September 16, 2015

**Adverse Drug Event Reporting in U.S. Beset by Incompleteness and Inaccuracy**

*Tufts CSDD says a high proportion of health care professionals have no ADE reporting experience*

BOSTON – Sept. 16, 2015 – Voluntary adverse drug event (ADE) reporting in the United States is incomplete, inaccurate, and inefficient, which could deny or limit patient access to safe and effective treatments, according to recent studies completed by the Tufts Center for the Study of Drug Development.

“While ADE reporting aims to ensure and enhance patient safety, a high proportion—nearly 40%—of health care professionals have never reported an ADE,” said Ken Getz, associate professor and director of sponsored research at Tufts CSDD. “Aggravating the situation is the fact that 60% of health care professionals report it is often too difficult to determine if a drug-in-question caused an adverse event.”

Adverse drug event reports are submitted to the Food and Drug Administration for injuries and harm resulting from the use of a drug, changes in dosage level, discontinuations of drug therapy, and medication errors.

“Inaccurate reporting, in particular, is problematic,” Getz said, “as it may mislead drug safety professionals to draw incorrect conclusions, cause manufacturers to wrongly suspend and withdraw medical interventions, lead health professionals to mistakenly alter their clinical practices, and deny or limit patient access to safe and effective treatments.”

Getz said an expected increase in approvals of similar versions of already approved biologics in the U.S. and Europe, along with growing use of social media and electronic medical records, is likely to increase awareness and reporting of adverse events.

Key findings from the studies, reported in the September/October Tufts CSDD Impact Report, released today, included the following:

- Pharmacists are more aggressive about ADE reporting, compared to nurses and physicians.
- ADE reports submitted by patients tend to be more complete than reports submitted by health care professionals.
- Completeness and accuracy of ADE reports vary by therapeutic area, with those for CNS drugs posting the highest drug name accuracy and some of the lowest lot number completion rates.
The findings were based on a Tufts CSDD analysis of 10.2 million adverse report records filed with the U.S. Food and Drug Administration, augmented by a survey of 123 health professionals.

To purchase a single report or subscription, please visit the reports page.

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.

--end--

Contacts:

Tufts Center for the Study of Drug Development
Sandra Peters – 617-636-2170
CSDDpublications@tufts.edu

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