



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## While total approvals decline, U.S. is preferred market for first launch

*U.S. drug approvals dropped to 48 in 2005-07 from peak of 110 in 1996-98*

- U.S. approval of new drugs has steadily declined from its peak in the 1996-98 period.
- The number of U.S. approvals marketed first in the U.S. continues to climb, and reached an all time high of 75% in 2005-07, from a low of 20% in 1987-89.
- Combined clinical and approval times have dropped to the lowest level since the late 1990s.
- Following a jump in clinical times for priority and standard drugs in 2002-04, those numbers in 2005-07 returned to levels similar to those observed in 1996-98 and 1999-01.
- Average total time from IND filing to NDA approval for drugs approved in 2005-07 was longest for endocrine drugs—8.9 years—and shortest for antineoplastic drugs—6.1 years.