



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.