



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Causes of clinical failures vary widely by therapeutic class, phase of study

Tufts CSDD study assessed compounds entering clinical testing in 2000-09

- Reasons for failure were identified for 41.4% of Phase I failures, 52.3% of Phase II failures, and 61.1% of Phase III failures.
- Commercial issues were the leading cause of Phase I failures.
- Efficacy issues outnumbered commercial considerations by 2:1 as the leading reason for Phase II failures.
- Efficacy and safety factors outranked commercial issues in Phase III failures.
- Efficacy issues dominated other reasons for failure for respiratory and systemic anti-infective drugs.
- Nearly half of cardiovascular failures were related to commercial issues.