



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## Biopharmaceutical product approvals in the U.S. rose dramatically in 2000s

*Recombinant proteins comprised the majority of new biotech approvals*

- During the 2000-09 period, 65 biopharmaceutical products received U.S. marketing approval, up from 39 in the 1990s and 13 in the 1980s.
- New biopharmaceutical approvals in the 2000s were more evenly distributed in six therapeutic categories, compared to those of 1980-89 and 1990-99.
- Average combined clinical and approval phase lengths for new biopharmaceuticals and NCEs approved during the 2000s were equivalent: 95 months.
- Average clinical phase length for biotech products approved in the 2000s was longest for anticancer biologic products (94.5 months) and shortest for cardiovascular/hemostasis treatments (65.8 months).
- Priority-reviewed new biopharmaceutical approvals increased after 2002.
- Orphan and fast track designations had little effect on phase lengths for recently approved new biopharmaceuticals.