



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## Adverse drug event reporting in U.S. beset by incompleteness and inaccuracy

*High proportion of health care professionals have no ADE reporting experience*

- More than two-thirds of all adverse drug event (ADE) reports do not include dosage level, and 90% lack lot numbers.
- ADE report completeness and accuracy vary by therapeutic area, with those for CNS drugs posting the highest drug name accuracy and some of the lowest lot number completion rates.
- ADE reports submitted by patients tend to be more complete than reports submitted by health care professionals.
- Pharmacists are more aggressive about ADE reporting, compared to nurses and physicians.
- Difficulty verifying a drug as the cause of an adverse event is the top reason given by health care professionals for not filing an ADE report.
- Better biosimilar naming conventions could improve completeness and accuracy of ADE reports.