Data Management AND FUNCTIONAL OUTSOURCING

When looking across industry at the top 50 companies based upon 2010 drug sales, one notices a trend appearing across these organizations. The trend of outsourcing by function to a service vendor or CRO of demonstrated technical skills, rather than complete sourcing to a preferred vendor. Even when decisions are made to source to one or two CROs publically, still, for certain services, vendors are chosen for skill sets others are deemed generic.

The responsibility of an individual within data management is to ensure data cleanliness and completeness. It is a role that is currently undergoing a transformation in both what these two items mean as well as where they are performed. It is normal for this to be a global role in the clinical trials process rather than a centralized role of years past. This traditional role involves study specifications, data management plans, database builds, cleaning, and locking an individual trial. Data management is a process that has been described as commoditized due to this globalization effort. But has it been truly commoditized in the outsourced environment?

The Role of the Data Manager

In this era of complex trials, multiple systems (EDC, ePRO, CTMS, eSAE, ect.), it is not feasible to enable an individual to cover all of these skill sets. In this highly specialized environment the role of a data manager is to have a skill set to manage the process and have the experience and knowledge to perform not only data review, but clinical review. Looking at the skills required during this globalization of CDM one would include project management, light technical programming skills, knowledge of standards both internal to a company and external such as CDASH, and be able to understand the difference between clinical and data review.

When one considers clinical review, one thought could be: "Why doesn't this occur from the clinical monitoring staff?" The reality has been that monitors are the proven specialists for their roles in the relationship to the site and the information collected there. The data management process will review many sites' data for a larger trial and perhaps many trials with data of similar design. This brings consistency to the data, which is required for analyses and interpretation purposes.

The clinical trial process continues through its evolution of change, including industry-wide standard usage such as HL7 and CDISC. This process change is bringing new techniques such as adaptive design, targeted source data verification, remote monitoring, and electronic health records the lines for data management and monitoring become further blurred until the point of data harmonization and clinical review are taken into account. The trials themselves are becoming clinically more complex with the type of information being collected. The trend toward personalized medicine at the biochemical and clinical scale places more stress on the review process to ensure the data collected is consistent with a patient/subject and across a trial.

Data Review and Clinical Review: A Requirement in the New Frontier

The individuals who bridge both data review and clinical review bring their organizational value by reducing queries sent multiple times, streamlining data set-up, and providing greater harmonization to data interpretation. The skill sets of having both clinical interpretation and computer technology or who have demonstrated consistent understanding of data review and project management as demonstrated through SCDM certification; yield a higher value to the study trial.

Increasingly, this complexity in clinical trials and the choice of an FSP provider sub-specialty have required companies to revisit the skill sets required from their data management provider. It is no longer an assumption that the clinical team and the data management team originate from the same clinical research organization. This trend delivers the statement that a provider offering specialties, with a history of remaining constant with the clinical and technical complexity of today's trials, ensure high site data.

FSP models are effective today for a number of reasons. In today's complex trials, a provider can offer sponsors access to multiple resources with their own specialized skill sets, delivering their expertise regardless of location and time zone.

An EDC data base builder in Australia, an edit development programmer in India, a clinical reviewer in the U.S., can all be coordinated by the lead data manager, who is free to manage timelines and focus on holistic data review. The result is higher quality, shorter timelines, and most importantly, high-quality data. In offshoring models the cost savings can be substantial. With the business requirement of managing the expense of clinical trials vs. the scientific necessity of gathering clear information, data management providers offering a full complement of specialized services provide a solution for both needs. PV

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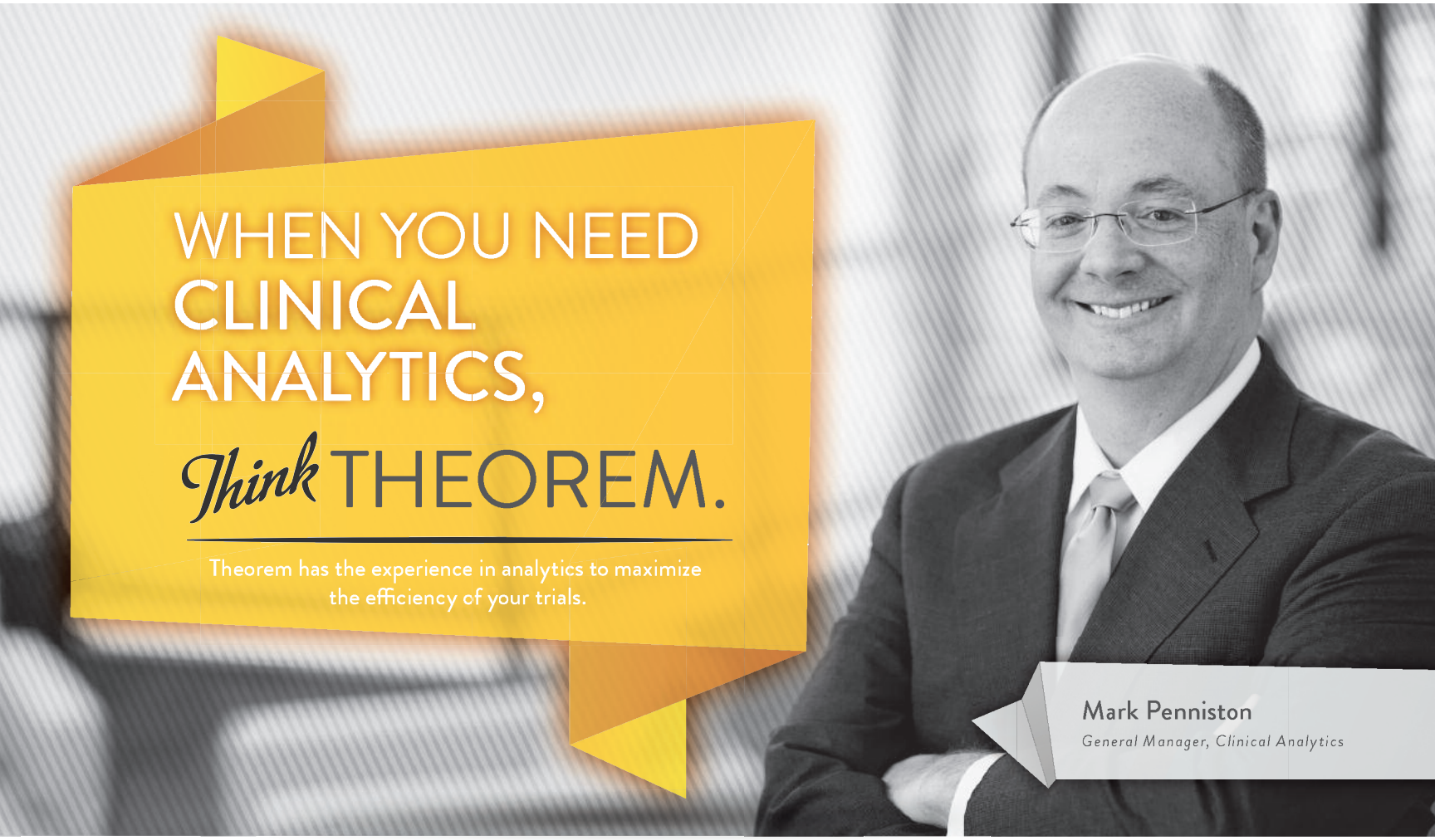

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