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"Nature Reviews Drug Discovery" Publishes New Findings on Trial Complexity Based Upon Benchmark Data from Medidata

Analysis Drawn from Medidata's PICAS Database Uncovers a Significant Increase in the Number of Distinct Procedures Impacting Both Trial Cost and Site and Patient Burden

Drug Development Sponsors Can Use Data to Benchmark Against Organizational Practices and Help Optimize Protocol Design

NEW YORK--(BUSINESS WIRE)-- Medidata (NASDAQ:MDSO), the leading global provider of cloud-based technology and data analytics for clinical research, completed an analysis based on nearly 10,000 protocols from Medidata's Pharmaceutical Investigator Cost Assessment Service (PICAS®) database, indicating that clinical trial complexity has continued to rise sharply over the past decade. The results of the study, conducted in collaboration with the Tufts Center for the Study of Drug Development, and entitled "Trends in clinical trial complexity," was published in the May issue of *Nature Reviews Drug Discovery,* part of the Nature Research portfolio. For a complimentary copy of the article, go here.

The study found that the mean number of distinct procedures carried out per protocol increased significantly for Phases I, II and III, most notably among Phase II and III protocols. The frequency with which each distinct procedure was performed grew at an even faster rate, leading to higher growth in the mean number of total procedures and resulting in greater burden on study staff administering protocols and on patients participating in them.

"The study findings are compelling given the increased attention that drug developers are placing on improving clinical trial speed and efficiency," said Kenneth A. Getz, Center for the Study of Drug Development at Tufts University, principal investigator and lead author. "Complexity must be managed more actively and prudently to optimize clinical trial performance since complexity is associated with higher costs, study delays, lower enrollment rates and larger numbers of unplanned protocol amendments."

Phase I protocols were the most complex, with the highest mean number of distinct procedures (36) and total procedures (253) carried out in the 2011-2015 period. Phase III protocols saw the highest relative growth in total procedures carried out, increasing by 70% from a mean of 110 procedures in 2001-2005 to 187 in 2011-2015. A mean of 22 distinct procedures were carried out for each Phase III protocol in 2001-2005, compared with 35 in 2011-2015 — a 59% increase.

"The increasing complexity of clinical trials is taxing for patients, researchers and sponsors," said Mike Capone, Medidata's chief operating officer. "Medidata's PICAS database has access to meaningful data and industry benchmarks that can be used to guide protocol design and reduce trial complexity—optimizing drug development and ultimately increasing the speed and chance of bringing much-needed therapies to patients."

The dataset used for the analysis is based on clinical trial protocols drawn from Medidata's PICAS database of negotiated research grants. The PICAS database contains detailed protocol and investigative site contract data from more than 170 global pharmaceutical and biotechnology companies. A total of 9,737 protocols were evaluated; 76% of the protocols were provided by companies in the top 25 largest globally and 24% by mid-sized and smaller companies. All protocols included in this analysis received ethical review board approval between 2001 and 2015.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including more than 850 global pharmaceutical companies, innovative biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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