CLINICAL TRIAL SUCCESS:
OPTIMAL CRO PERFORMANCE IS INCREASINGLY CRITICAL

Ross Weaver, PharmD, MBA, Managing Director, Clinical SCORE

CLINICAL SCORE

High trial volume. Greater complexity. Diminishing site participation. Increased outsourcing. Underwhelming patient enrollment .... They all add up to costly delays. In this environment, it is more critical than ever that contract research organizations (CROs) perform well. Anonymous site-staff feedback can strengthen collaboration between CROs and Clinical Operations and provide the insights necessary to get, or keep, trials on track.

WHY
CRO/SITE RELATIONSHIPS MATTER

If it seems a little like sponsors are playing a game of musical chairs these days, it's not your imagination. Researchers from Duke University recently found that more than half of the principal investigators (PIs) they surveyed never conduct a second trial. Some weren't sure how to get into another trial; some declined for personal reasons. Most investigators surveyed cited several barriers, including the difficulties of workload balance, the time burden and dissatisfaction with payment issues.[1]

Yet at a recent industry conference on Clinical Research as a Care Option, it became clear that for some sites, such as Wilmington Health in North Carolina, participation in research is very worthwhile. For these accountable care organizations (ACOs) and other provider groups, identifying patients who meet study criteria and proactively offering them trial participation is part of a strategy to deliver quality care cost effectively. These providers incorporate clinical trials as a standard option for certain patients where existing treatments are not likely to have an optimal outcome or be cost effective. These commercial sites have figured out how to make trials work for them. They can enroll patients — and they can pick and choose the trials they want to participate in.

One of the factors these high-volume investigators consider when deciding which trials to offer their patients is "Who is the CRO that will run the trial?" Considering the extra demands that running a clinical trial places on a practice

— for initiation, implementation, data and safety reporting, etc. — it only makes sense. All else being equal, PIs and other decision makers choose to do business with CROs who are easy to deal with. These pairings — high-performance sites and high-performance CROs — are most likely to contribute to a trial's success. The corollary is that CROs that have more problems are left working with sites that may not have an established track record of clinical trial success. Considering the thousands of new trials launched each year, it's hard to get a seat at the best table.

CRO/SITE ISSUES THAT AFFECT TRIAL SUCCESS

Our survey of PIs and SCs representing 28 medical specialties in 25 countries around the world identified roadblocks to successful trials. The chief area of frustration was software problems — including too many systems and passwords, and repetitive or confusing data entry. Some of the other barriers included:

- Late site payments
- Patient reimbursement concerns
- Clinical research associate (CRA) turnover
- Lack of adequate training for CRAs
- Confusing training materials
- Inadequate investigator meetings
- Problems with the central lab

Those are the types of obstacles that discourage quality sites from delivering studies on time. Of course, the impact of any of these or other issues will vary depending on the specific trial, site and CRO. But the end results of these barriers and inefficiencies are the same: trials take longer. For example, according to research from the Tufts Center for the Study of Drug Development (CSDD), actual enrollment typically takes almost twice as long as planned.[2] These delays are expensive. The good news is that incremental improvements in performance can make a significant difference. Assuming a mean time of 6.7 years for the clinical portion

of the drug development cycle, with a capitalized development cost of $2.56 billion, improving the cycle time by 10 percent saves $250 million — or over $1 million per day.[3]

HOW TO GET GOLD
INSTEAD OF LEAD

Clinical operations teams recognize that problems exist, but may not always grasp their full impact on a trial's success or failure, having no effective means of identifying specific issues in order to correct them. Sites disengage from trials, and no one connects the dots. Satisfaction surveys are a step in the right direction, but still fall short. Due to the business nature of the relationship, sponsors who conduct the research "in house" cannot expect to obtain candid, unbiased responses, and their results do not provide an accurate picture. Often, they gather information after the fact, missing vital opportunities to get a trial on track. Anecdotal input from sites addresses issues of vocal sites, but often does not address the root causes of delays. The data has no real value.

The gold standard is a blinded process that generates real-time, quantitative anonymous site feedback. Valid feedback uncovers actionable information to strengthen collaborative relationships. Unlike conventional satisfaction surveys, it should collate site-specific feedback across trials, geographies, therapeutic areas, programs and partnerships. Such information is valuable both for immediate, practical problem solving and for long-term strategic decision-making.

The right kind of research program has the power to transform sponsor/CRO/site relationships, enhancing collaboration with the goal of improving the trial experience for all stakeholders.

Designed to avoid biases, Clinical SCORE's proprietary process:

- Reveals strengths and weaknesses across all relationships, including CROs, study suppliers, hardware and software systems
- Identifies broad areas of concern

- Isolates specific actionable issues
- Provides recommended actions to accelerate trials

Clinical SCORE's research process offers a cost-effective approach to enhancing efficiencies and reducing trial duration. For example, when sites in a specific geography stopped enrolling patients, Our Research identified delayed site reimbursement as a key problem; the issue was addressed promptly and resolved before additional time was lost. Similarly, we unearthed language and cultural barriers in Eastern Europe at the root of slow enrollment in another trial; based on our insights, the CRO hired local trainers to get enrollment back up to speed. Considering the investment sponsors make in CROs, and the financial ramifications of poor site engagement, it makes sense to ensure that sites are engaged in ongoing studies.

When you're ready to transform your CRO/site relationships into gold, visit ***https://clinicalscore.com/clinical-solutions/*** *or call Ross Weaver at 1-484-202-6630.*

1. Amy Corneli, PhD, MPH, et al. One and done: Reasons principal investigators conduct only one FDA-regulated drug trial. *Contemporary Clinical Trials Communications*. Vol. 6. June 2017, pages 31-38. Published online ahead of print at http://doi.org/10.1016/j.conctc.2017.02.009. Accessed April 11, 2017.
2. Tufts Center for the Study of Drug Development. *The Cost of Clinical Trial Delays*. (2015). Retrieved April 4, 2-17, from: https://www.ctti-clinicaltrials.org/files/pgct-session5.1-getz.pdf.
3. *Ibid*.

Clinical SCORE Co-founder, **Ross Weaver** is the company's Managing Director and the Account Director for the company's Clinical Trial Insights (CTI)™ product. Ross was previously a Vice President at Adjility Health, a Senior Partner at Weaver & Holihan, and the President of Weaver & Associates. His extensive industry experience also includes former Director of Licensing, Director of New Products Planning and Manager of New Products Marketing Research Manager at AstraZeneca, and Senior Scientist, Division of Drugs, AMA.

Ross completed a post-doctoral fellowship in Applied Pharmacokinetics at the University of Minnesota, Minneapolis, MN, and holds a Masters of Business Administration in Marketing and Finance from the University of Chicago, Chicago, IL, a PharmD from the University of Tennessee, Knoxville, TN, and a Bachelor of Science in Pharmacy from the University of Kansas, Lawrence, KS.