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Data Standards and CDISC: A Statistical Perspective

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ABSTRACT

With eCTDs, the CDISC/Standard Data Tabulation Model, and CRADA-generated electronic review tools, the FDA has taken some giant steps to improve the efficiency of regulatory review. Are we done yet? We have places to put data and tools to help us ask questions—now comes some of the “hard part.” How do we unambiguously communicate the business of our regulatory science (statistical plans, results, programs, etc.)? From a statistician’s perspective: What is the relevance of what we have accomplished, what has changed, and what we still need to do to “get it right.”

NOTE

No paper was made available for publication. Please contact the author directly.

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