



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

New Breakthrough Therapy Designation program aims to cut clinical trial time

Only 30% of the first 113 BTM requests were approved

- The BTM was designed to supplement and complement the FDA's other expedited development and review programs – priority review, fast track, and accelerated approval.
- BTM drugs can utilize biomarkers to measure impact on irreversible morbidity and mortality (IMM).
- Central nervous systems drugs and diagnostics are likely to be significant beneficiaries of the BTM program.
- Orphan and oncology drugs dominated the first class of BTMs awarded by the FDA.