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Tufts Center for the Study of Drug Development
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Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Marketing exclusivity for first-in-class drugs has shortened to 2.5 years

Follow-on approvals underscore competitive nature of new drug development

- Marketing exclusivity periods for first-in-class drugs have fallen dramatically in recent decades – from a median of 10.2 years in the 1970s to 2.5 years in the 2000-03 period.
- Average time between first and second follow-on drugs fell even more rapidly – from a median of 16.1 years in the 1960s to 1.1 years in 2000-03.
- Nearly one-third of all follow-on drugs have received a priority rating from the United States Food and Drug Administration (FDA).
- Since the early 1990s, 90% of follow-on drugs had initial pharmacologic testing and 87% were in clinical studies somewhere in the world prior to the first-in-class drug approval.
- Patent filings for follow-on drugs often occur in advance of first-in-class patent filing.