
Waife & Associates, Inc.
Finding Efficiency in Clinical Research

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

Why does this happen in biopharma clinical development?....

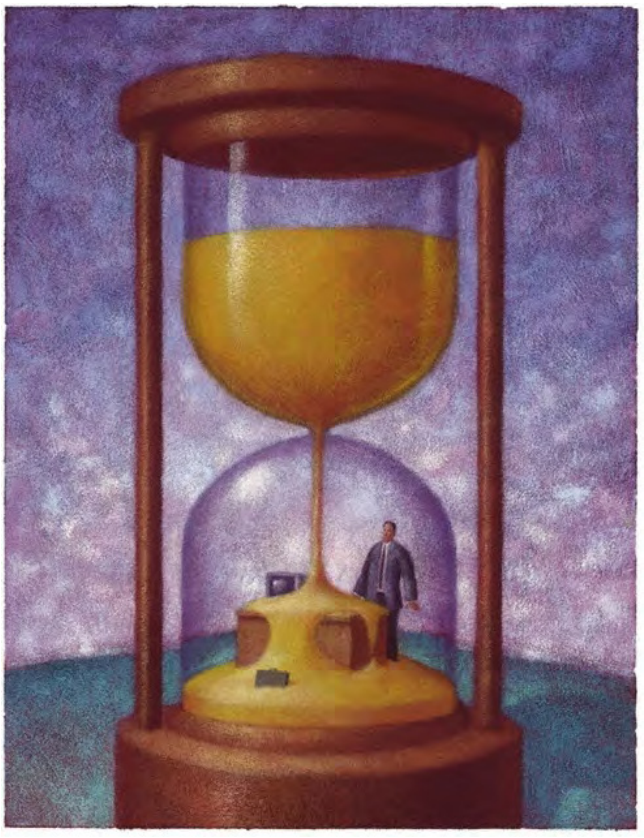
•Your matrixed clinical development organization is better at developing meetings than developing drugs.
•Your EDC company offers you a consulting partner who has never done an EDC trial before.
•You think you're saving money and time by contracting out the bulk of your work, but you're as swamped as ever managing the contractors.
•The Adverse Event System you spent many hours specifying and purchasing sits in a corner, barely used.
•You're a young company which can't get control over its data without spending millions on tools and people.
•It's been two years since you bought your new CTMS and you are still figuring out who should use it, for what, and why.
•You can't answer the most basic ROI questions because you don't know what things really cost.
•Your managers have no training in management.

Waife & Associates, Inc. ***Known to Know®***.
For over 20 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.

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:

- Clinical research governance
- Running global study teams
- Clinical roles and responsibilities
- Managing outsourced functions and vendors
- Eliminating Non-Value-Added work
- Exploiting information technology and metrics
- Emerging from mergers with effectiveness intact
- The effective use of time.

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
- Appreciative Inquiry

In fifteen years of direct service on clinical operations issues, we have developed a deep and mature understanding of the necessary and the possible. Few other organizations exist who can contribute this expertise without having some other agenda in mind, like selling you CRO services, contractors, outsourcing or software.

Our adaptation of Appreciative Inquiry to clinical development is just one example of this sophistication. Originally developed as a generic tool for organizational performance improvement, its focus is on learning on what we do ***right***, instead of what we do ***wrong***. It looks forward to capitalizing on our staff's strengths, discoveries, and innovations. Instead of punishing misguided processes through outsourcing and reorganization, it provides the basis for using our resources in optimal performing fashion.

Understanding the globalization of study conduct is another key W&A attribute. Even the smallest biopharmas face the challenges of running global trials effectively, and even the largest biopharmas sometimes still do it poorly. W&A has the direct multicultural experience to help you be global successfully.

Clinical development ***is*** different from company to company, and should be. Our emphasis on placing it in the context of your unique business circumstances is at the heart of Waife & Associates' approach to clinical operations process improvement.

Clinical Operations is controlling the Critical Path – we move the obstacles out of the way.

Organizational Preparedness™ for Technology Adoption

Most technology implementations fail not because of a fault of the software, but because the software user is not prepared to use 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 of 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, drug safety, 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 & Drug Safety Optimization

Today's biopharmas need basic and continuous improvement for your "crown jewels" - your clinical data management, and your drug safety operations

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.

Undoubtedly, these days this means not just use of EDC, but optimal use of EDC. It also means re-examining strategically how your data is stored and analyzed. You have many more options than ever before, not the least of which is outsourcing. How, when and why to make these choices, and to manage the results effectively and efficiently, is something every company can use help with. When you are faced with daily deliverables, it is hard to do the strategy alone.

And for smaller companies, these challenges are even more difficult. The temptation to outsource without both the necessary supporting strategies and tactics is fraught with difficulties down the road.

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.

Drug Safety optimization is the last frontier of biopharma operations. Less has been done to examine and improve the efficiency of drug safety operations than in almost any other operational function in the industry. The work is getting done, and the public's safety is undoubtedly protected, but the means by which this is achieved can be, in some companies, only described as antique.

Waife & Associates is able to apply its experience and change management techniques with great effect in drug safety. The opportunities for reducing re-work, eliminating non-value-added work, optimizing global safety management, re-examining roles and responsibilities, and making effective use of existing information technologies are widespread. Drug safety departments are not only too busy to be self-reflective, their workloads are growing faster and faster. We're here to help.

Data is the deliverable. Safety is the essence. 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 change or technology?

Waife & Associates has provided a unique service to the clinical research industry for over a decade: a domain-informed comprehensive set of financial analysis services and metrics for clinical operations, data management, and drug safety.

These services provide the answers to questions you may well be asking in your organization:

•What are our true costs of doing business?
•What constitutes an appropriate measure for ROI?
•How can we use metrics to improve our business practices?
•How can metrics help us justify much-needed projects to upper management?
•How can metrics 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. Too often, ROI and metrics used in our industry focus on time without measuring output.

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.

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

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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
- Vendor Oversight Management Improvement
- Organizational Preparedness™ for Technology Adoption
- Clinical Data Management & Drug Safety Optimization
- Industry and Vendor Analysis for EDC, CDW, CTMS, AES, ePRO
- Applying Metrics
- Practical ROI Analyses
- Vendor Oversight Management Improvement
- Custom Industry Research Projects
- The Clinical Research Executive Forum® for conferences worthy of your time.

Waife & Associates, Inc.
In clinical development change management, we are Known to Know®.
Twenty years. 240 clients.

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