



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Biotech products accounted for 35% of all new FDA approvals in 2000-16

More than 400 biotech products were in Phase III trials at the end of 2016

- Biotech products in Phase III clinical trials spanned a broad range of molecules, with monoclonal antibodies (mAbs) accounting for 34.5% of the total.
- Whereas one-third of all biotech products in Phase III trials focused on oncology, biotech products spanned a large number of disease areas.
- Biosimilars accounted for more than 60 products in Phase III trials in 2016.
- Worldwide, 220 major pharmaceutical and biotechnology firms were pursuing Phase III trials for biotech products at the end of 2016.
- The recent pace of biotech product approvals is likely to continue for the next decade.