CLINICAL LEADER

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Survey Signals Contract Research Organizations Driving A Digital Revolution

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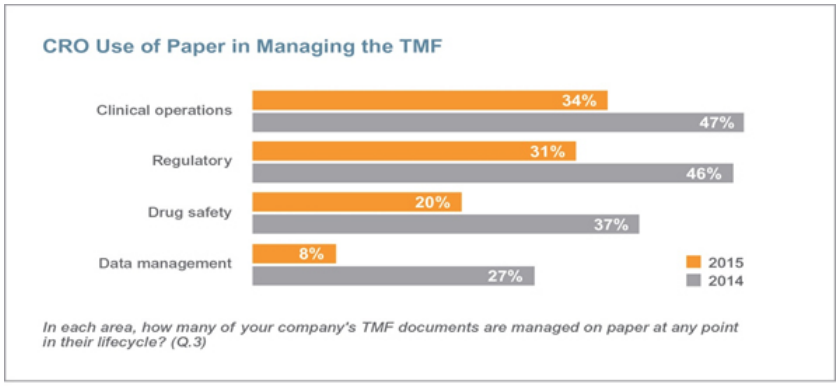
It has taken only a few years for electronic trial master file (eTMF) applications to gain traction. New research shows a striking decrease in contract research organizations' (CROs') use of paper and paper-based processes and a corresponding rise in electronic processes across many content-intensive areas. Some of these include clinical operations, regulatory, drug safety, and data management. The global *Veeva 2015 Paperless TMF Survey: Annual CRO Report* , in fact, found that 38 percent of CROs surveyed now use eTMF applications versus just 21 percent in 2014 – a significant increase.[1]

Even more interesting, this sharp drop in paper is most dramatic with CROs compared with sponsors, pointing to CROs as a major driver of the digital revolution across clinical development. According to data collected from the full *Veeva 2015 Paperless TMF Survey: Annual Report*, only a quarter (24 percent) of sponsor organizations with electronic TMFs are using eTMF applications.



There are a number of reasons CROs have become such change agents in clinical trial processes – topmost is the reinvented CRO/sponsor relationship. Over the last five to 10 years, interaction between CRO and sponsor has morphed from largely tactical to strategic. CROs have come a long way from small, specialty shops to vital, global organizations that are extremely savvy with study processes and aptly equipped to manage an entire trial without direction from the sponsor. Just hand over the investigational product and a high-level development plan, and then many CROs can take it from there. Today's CROs provide sponsors with greater flexibility, more streamlined operations, and risk mitigation.

Another key driver of eTMF application adoption is the rise in outsourcing industrywide. About 40 percent of all clinical trial operations today are managed completely by CROs, with a total market size estimated to be approximately $22 billion according to Industry Standards Research. This can partially be explained by the parallel upshot of specialty biotechs – innovators with the brainpower to uncover radically new therapies but often lacking the resources to invest in the requisite technology and manpower for trials. Further, the decline in blockbuster drugs has put pressure on larger companies to bring more drugs to market to make up for lost revenues – in this case, especially, CROs allow sponsors to run trials more efficiently and help spread the risk of development enabling a greater number of trials in process simultaneously.

In addition, not only are more life sciences companies outsourcing to CROs, but they are also outsourcing more of the clinical trial process itself. The 2014/15 Nice Insight Pharmaceutical and Biotechnology survey shows that the average number of contracted services has dramatically increased across all types and sized organizations. The average number of services commonly outsourced now versus just two years ago in 2013 has risen from 4.7 to 7.5.[2]

A third explanation for CROs propelling the move to digital is the increase in competition for business. There are nearly 700 CROs in the U.S. and more than 2,000 worldwide, but the top eight control about 62 percent of the market, which means there are hundreds fighting for less than half of the pie.[3] By embracing technology and making it part of their core offering, CROs can distinguish themselves and offer sponsors advanced solutions for competitive advantage. With advanced digital solutions, CROs are wisely increasing overall process efficiency, study visibility for sponsors, and inspection readiness.

Big Implications For The Industry

This technology revolution is happening fast – light speeds, in fact. Possibly most seismic, is the decreased use of paper and paper-based process in clinical operations – a group that manages the greatest number of TMF documents day to day. According to Veeva's research, clinical operations' reliance on paper dove 13 percentage points from 47 percent in 2014 to 34 percent this year. Such a drop in paper is expected to positively impact many critical trial processes – most notably, study start-up.

As more CROs now handle much of study start-up activities, they are hyper-motivated to improve this critical area of clinical trial processes and are turning toward new eTMF technologies. Manual exchange of paper documents with sites is simply too slow and adds to the bottlenecks impeding fast study start-up. Since most documents required for site activation are also required as part of the trial master file, providing all parties – internal and external – access to an eTMF with a single instance of each document removes much of the back-and-forth, and provides a full electronic audit trail. Sponsors can have real-time visibility into progress, and CROs can focus attention on sites that need more attention. An impressive two-thirds of CROs surveyed (66 percent) agree that clinical development time would decrease if study/site start-up documents were managed in an eTMF application.

Additionally, more than half (57 percent) of CROs report improved audit- and inspection-readiness as a result of eTMF application adoption. The overwhelming majority specifically cited a reduction in missing documents (92 percent); misfiled documents (89 percent); duplicate documents (86 percent); incomplete documents and/or missing signatures (84 percent); and expired documents (81 percent).

Continued growth of digital technologies across clinical operations is a must for mass-improvement of trial processes. In addition to improving efficiency and the visibility of trial content for all parties – long term, eTMF applications can also enable CROs to harness critical performance data. As more operational data is collected over time and across multiple trials, companies can identify important trends about study execution and site performance. The eTMF will inform business decisions by capturing an array of quality, performance, and operational metrics across multiple sites and studies to better meet sponsor needs. And, with more sponsors benefitting from ever-improving trial processes by their eTMF-equipped CRO partners, it will be hard to ignore the benefits and efficiencies of a paperless clinical trial, making it inevitable that they, too, will join the revolution.

About the Author:
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Sources:

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2. Nice Institute's Annual Outsourcing Report, By Nigel Walker, as published in Life Sciences Leader. Read more: http://www.lifescienceleader.com/doc/outsourcing-increasing-to-cros-and-cmos-known-for-quality-and-cost-effectiveness-0001
3. "Global Trials Growth Driving CRO Consolidation," by Dan Stanton, *Outsourcing-Pharma*. July 29, 2014. Read more: http://www.outsourcing-pharma.com/Clinical-Development/Global-trials-growth-driving-CRO-consolidation-says-M-A-report