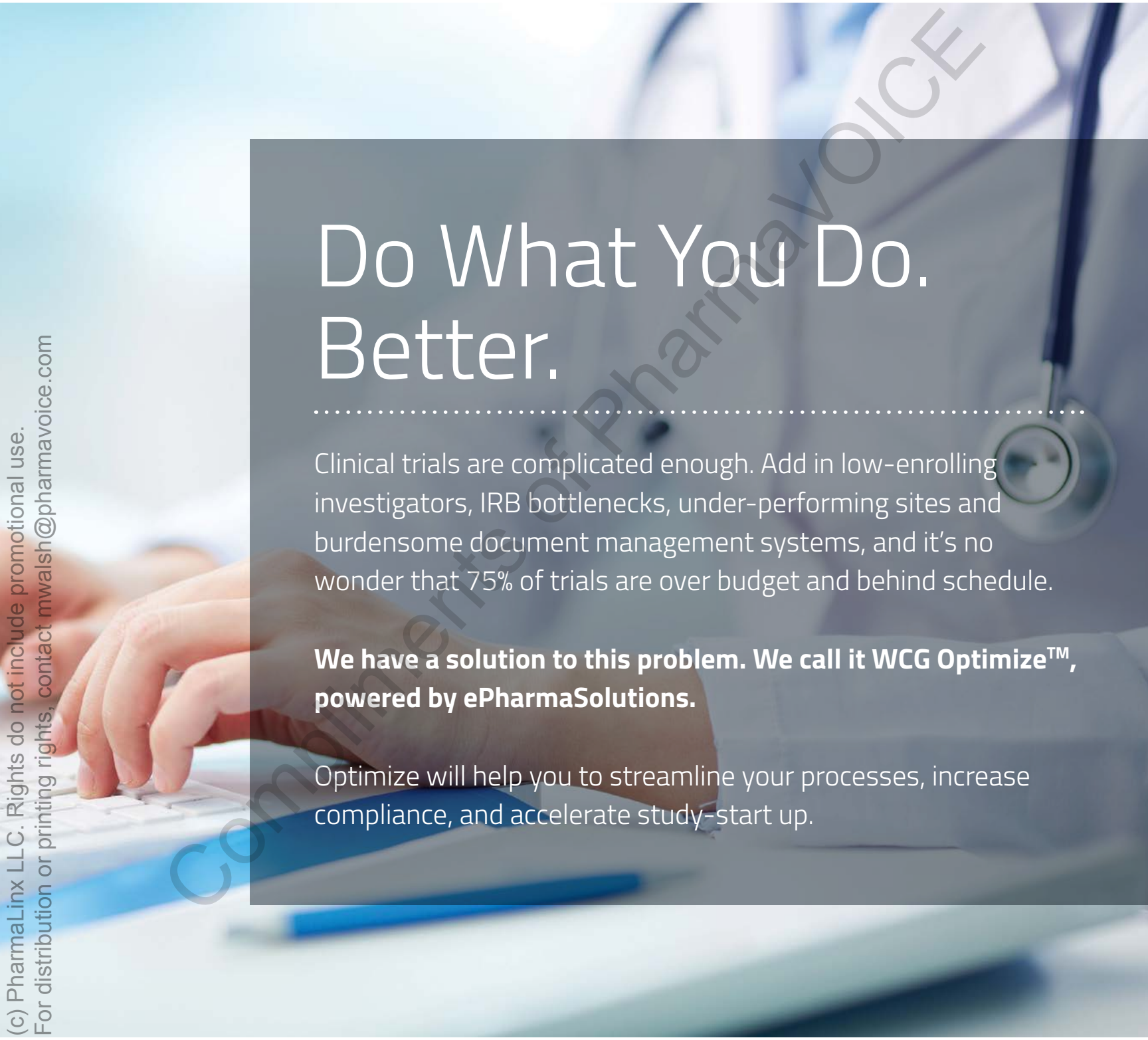

Do What You Do. Better.

Clinical trials are complicated enough. Add in low-enrolling investigators, IRB bottlenecks, under-performing sites and burdensome document management systems, and it's no wonder that 75% of trials are over budget and behind schedule.

We have a solution to this problem. We call it WCG Optimize™, powered by ePharmaSolutions.

Optimize will help you to streamline your processes, increase compliance, and accelerate study-start up.

Proven processes. Agile technology. Amazing results.

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