Clinical Research Can Now Be Truly Patient-Centric By Quantifying Patient Burden with Medidata

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Patient Burden Index uses data-driven approach to provide objective insight when creating trial protocols to improve study retention and recruitment

NEW YORK--(BUSINESS WIRE)--Jun. 25, 2018-- To make clinical research truly patient-centric, Medidata (NASDAQ: MDSO) announced the launch of the Patient Burden Index (PBI) on the Medidata Cloud, the Intelligent Platform for Life Sciences. PBI empowers sponsors and CROs to identify and address high-burden procedures and visits that can impact patient participation and retention in a clinical trial.

Medidata built a unique analytical approach to patient centricity, solving complex study design and burdensome procedures that currently lead to high patient dropout, execution challenges and struggling investigators. The dropout rate for a clinical study today is often very substantial, sometimes more than 30%.[1] A recent Medidata white paper outlines how incorporating factors such as patient pain, anxiety, hospitalization, and other components of patient experience into the initial trial design is instrumental to a study's success.

To address today's challenges, Medidata developed the Patient Burden Index, a component of the protocol optimization tool, Edge Design Optimizer, to improve visualization of the patient experience. PBI is built upon the industry's largest pool of patient data, and the deep industry knowledge of data scientists, life science experts and developers at Medidata.

"Until now, assessing patient burden has largely been subjective. PBI is the first solution of its kind that uses a data-driven, objective approach to patient-centric trial design," said Glen de Vries, co-founder and president, Medidata. "PBI empowers sponsors and CROs to address key challenges around study experience and patient retention."

By communicating the potential hardship of patient procedures, sponsors and CROs can fine-tune protocol development and operational plans. Medidata identified eight risk components for researchers to address directly, including:

- Anxiety—the level of anxiety caused by a procedure
- Pain—the level of physical pain caused by a procedure
- Invasiveness—a procedure's level of physical invasiveness (e.g., blood draw; device implantation)

PBI is a new feature within the Edge Trial Planning and Management family of clinical operations solutions. Edge is one of three product families on Medidata's unified platform, which are powering the digital transformation of the entire clinical trial process.

Medidata at DIA - Booth #1907: Visit Medidata at DIA this week, and discover new ways to power smarter trials and healthier people together. The company will host evocative thought leadership and partner presentations, live product demos, and much more throughout the three day event, including:

- *Medidata + SHYFT: The Intelligent Platform for Life Sciences* - June 25, 4:45 PM EST
- *Data Driven Insights for Study Design and Operational Feasibility* - June 26, 3:15 PM EST

About Medidata

Medidata accelerates the digital transformation of life sciences through its unified platform, pioneering analytics, and unrivaled expertise. The Intelligent Platform for Life Sciences seamlessly delivers market-leading applications powered by artificial intelligence and real-world analytics to reduce risk, optimize revenue, and ultimately help patients.

More than 1,000 pharmaceutical companies, biotech, medical device firms, academic medical centers and contract research organizations around the world can now manage and optimize value across the clinical and commercial continuum. For more information: www.mdsol.com

[1]National Research Council, 2010, The Prevention and Treatment of Missing Data in Clinical Trials, published by The National Academies Press, p. 39

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