



## Research, Optimized.

### Designing a Productive eTMF Program

A rapid and successful transition to electronic Trial Master Files, and its related technologies and functions, is a subtle and complex mix of process, governance and technology

# W&A SERVICES

#### Pragmatic Solutions

We design solutions and help you actually implement your strategies

#### Domain Expert

Senior industry managers who understand what you do

#### For 20 Years, Known to Know®

Leading the industry's focus on process improvement since 1993

Electronic Trial Master Files (eTMFs) are gaining traction in the biopharma industry, and while the technology is not new, there is fresh recognition that there is more to an eTMF than just document storage. Today's eTMF systems include not only the options to process documents and manage clinical site interactions, but also a powerful method to provide insight into, and oversight for, your clinical trials.

Like EDC before it, the adoption of eTMF is undergoing growing pains. This is exacerbated by the universe of options that an eTMF offers, and the overlapping, incomplete vendor offerings. A successful adoption of eTMF is dependent on individual company cultures and organizational structure, combined with informed and specific vendor selection. Following someone's "templated" approach to adoption will prove to be painful and a waste of time and resources.

Waife & Associates Inc. can assist with eTMFs on multiple fronts. Our long-term industry expertise with technologies applied to clinical development, coupled

with our core competency in process development and change management, brings unique added value to eTMF implementations. Specifically, Waife & Associates can:

Facilitate process development around the most efficient and targeted use of eTMF functionality within your particular clinical development environment.

Identify additional functionality that can be applied to support an unmet or unfulfilled need in clinical program management.

Apply significant expertise in working with, and understanding the functionality of today's eTMF vendors.

Develop a phased implementation strategy that is focused and cost-effective, plus carrying through its implementation with you, while relieving you of heavy internal resource and time requirements.

To contact us on your eTMF project, please write Steve Shevel at [shevel@waife.com](mailto:shevel@waife.com) or [info@waife.com](mailto:info@waife.com), and visit our website, [waife.com](http://waife.com).