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Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

User fee era in U.S. currently poses mixed regulatory burden for sponsors

Tufts CSDD analysis completed in advance of PDUFA reauthorization this fall

- Regulatory burden from the pre- to post-FDAAA period decreased for NME/newBLA approvals, but increased for sNDA/sBLA approvals.
- During the same period, spending on outsourced regulatory services rose dramatically.
- The difference between optimal and sub-optimal sponsor experiences with the FDA review process was less for NME/newBLAs than for sNDA/sBLAs.
- Ten of 21 regulatory activity variables were considered significant by sponsors, when optimal and sub-optimal approvals were compared on a disparity index.
- Overall, two variables were most consistently significant when both disparity index and statistical significance testing were considered for all cohorts.