



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## Fast track designations more than doubled during the last five years

*Fast track drugs, on average, had shorter total clinical and approval times*

- Fast track designations for new drug candidates have grown substantially, from an average of 22 per year during 1998-02 to 49 per year during 2003-07.
- Anticancer candidates received the largest share of fast track designations since the program began.
- Fast track indications are more likely to be terminated during development than non-fast track indications.
- Efficacy was the primary reason for termination of fast track-designated candidates, accounting for 74% of terminations in 1998-02 and 49% in 2003-07.
- Total average clinical and approval time for fast track drugs was 5% faster than for all drugs (73.1 vs. 77.0 months).