



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## U.S. healthcare stakeholders uncertain on benefits of risk evaluation strategy

*Tufts CSDD survey is first assessment of REMS program since launch in 2008*

- Most respondents said it is virtually impossible to measure the benefits of a Risk Evaluation & Mitigation Strategy (REMS), compared to its costs, for a *newly approved* drug.
- 58% said two years are required to effectively measure the benefits of a REMS for an *already marketed* drug.
- 86% felt that under current guidelines, risk and benefit information was not well-balanced in REMS communications.
- A strong majority said the REMS program needs a major overhaul and felt that a REMS is a poor substitute for other improvements needed system-wide in drug education, communication, use monitoring, patient access, and delivery of care.
- Only 22% of respondents thought the REMS program has been an improvement over the existing risk management system.