



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Oncology drugs get faster approvals than non-oncology drugs in U.S.

But in the EU, non-oncology drugs get faster approval than oncology drugs

- Total development and approval time for NME and new BLA oncology and non-oncology approvals in the U.S. was 8 years in 2002-06 and 7.4 years in 2007-11.
- During 2007-11, FDA approval times for oncology drugs were 10 months shorter than EMA approval times.
- Total development and approval time in the U.S. for fast track drugs during the 2000s dropped by 20% – from 8.3 years in 2002-06 to 6.6 years in 2007-11.
- Orphan designations for U.S. oncology drugs rose during the 2000s; other designations fell.
- U.S. oncology drug approval times were half those of Europe during 2007-11, regardless of designation status.