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Quantifying the Value of a Day of Delay in Drug Development

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Quantifying the Value of a Day of Delay in Drug Development

The financial value of time is an essential measure used by drug development professionals to inform budget and resource planning as well as investment decisions. Two figures — the value of a day in delayed or lost prescription sales, and the direct daily costs to conduct a clinical trial — are frequently and widely cited. However, they often rely on antiquated and inaccurate estimates that were introduced more than 30 years ago.

The value of unrealized drug sales — at $4 – 5 million-per-delay-day for a given drug— is based on estimates calculated in 1993 from two separate sources: the Office of Technology Assessment and the Boston Consulting Group. These estimates were based on the expected annual revenue from prescription sales of a typical 1990s-era blockbuster drug divided by 365 days in a year.

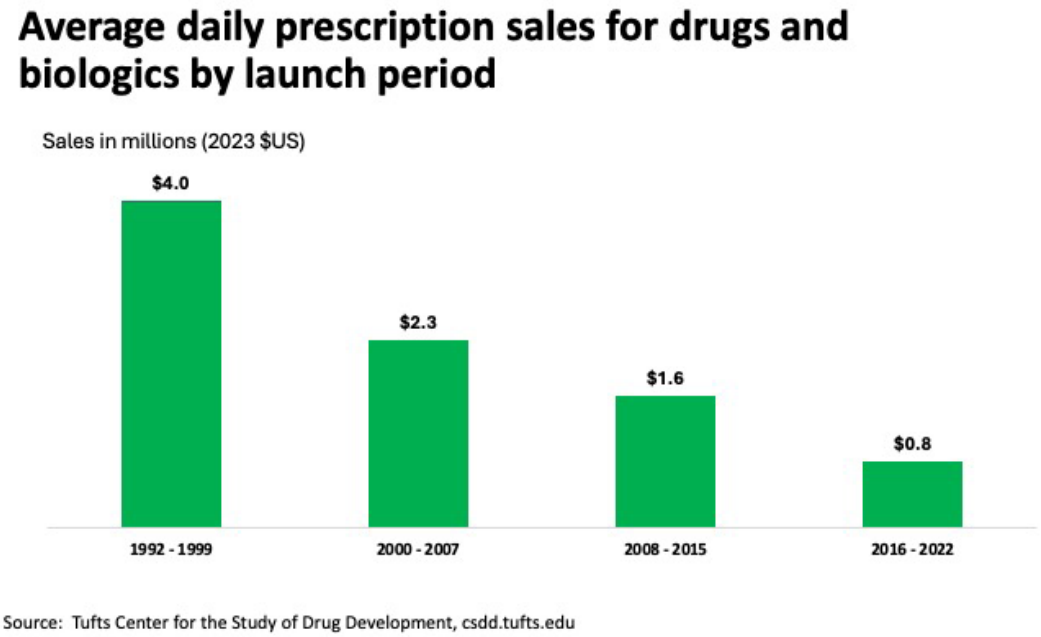
In October 2023, the Tufts Center for the Study of Drug Development (Tufts CSDD) research team conducted a robust study to provide more accurate measures of the out-of-pocket cost of a missed day of prescription drug or biologic sales and of the cost of a day conducting a clinical trial. Tufts CSDD also conducted this analysis to test the hypothesis that average prescription drug sales per day have been decreasing over time. Recently launched drugs and biologics are targeting ever more narrowly defined patient populations including those living with rare and ultra-rare diseases.

The Value of a Day of Lost or Delayed Prescription Sales

Tufts CSDD created a dataset drawn from commercially available data, supplemented by primary research. Specifically, we gathered pharmaceutical sales data in US dollars ($s) for drugs and biologics launched anywhere around the world since January 1st, 2000. Drugs for which there was no 2022 sales data and those approved as treatments for COVID-19 were removed from the dataset. All sales data was converted to 2023 $US dollars using the Gross Domestic Product (GDP) Implicit Price Deflator published by the Federal Reserve Bank.

The average value of a sales day was calculated by dividing total aggregate sales of a given drug or biologic by the number of days for which generated sales estimates were available, beginning with the day the drug was first launched. We analyzed a number of subgroups including therapeutic area and launch year. Correlations and the Kruskal-Wallis test were conducted to test for significant differences.

In all, 645 drugs were analyzed, the majority (61%) included the US among countries where the biologic or drug was first launched. The two largest therapeutic areas were oncology which represented 28% of the total products analyzed and CNS which represented 27% of the total.



Source: Tufts Center for the Study of Drug Development, csdd.tufts.edu

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At the present time a single day of delay is worth approximately $800,000 in lost prescription drug or biologic sales. The $4 - 5 million figure has been a gross misestimation for more than 25 years. Therapeutic areas with the highest relative average prescription drug sales — in 2023 $US dollars — included cardiovascular, hematology, and oncology drugs and biologics at a median of $1.4 million, $1.3 million, $840,000 respectively.

Average Daily Prescription Sales by Therapeutic Area

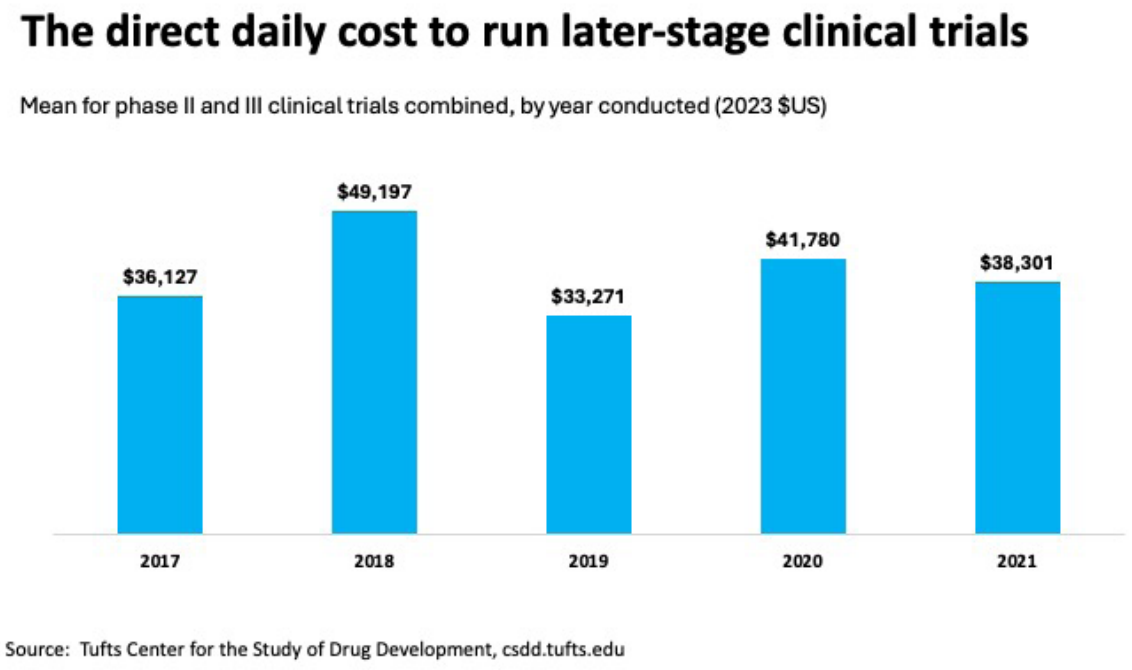
Top Therapeutic Areas	Mean Sales per Day (millions, $US 2023)	Coefficient of Variation around the Mean
Cardiovascular	$1.97	0.96
Hematology	$1.89	1.08
Immunology/Infectious diseases	$1.90	1.15
Oncology	$1.50	1.25
Inflammatory	$1.73	1.27
Respiratory	$1.71	1.21
Neurology/Psychiatric	$1.42	1.31
Genitourinary/Sexual Function	$1.56	1.29
Gastrointestinal	$1.83	1.30
Musculoskeletal	$1.63	1.27

The Tufts CSDD study also found — as we hypothesized — that average prescription drug and biologic sales per day have been steadily declining over time —decreasing by approximately $80,000 to $100,000 each year. A negative correlation was observed between average sales per day and the year the product was first launched.

The Value of a Day of Delay in Clinical Trials

The value of a day of direct costs to run a clinical trial comes from Medidata Solutions. Estimated to be approximately $35,000, the figure is based on a robust analysis that was conducted more than three decades ago (1990s).

Tufts CSDD's updated analysis is based on proprietary budget data gathered during our protocol design benchmark studies conducted between 2016 and 2021. Protocols for COVID-19 drugs were not included in this analysis. Actual clinical trial budgets were inflated to 2023 $US dollars using the GDP Implicit Price Deflator. Total clinical trial durations were calculated as the number of days from protocol approval to database lock (or primary completion date if database lock date was not available). Average cost per day was calculated by dividing the total budget for each protocol, expressed in 2023 $US dollars, by the total reported duration of the clinical trial.



Total budgets for 447 protocols were analyzed. The results indicate that, across all therapeutic areas, the mean direct cost to conduct a clinical trial per day is approximately $40,000 for Phase II and Phase III trials — approximately half of the inflation-adjusted 30-year-old estimate. Phase III clinical trials had the highest direct cost per day at $55,716. Phase II clinical trials cost roughly half that amount at $23,737 per day. Phase IV and phase I trials had the lowest daily cost at $14,091 and $7,829 per day, respectively. Clinical trials in respiratory, immunology and rheumatology, and dermatology had the highest direct costs per day. Although the daily direct cost to conduct a clinical trial fluctuated over time, there was no discernible trend.

Average Direct Cost Per Day in Phase II & III Clinical Trials by Therapeutic Area

Top Therapeutic Areas	Mean Direct Cost per Day (2023 $US)	Coefficient of Variation
Respiratory	$50,351	0.38
Immunology	$51,340	0.92
Gastroenterology/Endocrine	$36,395	0.77
Neurology	$39,437	0.64
Dermatology	$41,004	0.74
Oncology	$33,365	1.22
Cardiovascular	$30,657	1.31

Discussion

At this time, the value of a single day of delay is worth approximately $800,000 in unrealized or lost prescription drug sales and $40,000 in direct daily clinical trial costs. As drug and biologic success rates — IND filing to Food and Drug Administration approval — have been declining during the past several decades (a measure of increasing risk), so too have the average daily sales per drug or biologic that enters the market (a measure of return).

The direct cost of a clinical trial delay day is less than half the inflation-adjusted 1990s figure suggesting that certain direct costs may be lower today (e.g., operating, procedural and technology costs). The estimate may also reflect intensifying demand that sponsors and CROs place on investigative sites to drive operating efficiencies and work harder with lower relative study grants.

For a more detailed discussion of the methodology and results of this research, please refer to:

Kaitin K, editor. Dollar Value of One Day Delay in Drug Development is Now 20% of Blockbuster Era Levels. Tufts CSDD Impact Report. July/August 2024: 26(4).

Smith Z., DiMasi J., Getz K. New Estimates on the Cost of a Delay Day in Drug Development. Ther Inn & Reg Sci 2024. https://doi.org/10.1007/s43441-024-0667-w

About Tufts CSDD

The Tufts Center for the Study of Drug Development (Tufts CSDD) is a 48-year-old independent, academic, non-profit research center based within the Tufts University School of Medicine in Boston, Massachusetts.

Tufts CSDD's research team is multidisciplinary, globally-focused, and dedicated to optimizing drug development performance, quality and efficiency through robust, data-driven assessments, analysis, and insight.

For more information about this report and Tufts CSDD, and to communicate with the White Paper authors, please visit csdd.tufts.edu.

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