



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

# Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

## First-in-class drugs in competitive development races with later entrants

*83% of later-in-class drugs in Phase II or later when first-in-class drug approved*

- 48.5% of 40 pharmacologic classes had three or more entrants at the end of 2014.
- Half of all competitive entries within a pharmacologic class for classes where the first compound was approved 1998-11 occurred in less than 2.7 years; only 2.3 years for 2005-11.
- For pharmacologic classes with at least three approved compounds, competition occurred relatively rapidly, particularly for fourth entrants.
- More than half of all later-in-class drugs received a priority rating from the FDA.
- Nearly all pharmacologic classes had a product patent on at least one later-in-class drug filed in the United States or elsewhere before the first-in-class drug was approved.
- About 90% of all later-in-class drugs had at least initiated Phase I clinical testing abroad or in the U.S. prior to U.S. marketing approval for the first-in-class drug.