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Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Postmarketing studies are becoming the norm in U.S., Europe, and Japan

Over 75% of new drug approvals in the U.S. & EU, and over half of those in Japan, had postmarketing study commitments

- The average number of postmarking studies per new drug, of those requiring studies, ranges from 10.8 in Europe to 8.9 in the U.S. to 1.7 in Japan.
- The number of postmarketing commitments also varies by therapeutic area.
- When required, postmarketing commitments in the EU and Japan are more likely than in the U.S. to relate to safety concerns.
- Half of the products approved with postmarketing commitments in the U.S. and EU had pediatric study requirements, compared to only 6% in Japan.
- The timing of agreements regarding postmarketing commitments between sponsors and the regulatory agency is more consistent in Japan than in the EU and U.S.