



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Diabetes drug development is riskier compared to all drug development

One in 13 investigational diabetes drugs receives U.S. marketing approval

- 44% of new endocrine drugs approved in the United States in 1995-15 were for diabetes and related conditions.
- Large molecule products accounted for 33% of diabetes, and 20% of non-endocrine, drug approvals.
- After declining from the 1995-02 to the 2002-08 periods, mean clinical development time for diabetes drugs increased.
- During 1995-15, mean regulatory approval phase time was 15.7 months for diabetes drugs.
- Median clinical development time for diabetes drugs declined about 7% from 1995-01 to 2002-08 before increasing notably.