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Faster New Drug Approval Times Are More Than Offset by Longer Clinical Times in U.S., According to Tufts Center for the Study of Drug Development

For drugs in expedited development programs, average total clinical and approval time was 11% lower

BOSTON – July 16, 2020 – Although regulatory approval time for new drugs in the United States is shortening, the time needed, on average, to complete clinical development of those drugs is lengthening by a greater amount, leading to longer times to develop and bring new drugs to market in this country, a newly completed study by the Tufts Center for the Study of Drug Development has found.

Average total time to conduct clinical studies and then complete the approval phase increased by 4.8 months from 2008-13 to 2014-18, according to Tufts CSDD, with mean clinical times increasing by nearly seven months and approval times dropping by nearly two months.

However, average combined clinical and approval time was 11% lower for drugs benefiting from expedited review by the Food and Drug Administration (FDA) compared to non-expedited review drugs during the same time, the study found.

"While the FDA has taken steps in recent years to help speed access to new medicines through the use of facilitated regulatory pathways, the development process itself has been getting more time consuming, due, in part, to increasing numbers of clinical study participants," said Joseph A. DiMasi, director of economic analysis and research associate professor at Tufts CSDD, principal investigator of the study.

Other findings from the study, based on 377 new drugs and biologics approved for marketing in the U.S., summarized in the July/August *Tufts CSDD Impact Report*, released today, include the following:

- Mean approval phase decreased by 1.9 months for all approved drugs during 2014-18, compared to 2008-13, while mean clinical phase increased by 6.7 months over the same period.
- Clinical development times varied substantially for the therapeutic areas with the most drug approvals during 2008-18.
- Total average clinical and approval time was 11% lower for expedited review compared to non-expedited review drugs during 2008-18.
- The mean number of participants per clinical trial in Phases I-III increased from 2008-13 to 2014-18, with the highest growth (9.2%) observed for Phase II.

ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the efficiency and productivity of pharmaceutical R&D. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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