



***Waife & Associates, Inc.***



*Change Management for Clinical Research*

*There is a light through the fog...*



■ **We help biopharmaceutical companies  
build global competitive advantage in their  
clinical research operations.**

**Waife & Associates, Inc. *Known to Know*<sup>TM</sup>.**

For ten years we have helped clients large and small improve their ability to bring new therapeutics through clinical development. We do this through a combination of skills unique in the industry:

- Personal experience in clinical development
- Industry leading expertise in clinical research information technology
- Deep familiarity with process improvement tools and techniques.

Other companies may offer you one or more of these attributes – no one offers them all. Because each of our senior consultants does the work themselves, and because our overhead is low, we provide very high value in a short period of time, at a more reasonable cost.

Meeting the challenges of clinical development today can seem daunting. We offer a broad range of services to help you through the fog:

- Clinical Operations Process Improvement
- Organizational Preparedness<sup>TM</sup> for Technology Adoption
- Clinical Data Management Optimization
- Industry and Vendor Analysis for EDC, CDMS, CTMS, AES, EPD
- Business-Side Training<sup>TM</sup> for EDC
- Applying Metrics
- Practical ROI Analyses
- Project Team Effectiveness<sup>TM</sup>
- Industry Research Reports on EDC, CTMS & EPD
- The Clinical Research Executive Forum<sup>®</sup> for conferences worthy of your time<sup>TM</sup>.

**There is a way through the fog – we're here to help.**

# Clinical Operations Process Improvement

■ Every sponsor or CRO faces clinical operations pressures which we can help with. Too much to do; too much that's new; too much to lose.

Waife & Associates' staff have direct experience running clinical trials around the world. Over decades of experience we have learned what works and what doesn't in:

- Project management
- Monitoring management
- Clinical roles and responsibilities
- Interdepartmental communication and respect
- Managing outsourced functions and vendors.

The tools we use are highly productive in revealing operational improvement opportunities in a non-threatening manner:

- Process Mapping
- Convergence Interviewing
- Causal Analysis
- Language-Based Group Synthesis

One example of our service is described below: helping interdisciplinary project teams overcome inherent shortcomings in their formation, team skills and processes to be more effective in running your critical trial.

## Project Team Effectiveness™

High performing project teams execute drug development activities better, faster, cheaper and with higher quality outcomes than mediocre teams. The individuals on high performance teams have a special combination of scientific knowledge, strategic thinking, and interpersonal skills which are required to assemble and manage a high-performing team.

We can help project effectiveness by assisting with establishing and educating biopharma project teams in all phases of clinical programs, or in helping them get back on track. Our 10+ years of experience with **customized project-specific education** will visibly improve your project team's performance.

First, we work with both team members and management to diagnose the real or potential gaps between a high-performing team and your current reality. The result of the needs assessment will be a final program design, from which we develop a customized learning program. This program combines project-specific materials (protocols, Case Report Forms, clinical trial management forms and tools), Standard Operating Procedures and company policies, strategies, and goals. Most importantly, the program also includes the concepts and experiential activities necessary for team members to gain the critical interpersonal skills to succeed.

We then deliver your program at your facility to your project team, adhering to the training standards of your company, and ensuring documentation for regulatory purposes.

Additionally, we will identify other remedies for performance gaps. These techniques may include recommendations such as coaching, peer mentoring, or on-the-job training. A combination of these methods may provide the most effective – and least costly – way of improving the project team effectiveness.

**Your Project Team is controlling the Critical Path – we can help it be more effective.**



■ The interdisciplinary Clinical Project Team is often formed without regard to the skills and leadership abilities of its members.

# Organizational Preparedness™ for Technology Adoption



■ **Most technology implementations fail not because of a fault of the software, but because the user is not prepared to receive it.**

Nearly every aspect of clinical development today is enabled by some form of information technology. Investments in software and their implementation are large, time-consuming, and subject to increasing scrutiny. Effective use of technology is critical to all companies' competitive advantage. Clinical research IT does not come "off the shelf"; unfortunately you can't just rip open the package, pop in the CD, and start using EDC, or a new CDMS, or a CTMS.

Software implementations fail too often in our industry. While the blame is usually placed on the vendor, more often it is the sponsor who screws things up. They have the wrong vision, they are solving the wrong problem, they conduct an inadequate evaluation, they design their pilots poorly, they mis-set expectations with executives, staff and investigators, they skip the hard work on role changes, they don't plan for systems integration, and more.

Waife & Associates has worked with many companies, large and small, on implementations on every sort of clinical research IT application. Through our facilitation and project leadership, companies have been able to:

- Understand their needs, rooted in their own business, not the vendor's datasheet
- Properly set management expectation on what software can and cannot do, how much it will cost, and what tangible benefits they will receive, and when
- Evaluate vendors in a systematic and timely fashion, more deeply informed by industry experience
- Prepare for changes in workflow, roles and responsibilities
- Achieve interdepartmental and transoceanic alignment
- Train staff and investigative sites in the fundamentals of applying the software acquired
- Develop metrics in advance to track the impact of the software on operations
- Manage the vendors, and themselves, to ensure a win-win implementation.

Waife & Associates brings to this work its unique perspective from the inside of clinical development organizations *and* software vendors. We understand all sides – medical affairs, clinical operations, data management, IT, and the vendor. We anticipate the problems likely to occur and help you avoid the mistakes others have made before you. We call it Organizational Preparedness; you'll call it a lifesaver.

**Don't let your technology fail you – we can help you be prepared for success.**

# Clinical Data Management Optimization

■ **The most basic elements of clinical data management still need optimization in today's biopharmas – continuous improvement for your "crown jewels".**

Waife & Associates recognizes that your clinical data is the ultimate deliverable from every clinical trial. The optimal collection and maintenance of this data challenges you to continually pursue best practices in data management that combine: 1) preservation of data integrity; 2) regulatory compliance; and 3) an operational efficiency that can still speed drugs to market with limited resources.

Achieving this goal requires an "excellence in execution" from each member of the data management team and the continuous improvement of data management operations. With our many years of data management experience and our strategic view of the industry, Waife & Associates' staff understands how to apply these best practices to your organization in a team-building, nurturing manner that also allows you to meet the deadlines imposed by aggressive clinical timelines.



■ **Control over your own data may be one of the most mission-critical activities of an emerging biopharma, and yet it is one of the last to be professionalized.**

Whether you are looking to improve your data management department, or build one from the ground up, Waife & Associates can provide strategies and implementation for:

- Developing best practices for *your* data management environment
- Defining data management roles & responsibilities
- Writing SOP's & work instructions that truly reflect the way your business is done
- Providing pathways for the selection, implementation & integration of data management tools
- Facilitating successful links between clinical data management and clinical trial operations
- Collecting data management metrics and using them to forecast future resources
- Assessing and promoting SOP and best practice compliance in your company & your partners
- Defining hiring guidelines for the acquisition of new personnel
- Creating training curriculum for data management personnel
- Serving as a "virtual" data management director for companies in transition, or for companies just ceating the role of in-house data management.

**Data is the deliverable. We're here to help you deliver the goods.**

# Knowing the Cost of Doing Business

Finally there is a service that can help with that most difficult of questions: what is the financial return on my investments in process and technology?



Waife & Associates offers a truly unique service to the clinical research industry: a comprehensive set of metrics and financial analysis services for clinical operations, data management, medical writing and regulatory affairs. These services provide the answers to questions you may well be asking in your organization:

- What are our true costs of doing business?
- How good are we compared to others in the industry?
- How can we use metrics to improve our business practices?
- How can metrics form a solid basis for my ROI calculations?
- How can metrics help us justify much-needed projects to upper management?
- How can metrics provide "warning signals" to alert us to bottlenecks that threaten our timelines?
- How can metrics help us in forecasting our future resources?

In providing these answers, our Metrics/ROI practice is marked by the following qualities:

**An insistence on sustainability.** In contrast to those who come in, measure everything in sight one time and then move on, we help you build a metrics program and a metrics culture that is sustainable over time.

**A focus on productivity metrics.**

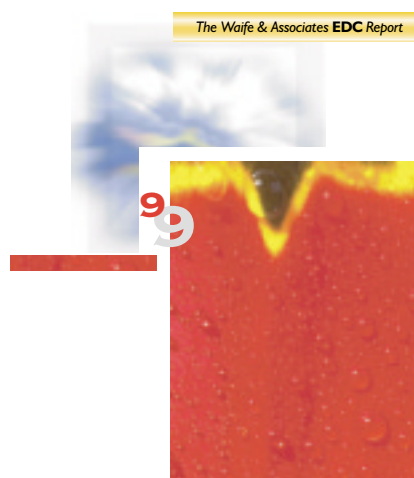
**A focus on the key drivers.** These core metrics quickly become the "currency of conversation" in the course of daily work, changing the way a busy organization talks about its workloads, bottlenecks, planning and expectations.

**The ability to "monetize" the metrics** (i.e., to translate them into financial terms) without confusing monetization with measurement.

**A "units"-based approach.** We lead you through a discovery exercise to uncover the true unit of work for each of your core metrics.

**We help you develop sustainable measurement without diverting resources from your business.**

# Waife & Associates Industry Research Reports



- The only comprehensive independent reports on the clinical research technologies most in demand: EDC, CTMS, EPD

## The Clinical Research Executive Forum<sup>®</sup>

- A series of exclusive Executive Retreats on Clinical Operations and clinical research information technology



For more information on our Reports or the Forum, please visit [www.waife.com](http://www.waife.com)

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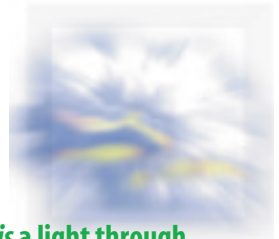
## Waife & Associates, Inc.

Senior domain expertise, directly applied.  
To your needs, at your pace.

We empower you; we don't replace you.  
We save you time and money. And most importantly,  
we keep you from making the mistakes others have made.

Think of us for:

- Clinical Operations Process Improvement
- Organizational Preparedness™ for Technology Adoption
- Clinical Data Management Optimization
- Industry and Vendor Analysis for EDC, CDMS, CTMS, AES, EPD
- Applying Metrics
- Practical ROI Analyses
- Project Team Effectiveness
- Industry Research Reports** on EDC, CTMS & EPD
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the fog.**

**Waife & Associates, Inc. For a decade, we have been Known to Know™.**  
**Ten years. 130 clients.**  
**We hope you will join them.**



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