Real world evidence use in clinical & post-approval research set to expand

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Pharmaceutical Companies Poised to Build Infrastructure to Accommodate Real World Evidence, According to the Tufts Center for the Study of Drug Development

BOSTON – Nov. 8, 2017 – Real world evidence is poised to play a growing role in drug development during the next three years, but the availability and cost of acquiring data remain key challenges, according to a recently completed study conducted by the Tufts Center for the Study of Drug Development.

Large pharmaceutical, biotechnology, and contract research organizations plan to increase internal staff dedicated to collection and analysis of real world data by 25% between now and 2020, according to a survey conducted by Tufts CSDD.

"Drug developers are utilizing real world evidence across a number of areas, including assessing the economic value of products, gaining insight into drug safety and effectiveness, and evaluating quality of life outcomes," said Mary Jo Lamberti, PhD, senior research fellow at Tufts CSDD and lead investigator on the study. "While the cost and effort to integrate data sources, and then convincing regulators and payers of the validity of that evidence, pose hurdles to expanded use of real world evidence, developers are confident that emerging technologies will help them address those issues."

Real world evidence (RWE) is data collected from sources outside of randomized controlled clinical trials and can include data from electronic health information, social media, and mobile and wearable devices.

Study results were reported in the November/December Tufts CSDD Impact Report, released today.

The study also found that:

- Commercial functions within drug development organizations are the primary users of RWE today, although 40% of R&D operations rely on it.
- Social media data is projected to be used by 42% more companies in 2020, compared to 2017, whereas fewer companies expect to be using claims and prescription data in three years.
- 60% of respondents said availability of data poses the greatest challenge in utilizing RWE, followed by lack of external stakeholder trust in RWE, cost of acquiring data, cost
and effort of data integration, determining causation, and quality and reliability of claims and electronic health record data.

ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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Contacts: Tufts Center for the Study of Drug Development

Rachel Stanton – 617-636-2170
Rachel.Stanton@tufts.edu

Business Communication Strategies

Peter Lowy – 617-734-9980
lowy@bus-com.com