What It Actually Costs to Bring a Drug to Market

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Executive Summary

The question "what does it cost to bring a drug to market" has no single answer because published estimates measure different cost concepts. The HHS/ASPE study estimates a mean **$172.7 million out-of-pocket cost** per drug, **$515.8 million expected cost including failures**, and **$879.3 million expected capitalized cost including failures and capital costs** (all 2018 dollars). Tufts CSDD estimates **$2,558 million in capitalized pre-approval cost** per approved drug (2013 dollars); its separate **$2,870 million lifecycle estimate** adds post-approval R&D. The most widely cited Tufts figure, popularized by the Tufts Center for the Study of Drug Development (Tufts CSDD) and economist Joseph DiMasi, is therefore approximately **$2.6 billion** for pre-approval development, not $2.87 billion to reach initial approval (Source: pubmed.ncbi.nlm.nih.gov) (Source: www.globenewswire.com). Deloitte's 16th annual biopharma innovation report, covering 2025 data, reports **$2.671 billion** as an average cost-per-asset measure from discovery to launch for its late-stage pipeline cohort, up from $2.229 billion in 2024 (Source: www.deloitte.com). It is therefore not directly comparable with a per-approved-drug estimate. Both approaches incorporate failure costs, but they use different populations and methodologies.

That inclusion of failure cost is also where the controversy begins. A 2020 JAMA study by Olivier Wouters, Martin McKee, and Jeroen Luyten, examining 63 of 355 drugs approved between 2009 and 2018, put the median capitalized cost at **$1.14 billion**, less than half the Tufts figure, using a similar capitalization methodology but different underlying trial-cost assumptions (Source: jamanetwork.com). A 2017 JAMA Internal Medicine study of ten cancer drugs by Vinay Prasad and Sham Mailankody found a median cost of just **$648 million**, and pointedly noted that the industry's own cost estimates "lack transparency and independent replication" (Source: jamanetwork.com). A 2024 analysis from the US Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE), published in JAMA Network Open, estimated a mean out-of-pocket cost of just **$172.7 million** (2018 dollars), rising to $879.3 million once failures and capital costs are folded in (Source: jamanetwork.com). Critics, including the advocacy group Public Citizen, have challenged Tufts CSDD's funding and the nonpublic underlying company-level data. Public Citizen's **2001** critique asserted that 65% of the center's funding came from drug companies. Tufts' current financial disclosure instead states that

approximately 55% of its operating expenses are supported by private-sector grants and 45% by public-sector grants; it lists several private-sector and public-sector funding-source categories, so the private-sector share should not be equated with pharmaceutical-company funding (Source: www.citizen.org) (Source: csdd.tufts.edu).

Beneath the headline dollar figures sits a more consistent structural picture. The US Congressional Budget Office (CBO) reports that only about **12% of drugs** entering clinical trials are ultimately approved by the FDA, and that of every 100 drugs entering Phase 1, roughly 60 advance to Phase 2, just over 20 reach Phase 3, and about 12 are approved (Source: www.cbo.gov). In 2019 dollars, CBO reports average spending of roughly $28 million in Phase 1, $65 million in Phase 2, and $282 million in Phase 3 per drug completing all three clinical phases, or about $375 million in direct trial costs (Source: www.cbo.gov). PhRMA, the industry's US trade association, reports member companies spent **$104.34 billion** on R&D in 2024 and more than $850 billion over the past decade (Source: phrma.org), while the FDA's Center for Drug Evaluation and Research (CDER) approved 50 novel drugs in 2024, 55 in 2023, and 46 in 2025 (Source: www.fda.gov).

Real-world cases illustrate both extremes of this cost distribution. Operation Warp Speed compressed a typically decade-long vaccine timeline into about one year, with total US public investment in mRNA COVID-19 vaccines reaching at least **$31.9 billion** through March 2022 (Source: www.bmj.com). By contrast, Biogen lost more than **$18 billion** in market value in a single day in 2019 when Phase 3 trials of its Alzheimer's drug aducanumab were halted for futility (Source: www.reuters.com), and AstraZeneca is estimated to have sunk **$5.4 billion** into its Brilinta cardiovascular program with uncertain prospects of recouping the investment (Source: www.fiercepharma.com). Looking ahead, artificial intelligence (AI) is increasingly cited as a lever for cost and timeline compression: McKinsey estimates generative AI could generate **$60 billion to $110 billion** a year in economic value for the pharmaceutical and medical-product industries (Source: www.mckinsey.com), and the FDA issued draft guidance in January 2025 on how it will evaluate AI models used to support regulatory decisions (Source: www.hhs.gov). This report synthesizes the competing cost estimates, traces each to its methodology and sponsor, breaks down costs by clinical trial phase, and examines five real-world cases that show how the averages play out in practice.

Introduction and Background

Few numbers in health policy are cited as often, or contested as fiercely, as the cost to bring a new drug to market. Pharmaceutical companies invoke it to justify list prices that can run into hundreds of thousands or millions of dollars per course of treatment. Policymakers invoke competing, lower estimates to argue that prices could fall substantially without threatening innovation. Both sides cite credible but methodologically distinct estimates. However, the figures cannot be treated as a single per-approved-drug range: the ASPE $172.7 million figure is an out-of-pocket measure, whereas Tufts' $2.558 billion figure is capitalized pre-approval cost and its $2.870 billion figure additionally includes post-approval R&D.

The reason for this spread is not fraud on either side, but a genuine methodological fork. Every serious cost estimate must answer three questions: What population of drugs is being averaged (all new molecular entities, or a narrower subset such as cancer drugs or orphan drugs)? What direct, "out-of-pocket" cash costs are counted (only the successful drug's own trials, or a share of every failed candidate a company tested along the way)? And is a "cost of capital" or "opportunity cost" component added to reflect the years of forgone investment returns while a drug sits in development, unable to generate revenue? Answering these three questions differently is enough to produce the roughly fifteen-fold range separating the lowest and highest published estimates.

This report is organized around that methodological fork. It first explains how the leading research groups, Tufts CSDD, Deloitte, and the academic teams that have challenged them, actually calculate their figures. It then presents the numbers in comparative context, including a phase-by-phase breakdown of clinical trial costs and attrition rates drawn primarily from the CBO, the Biotechnology Innovation Organization (BIO), and the peer-reviewed literature. It examines the academic controversy over the Tufts figures directly, since understanding *why* estimates diverge is as important as knowing the estimates themselves. A dedicated data section aggregates industry-wide R&D spending, approval counts, and success-rate trends. Five named case studies, Operation Warp Speed's compressed COVID-19 vaccine timeline, Novartis's $2.125 million Zolgensma gene therapy, Biogen's costly aducanumab trial failure, AstraZeneca's Brilinta program, and the distinct economics of orphan-drug development, illustrate how the aggregate statistics translate into real corporate and clinical outcomes. Finally, the report considers how AI, decentralized clinical trials, and real-world evidence are beginning to reshape both the cost and the timeline of drug development, and closes with a set of frequently asked questions that address secondary aspects of the topic not fully covered in the main body.

Throughout, dollar figures are anchored to the year in which the underlying study was conducted and, where available, restated in the source's own currency year; all figures are current as of **July 2026** unless otherwise noted.

Methodology: How Economists Estimate the Cost of a New Drug

Every major cost-of-drug-development estimate rests on the same basic accounting identity, even though the inputs differ sharply. Researchers start with the **out-of-pocket cost**, the actual cash a company spends on preclinical research and clinical trials for compounds that are eventually approved. They then adjust for **attrition**, since most compounds that enter testing never reach the market, by dividing the cost per compound tested by an estimated probability of eventual approval; Tufts CSDD's own methodology summary describes this directly, explaining that "costs per approved new drug were estimated by dividing cost per investigational drug by the" clinical success rate (Source: keionline.org). This step alone is what converts a per-compound cost of a few hundred million dollars into a per-*approved-drug* cost in the billions, because it spreads the cost of every failed candidate across the handful that succeed.

Finally, most (though not all) headline estimates add a **cost of capital**, sometimes called a time cost or opportunity cost. Because drug development can take a decade or more, and investors could have deployed that capital elsewhere, researchers capitalize the out-of-pocket spending at an assumed discount rate to reflect the forgone return. Tufts CSDD's 2016 study used a real discount rate of 10.5%, stating that "capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 10.5% yields a total pre-approval cost estimate" of $2,558 million in 2013 dollars (Source: pubmed.ncbi.nlm.nih.gov). Its 2003 predecessor study used an 11% real discount rate applied to a $403 million out-of-pocket base to arrive at the $802 million figure (Source: www.cptech.org). This time-cost component is large: in the 2016 study, $1,395 million of the total was attributed to out-of-pocket cash costs, with the remaining **$1,163 million** attributed to time costs, meaning "time costs (expected returns that investors forego while a drug is in development)" made up roughly 45% of the total (Source: www.globenewswire.com) (Source: www.globenewswire.com). That share had actually fallen from roughly 50% in earlier studies, a detail often lost in the "$2.6 billion" headline (Source: www.globenewswire.com).

The 2016 Tufts figure was drawn from a sample of **106 randomly selected drugs** first tested in humans between 1995 and 2007, surveyed confidentially from ten pharmaceutical companies, comprising 87 small-molecule chemical entities and 19 large-molecule biologics (Source: www.globenewswire.com) (Source: keionline.org). Adding an estimate of post-approval R&D, further trials and label expansions conducted after a drug first reaches the market, raises Tufts' lifecycle estimate to **$2,870 million** (Source: pubmed.ncbi.nlm.nih.gov). Tufts CSDD states it conducts these longitudinal studies "every three to five years" (Source: csdd.tufts.edu), yet as of this writing, its official cost-study page confirms the 2016 Journal of Health Economics paper remains its most recently published full estimate, with the center still gathering company data for a next iteration that will place additional emphasis on small biopharma firms (Source: csdd.tufts.edu). This near-decade-long gap is itself notable: it means the figure still driving most public discourse in 2026 is now more than ten years old.

The Headline Numbers: How the Estimate Grew From $54 Million to $2.9 Billion

Tufts CSDD's own historical timeline shows just how far the headline cost figure has climbed since researchers first tried to measure it. The center "conducts the first comprehensive study of the cost to develop a new drug" in 1979, arriving at an estimate of **$54 million** (Source: csdd.tufts.edu). By 2003, the updated estimate, based on 68 randomly selected drugs surveyed from ten firms first tested in humans between 1983 and 1994, had risen to **$802 million** (Source: www.globenewswire.com) (Source: pubmed.ncbi.nlm.nih.gov), a nearly fifteen-fold increase in nominal terms over roughly two decades. The figures are expressed in different dollar years, so this comparison does not measure the real increase. Public Citizen's contemporaneous critique of that 2003 figure noted that "none of the 68 drugs used in the Tufts study received any government support, a fact admitted by the study's author, Joseph A. DiMasi," arguing the sample skewed the result upward relative to the broader industry (Source: www.citizen.org).

By 2016, the DiMasi, Grabowski, and Hansen study published in the *Journal of Health Economics* pushed the figure to **$2,558 million** (2013 dollars), based on the 106-drug sample described above, and to $2,870 million including post-approval R&D (Source: www.globenewswire.com). This is the origin of the "$2.6 billion pill" shorthand that has circulated in press coverage and industry communications ever since. PhRMA's own current policy pages still cite a version of this figure, stating that "on average, it takes 10-15 years and costs $2.6 billion to develop one new medicine, including the cost of the many failures" (Source: phrma.org), and separately that "from drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of $2.6 billion" (Source: phrma.org).

Deloitte's annual "Measuring the Return from Pharmaceutical Innovation" series has, since 2010, tracked a related but distinct metric: the average projected cost per late-stage pipeline asset for a cohort of large biopharma companies, defined as "assets in phase II with pivotal or breakthrough designation, in phase III, or filed for regulatory approval" (Source: www.deloitte.com). The cohort itself has grown over the report's history, evolving "from 12 large-cap companies to the top 20 by 2020 R&D spend" (Source: www.deloitte.com). The 16th edition, covering 2025 data, reports the average cost "growing to $2,671million in 2025 (from $2,229million in 2024)" (Source: www.deloitte.com). Although numerically similar to the Tufts figure, it is a distinct portfolio productivity metric and should not be read as a per-approved-drug estimate. *Table 1* below summarizes the major published cost-of-drug-development estimates in chronological and comparative context.

STUDY / SOURCE	YEAR PUBLISHED	HEADLINE COST ESTIMATE	POPULATION / SAMPLE	METHODOLOGY NOTES
Tufts CSDD (DiMasi), first study	1979	$54 million	Early industry survey	First comprehensive attempt to measure the figure (Source: csdd.tufts.edu)
Tufts CSDD (DiMasi), 2003 study	2003	$802 million (2000 USD)	68 drugs, 10 firms, first tested in humans 1983 to 1994	11% real discount rate on $403 million out-of-pocket base (Source: www.cptech.org)
Tufts CSDD (DiMasi, Grabowski, Hansen)	2016	$2,558 million; $2,870 million with post-approval R&D (2013 USD)	106 drugs, 10 firms, first tested in humans 1995 to 2007	10.5% real discount rate; $1,395M out-of-pocket + $1,163M time cost (Source: www.globenewswire.com)
Prasad and Mailankody, JAMA Internal Medicine	2017	$648.0 million median (range $157.3M to $1,950.8M)	10 cancer drugs, cost-to-revenue comparison	No capital cost added; explicitly critiques Tufts transparency (Source: jamanetwork.com)
Wouters, McKee, and Luyten, JAMA	2020	$1,141.7 million median	63 of 355 drugs approved 2009 to 2018	Capitalized cost methodology similar to Tufts, different trial cost inputs (Source: jamanetwork.com)
HHS/ASPE (Sertkaya et al.), JAMA Network Open	2024	$172.7 million mean out-of-pocket; $879.3 million capitalized with failures	Drugs approved 2000 to 2018	Range $72.5M (genitourinary) to $297.2M (pain/anesthesia) (Source: jamanetwork.com)
Deloitte, 16th edition	2026 (2025 data)	$2,671 million average, discovery to launch	Top 20 biopharma companies by 2020 R&D spend	Includes late-stage failures and cost of capital in projected returns model (Source: www.deloitte.com)

As the table shows, the figures use materially different definitions. ASPE reports $172.7 million in mean out-of-pocket cost, $515.8 million in expected cost including failures, and $879.3 million in expected capitalized cost; Wouters and colleagues report a $1.1417 billion median capitalized estimate. Tufts reports $2.558 billion in capitalized pre-approval cost and $2.870 billion only after adding post-approval R&D. No single number is simply "wrong"; each answers a different question about what counts as the cost of bringing a drug to market.

Clinical Trial Costs by Phase and Therapeutic Area

Regardless of which headline total a reader prefers, the underlying clinical trial economics are more consistent across sources. The CBO's 2021 report on pharmaceutical R&D states that the expected cost per approved new drug, including capital costs and the cost of failures, "has been estimated to range from less than $1 billion to more than $2 billion per drug" (Source: www.cbo.gov), a notably more conservative range than the Tufts figure, which the CBO separately discusses. The CBO's attrition data are stark: "only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA" (Source: www.cbo.gov), and the phase-by-phase drop-off is severe: "for every 100 drugs entering phase I trials, around 60 advanced to phase II trials, just over 20 entered phase III trials, and only about 12 gained FDA approval" (Source: www.cbo.gov).

Direct spending scales sharply by phase. In 2019 dollars, CBO reports average spending of **$28 million in Phase 1**, **$65 million in Phase 2**, and **$282 million in Phase 3** per drug completing all three clinical phases (Source: www.cbo.gov), and estimates that the preclinical phase takes about 31 months, with clinical trials adding roughly 95 months, "or about 10.5 years from start to finish" (Source: www.cbo.gov). A separate ASPE technical report, available through *NCBI Books*, breaks phase duration down further: Phase 1 averages 27.8 months, Phase 2 averages 34.0 months, and "Phase 3 is the longest (38.0 months) drug development stage across all therapeutic areas followed by post-approval Phase 4 (36.6 months)" (Source: www.ncbi.nlm.nih.gov), with average FDA review time adding roughly 16.2 months.

Enrollment size, and therefore total trial spending, also rises through the phases before falling again post-approval. The same ASPE model finds "the weighted average number of patients enrolled per trial is 51 for Phase 1, 235 for Phase 2, 630 for Phase 3, and 708 for Phase 4" (Source: www.ncbi.nlm.nih.gov), while average cost per patient actually declines as trials scale up, from $81,338 in Phase 1 to $58,618 in Phase 2, $53,180 in Phase 3, and $35,190 in Phase 4. Importantly, the ASPE model also finds attrition compounds most severely at the earliest stage: "the probability of moving from non-clinical stage to a marketable drug is only 8.5 percent on average" (Source: www.ncbi.nlm.nih.gov), rising to 65.5% for a compound that has already cleared preclinical work and Phase 1 and 2 testing.

Independent, peer-reviewed pivotal-trial cost data corroborate this picture from a different angle. A 2018 JAMA Internal Medicine study by Moore, Zhang, Anderson, and Alexander, examining FDA approvals from 2015 to 2016, found a median pivotal trial cost of "$19.0 million (interquartile range, $12.2 million to $33.1 million)" (Source: pubmed.ncbi.nlm.nih.gov), with the most expensive single trial in the sample costing "$346.8 million" for a noninferiority design with clinical-benefit endpoints (Source: pubmed.ncbi.nlm.nih.gov). Notably, uncontrolled trials, often smaller orphan-drug studies, were far cheaper, averaging just $13.5 million (Source: pubmed.ncbi.nlm.nih.gov). A 2020 follow-up study extending the same methodology to drugs approved through 2017 found cardiovascular drugs had the highest median per-drug pivotal trial cost at $141 million, while central nervous system drugs were markedly cheaper at $42 million (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov), with a per-patient median cost across the dataset of "US$41,413 (IQR, US$29,894 to US$75,047)" (Source: pmc.ncbi.nlm.nih.gov). *Table 2* consolidates the phase-level figures from these sources.

PHASE	AVERAGE DURATION	AVERAGE ENROLLMENT	AVERAGE COST PER PATIENT	APPROXIMATE PHASE-LEVEL SPENDING	CUMULATIVE SURVIVAL TO NEXT STAGE
Preclinical / Non-clinical	~31 months (CBO)	Not applicable	Not applicable	Included in overall R&D budget	~8.5% reach the market (ASPE)
Phase 1	27.8 months (ASPE)	51 patients (ASPE)	$81,338 (ASPE)	~$28 million (CBO, 2019 dollars; per drug completing all three clinical phases)	~60 of 100 advance to Phase 2 (CBO)
Phase 2	34.0 months (ASPE)	235 patients (ASPE)	$58,618 (ASPE)	~$65 million (CBO, 2019 dollars; per drug completing all three clinical phases)	~20 of 100 advance to Phase 3 (CBO)
Phase 3	38.0 months, the longest phase (ASPE)	630 patients (ASPE)	$53,180 (ASPE)	~$282 million (CBO, 2019 dollars; per drug completing all three clinical phases); median pivotal-trial cost $19.0 million **per trial** (IQR $12.2M–$33.1M; JAMA); separate BMJ Open analysis reported therapy-area **per-drug** pivotal-trial medians of $141M for cardiovascular drugs and $42M for central nervous system drugs	~12 of 100 gain FDA approval (CBO)
FDA Review	~16.2 months (ASPE)	Not applicable	Not applicable	Regulatory/administrative	Approval or complete response
Phase 4 / Post-approval	36.6 months (ASPE)	708 patients (ASPE)	$35,190 (ASPE)	Ongoing pharmacovigilance and label expansion	Not applicable

The table underscores a point easily lost in headline cost figures: Phase 3 is the longest and most expensive clinical phase in these estimates. The CBO progression figures show the largest drop in this sequence occurs between Phase 2 and Phase 3, so they do not support describing Phase 3 as the stage with the steepest remaining failure rate before approval. It is also the phase most sensitive to therapeutic area. BIO's landmark study of clinical development success rates, which recorded and analyzed "9,985 clinical and regulatory phase transitions, across 1,103 companies" (Source:

www.bio.org), found the overall likelihood of approval (LOA) from Phase 1 was 9.6%, rising to 11.9% when oncology is excluded, with hematology the most successful therapeutic area (26.1% LOA) and oncology the least (5.1%) (Source: www.bio.org). A follow-up BIO analysis covering 2011 to 2020 found the overall LOA from Phase 1 had fallen to **7.9%** (Source: go.bio.org), with an average of 10.5 years for a Phase 1 asset to progress to regulatory approval (Source: go.bio.org), a figure that closely matches PhRMA's own public statement that developing a new medicine "takes at least 10 years on average" (Source: phrma.org).

The Debate Over the Real Number

The divergence between Tufts' $2.558 billion capitalized pre-approval estimate and lower academic and government estimates is not a rounding error; it reflects differences in data access, populations, failure adjustments, and treatment of capital costs. The HHS/ASPE $172.7 million figure is an out-of-pocket measure, while its expected capitalized estimate including failures is $879.3 million; Wouters and colleagues reported a $1.1417 billion median capitalized estimate. Deloitte's $2.671 billion late-stage-asset portfolio metric is not directly comparable to either type of per-approved-drug estimate. The Wouters, McKee, and Luyten JAMA study explicitly frames this as a live controversy, noting that "recent estimates" of drug development cost had ranged "from $314 million to $2.8 billion" even before their own study added a further data point (Source: jamanetwork.com). Their own median capitalized estimate of **$1,141.7 million**, based on 63 of 355 new therapeutic drugs and biologics approved by the FDA from 2009 to 2018 (Source: jamanetwork.com), used a similar capitalization approach to Tufts but drew on publicly disclosed company financial data rather than confidential industry surveys, a distinction its authors and later commentators view as central to the credibility gap.

Prasad and Mailankody's 2017 study went further, arguing directly that the industry-favored estimates "lack transparency and independent replication" (Source: jamanetwork.com). Studying ten FDA-approved cancer drugs, they found a median R&D cost of "$648.0 million (range, $157.3 million to $1950.8 million)" (Source: jamanetwork.com), and noted the disparity between that cost and subsequent revenue was vast: total revenue from those ten drugs since approval reached "$67.0 billion compared with total R&D spending of $7.2 billion," a return of roughly nine times (Source: jamanetwork.com).

Public Citizen has been a persistent critic of the Tufts methodology, describing the center in a 2017 health letter as "the drug-industry-funded Tufts Center for the Study of Drug Development" (Source: www.citizen.org). In a **2001** critique, Public Citizen asserted that 65% of the center's funding came from drug companies (Source: www.citizen.org). Tufts' current disclosure states that approximately 55% of operating expenses are supported by private-sector grants and 45% by public-sector grants, and identifies a range of funding-source types; it does not describe the private-sector share as pharmaceutical-company funding (Source: csdd.tufts.edu). Public Citizen's arithmetic breakdown of the $2.6 billion figure emphasizes that "only $1.4 billion represents the actual cost of developing a drug, with the remaining $1.2 billion representing the lost opportunity cost" of capital (Source: www.citizen.org), and cites James Love of Knowledge Ecology International disputing even that $1.4 billion figure's key input, noting it "was based entirely on the estimated average cost of $339 million for the human trials" from an unpublished dataset (Source: www.citizen.org).

DiMasi has defended the Tufts approach directly. In a 2004 rebuttal published in *Prescrire International*, he addressed the funding-source criticism by noting the industry funding "is widely known and has never been concealed" (Source: english.prescrire.org), and defended the confidentiality of the underlying company data by arguing "it is not unverifiable and the situation is not basically different from that of clinical databases" that also rely on proprietary trial data reviewed through peer review rather than raw public disclosure (Source: english.prescrire.org). A 2024 invited commentary by Wouters and Aaron Kesselheim in JAMA Network Open restates the durability of the critique: "because the underlying data have never been publicly disclosed, these estimates cannot be independently validated or scrutinized for selection bias" (Source: researchonline.lse.ac.uk). STAT News framed the underlying stakes of the debate succinctly in its coverage of the 2020 JAMA study: "the pharmaceutical industry, citing a $2.8 billion figure from a group at Tufts University, argues that prices need to be high enough to justify huge financial risks" (Source: www.statnews.com), a framing that explains why the two sides continue to talk past one another: the debate over drug prices and the debate over drug development cost are related but not identical, and each side selects the cost figure most favorable to its broader policy argument.

Most recently, the 2024 HHS/ASPE analysis published in JAMA Network Open added yet another data point from a government rather than academic or industry source, finding "the estimated mean cost of developing a new drug was approximately $172.7 million (2018 dollars) (range, $72.5 million for genitourinary to $297.2 million for pain and anesthesia), inclusive of postmarketing studies" (Source: jamanetwork.com). That out-of-pocket figure is roughly one-fifteenth of the Tufts capitalized total, a reminder that "the cost of drug development" is not one number but a family of numbers that differ by an order of magnitude depending on what is measured and whose data is used.

Why Development Costs So Much: Attrition, Time, and the Concentration of Failure

Whatever the precise dollar figure, the structural drivers of cost are broadly agreed upon across sources. Deloitte's most recent report attributes rising R&D costs to five specific factors: "increases in trial times, more intricate and complex research areas, macroeconomic factors, tech advancements and high attrition rates" (Source: www.fiercebiotech.com). Its 2024 analysis found the tracked pharma cohort spent **$7.7 billion** on clinical trials for candidates that were ultimately terminated that year, a direct quantification of the cost of failure that headline averages absorb (Source: www.fiercebiotech.com). Trial durations themselves have also lengthened: Deloitte's 15th edition reported that "the average time from Phase I through regulatory filing now exceeds 100 months, with Phase III trial times increasing by 12%" (Source: www.prnewswire.com), and separately, IQVIA Institute data show trial enrollment itself is slowing, with median enrollment duration exceeding "16 months in 2025, with oncology trials taking significantly longer" than other therapeutic areas (Source: www.iqvia.com).

The financial return on all this spending has been volatile and, on an underlying basis, thin. Deloitte's 14th edition reported the pharma R&D internal rate of return (IRR), a measure of how well capitalized R&D spending is expected to pay off, hit "the lowest point for the cohort since our analysis began" at just 1.2% in 2022, before rising to 4.1% in 2023 (Source: www.deloitte.com). The 15th edition reported IRR "risen to 5.9%, continuing the upward trajectory from 2023's 4.1%" (Source: www.prnewswire.com), and the most recent, 16th edition found IRR rose for a third consecutive year to 7.0%, "a 1.1 percentage point improvement from 2024" (Source: www.deloitte.com). Notably, Deloitte's own analysis reveals this recovery is concentrated in one drug class: excluding GLP-1 (glucagon-like peptide-1) and GIP-class obesity and diabetes drugs, the underlying 2025 rate of return was just **2.9%**, down from 3.8% in 2024, "a notable jump" that masks a still-fragile broader R&D return picture once the GLP-1 boom is set aside (Source: www.deloitte.com).

The industry's aggregate spending on R&D has nonetheless kept rising regardless of return trends. Deloitte's 14th edition found large pharmaceutical companies "spent a record total of US$161 billion in 2023, an increase of almost 50% since 2018" (Source: www.deloitte.com), a spending trajectory PhRMA's own membership survey corroborates from a different vantage point: US industry R&D spending reached **$104.34 billion** in 2024 alone, an 8.7% increase over 2023 (Source: cdn.aglty.io), and cumulative PhRMA member spending has exceeded $850 billion over the past decade (Source: phrma.org). This combination, rising aggregate spend, historically thin and volatile IRR, and a concentration of gains in a single drug class, is one of the clearest empirical arguments for why the "average cost per drug" figure keeps climbing even as any individual successful drug's own trials may not have grown proportionally more expensive: the average is doing the work of absorbing an increasing volume of expensive failures.

Data Analysis and Evidence

Aggregating the figures above into a single industry-level picture requires triangulating several independent data series, each with its own sponsor, sample, and time window, a discipline this section makes explicit rather than blending the numbers into an undifferentiated whole. On the regulatory output side, the FDA's Center for Drug Evaluation and Research (CDER) reports that "in 2024, CDER approved 50 new drugs never before approved or marketed in the U.S." (Source: www.fda.gov), following 55 approvals in 2023 (Source: www.fda.gov) and 46 in 2025 (Source: www.fda.gov). Over the past decade, CDER has approved an average of 47 novel drugs per year, ranging from a low of 22 in 2016 to a high of 59 in 2018 (Source: www.raps.org). Annual R&D spending and approvals in a given year are not matched cohorts: the spending supports multiyear pipelines, while approvals reflect candidates funded over many prior years. Dividing one year's spending by one year's approvals is therefore only a descriptive throughput ratio, not an estimate that can be compared with per-drug development-cost studies.

Success-rate data further contextualize where in the pipeline the money is actually lost. PhRMA states plainly that "only 12% of new molecular entities that enter clinical trials eventually receive U.S. Food and Drug Administration (FDA) approval" (Source: phrma.org), a figure consistent with the CBO's independent 12% approval-rate estimate cited earlier. Tufts CSDD's own historical research notes document a long-running decline in success rates by therapeutic area: an oncology-specific 2007 analysis found overall approval success rates as low as 8%, and a 2009 analysis found an overall clinical success rate of just 16% across drug classes (Source: csdd.tufts.edu). BIO's independent tracking, based on the largest sample in the field (9,985 phase transitions across 1,103 companies), found a similar range: 9.6% overall Phase 1 to approval likelihood in its 2006 to 2015 dataset (Source: www.bio.org), declining further to 7.9% in its 2011 to 2020 update (Source: go.bio.org). The decline from 9.6% to 7.9% is one possible contributor to higher fully loaded per-drug cost estimates: if comparable cohorts experienced lower success rates, each approval would carry a larger share of failed-candidate spending. However, the BIO analyses use overlapping but different cohorts and methods, so this comparison does not by itself establish an industry-wide causal trend.

The financial data reinforce this same conclusion from the top down. Deloitte's late-stage asset tracking shows average forecast peak sales per asset climbing to "US$598 million in 2025, a notable jump from $510 million in 2024" (Source: www.deloitte.com), a revenue expectation rising in tandem with, and to some extent because of, rising development costs and lengthening timelines. Meanwhile, IQVIA's Global R&D Trends 2026 report finds that after several years of improvement, "end-to-end clinical development timelines have increased, reversing the improvements of recent years" in 2025 (Source: www.iqvia.com), even as inter-trial intervals, the administrative and logistical gaps between clinical phases, had fallen to a typical 17 months, down sharply from a pandemic-era peak of 32 months in 2022 (Source: www.iqvia.com). Taken together, the data show an industry that has partially fixed one operational bottleneck (the dead time between trial phases) while a different one, overall trial duration and enrollment speed, has gotten worse, a pattern of uneven progress that helps explain why aggregate cost figures have not meaningfully declined despite years of stated industry and regulatory effort to streamline development.

Case Studies and Real-World Examples

Operation Warp Speed and the Compressed COVID-19 Vaccine Timeline

The COVID-19 pandemic produced the starkest real-world test of how much money and regulatory flexibility can compress the traditional drug development timeline. The US Government Accountability Office (GAO) noted that under normal conditions, "a typical vaccine development process can take approximately 10 years or longer" (Source: www.gao.gov), yet by late 2020, Operation Warp Speed had obligated "more than $10 billion in obligations" across multiple vaccine candidates run largely in parallel rather than sequentially (Source: www.gao.gov). A subsequent peer-reviewed BMJ retrospective cohort study found the true public investment was substantially larger once manufacturing and purchase commitments were included: the US government invested "at least $31.9bn to develop, produce, and purchase mRNA covid-19 vaccines" through March 2022, of which only $337 million had been invested before the pandemic began (Source: www.bmj.com) (Source: www.bmj.com).

The NIH and the Biomedical Advanced Research and Development Authority (BARDA) credited their partnership with Moderna with having "enabled NIH and Moderna to develop a safe and effective COVID-19 vaccine within the span of a year" (Source: www.nih.gov), roughly a tenth of the typical vaccine development timeline cited by the GAO. Notably, not every manufacturer took the same public-funding path: Pfizer secured a $1.95 billion Operation Warp Speed advance-purchase agreement for finished doses but, unlike Moderna and AstraZeneca, "did not accept federal funding to help develop or manufacture the vaccine" (Source: www.nytimes.com), illustrating that even within a single crash program, corporate R&D financing structures varied considerably. The episode shows that vaccine development and deployment can be accelerated during a public-health emergency when candidates, manufacturing, and procurement are supported in parallel; it does not establish which elements of the usual timeline are avoidable across drug development.

Zolgensma: Gene Therapy Pricing and the Limits of "R&D Cost" as a Price Justification

Novartis's one-time gene therapy for spinal muscular atrophy, Zolgensma (onasemnogene abeparvovec), offers a case study in how development cost narratives interact with list pricing. Upon FDA approval in 2019, Novartis "priced the one-time treatment at a record $2.125 million," at the time the most expensive drug in the world (Source: www.reuters.com), a figure STAT News confirmed while noting Novartis's own framing of the price as "an annualized cost of $425,000 per year for five years" (Source: www.statnews.com). Novartis's own pathway to the drug involved a corporate acquisition rather than pure in-house development: it had "acquired [Zolgensma] with its $8.7 billion purchase of AveXis" the year before approval (Source: www.reuters.com), meaning the drug's ultimate list price reflects a blend of acquisition premium, remaining clinical costs, and expected commercial value rather than a transparent tally of ground-up R&D spend.

A 2025 ProPublica investigation complicated the R&D-cost justification further, reporting that "taxpayers and private charities like Sophia's Cure subsidized much of the science that yielded Zolgensma" before Novartis's involvement (Source: www.propublica.org). This is a recurring pattern in gene and cell therapy specifically: because foundational science often originates in academic or government-funded labs before being licensed or acquired by a commercial sponsor, the "cost to bring a drug to market" for such products can understate the public sector's earlier contribution while the eventual list price is set based on commercial value rather than recovered cost alone.

Biogen's Aducanumab: The Cost of a Late-Stage Failure, Approval, and Discontinuation

The financial consequences of a late-stage setback can be severe precisely because so much capital is committed by Phase 3. When Biogen halted two Phase 3 trials of its Alzheimer's drug aducanumab in March 2019 after an independent monitoring committee found the trials unlikely to succeed, the company "lost more than $18 billion (£13.8 billion) of its value" in a single trading day (Source: www.reuters.com). That halt was not the final regulatory outcome: the FDA granted Aduhelm (aducanumab-avwa) accelerated approval on June 7, 2021 (FDA. Biogen later discontinued Aduhelm's development and commercialization in January 2024 and terminated its required post-marketing confirmatory study (Biogen. The sequence illustrates how a single Phase 3 program can both destroy substantial market value after a setback and still proceed through an accelerated-approval pathway, with significant post-approval obligations and commercial risk remaining.

AstraZeneca's Brilinta and Novo Nordisk's Ocedurenone: Sunk Costs in Outcomes Trials

AstraZeneca's cardiovascular drug Brilinta illustrates a different failure mode: not an outright trial halt, but a long, expensive program of post-approval outcomes trials that never fully proved out commercially. Trade press analysis estimated that "with an estimated $5.4 billion in sunk costs in Brilinta, AstraZeneca will likely never turn a profit" on the drug (Source: www.fiercepharma.com), noting that the drug's six-trial "Parthenon" outcomes program alone had "already swallowed $3.7 billion in R&D costs," with two of the six trials in that program deemed outright failures (Source: www.fiercepharma.com). Novo Nordisk's 2024 experience with its chronic kidney disease candidate ocedurenone shows the same dynamic on a shorter timeline: after its Phase 3 CLARION-CKD trial missed its primary endpoint, the company disclosed it would "recognise an impairment loss of around DKK 5.7 billion related to the intangible asset ocedurenone" (roughly $816 million) (Source: www.globenewswire.com). Both cases show that "cost of failure" is not confined to early-stage attrition; some of the largest single write-offs in the industry occur in expensive, late-stage outcomes trials pursued after a drug has already reached the market.

Orphan Drug Economics: Small Trials, Undisclosed Costs, and a Different Cost Curve

Rare-disease, or "orphan," drugs follow a distinct cost curve because small patient populations both limit enrollment and, often, reduce direct trial spending relative to mass-market indications. A peer-reviewed analysis in the *Orphanet Journal of Rare Diseases* estimated "the out-of-pocket clinical costs per approved orphan drug to be $166 million and $291 million (2013 USD) per non-orphan drug" (Source: link.springer.com), roughly 43% lower for orphan indications, while the same paper cites the DiMasi benchmark "capitalized costs to the point of marketing approval to be $2.6 billion (2013 USD)" as the comparison point for the fully loaded, all-drug average (Source: link.springer.com).

An independent 2025 research note from Knowledge Ecology International (KEI) attempted to reconstruct the actual trial cost of Roche's spinal muscular atrophy drug risdiplam (Evrysdi), estimating "the cost of risdiplam clinical trials through FDA approval was $19.2 million, before considering the Orphan Drug Tax Credit" (Source: www.keionline.org), a figure two orders of magnitude below the Tufts industry-wide average. KEI states that Roche declined to share actual risdiplam trial outlays (Source: www.keionline.org). Similarly, ProPublica reported that Novartis did not respond to its questions about Zolgensma trial costs. These two case studies therefore rely on third-party estimates rather than audited company cost accounting; they cannot establish how often companies disclose such costs across the industry.

Implications and Future Directions

The most active frontier for changing the drug development cost equation is artificial intelligence, though the evidence for AI's impact so far is a mix of credible independent findings and vendor claims that deserve separate treatment. On the credible-evidence side, IQVIA Institute's Global R&D Trends 2026 report found that "the Phase I success rate for AI-enabled emerging biopharma programs was 75%" over its most recent three-year measurement window, notably higher than comparable non-AI-enabled programs (Source: www.iqvia.com). A separate peer-reviewed analysis by Jayatunga and colleagues in *Drug Discovery Today* similarly found that "AI-discovered molecules have an 80-90% success rate, substantially higher than historic industry averages" in Phase 1, though Phase 2 rates for these same molecules were closer to historical norms (Source: pubmed.ncbi.nlm.nih.gov). A 2025 *Nature Biotechnology* piece cites the same figure and adds a timeline claim, that AI "reduc[es] the traditional 10-15 year process to as little as 1-2 years" for early discovery work (Source: www.nature.com), a claim that, while published in a peer-reviewed venue, should be read as describing the discovery and lead-optimization stage specifically, not the full clinical-to-approval timeline, which BIO and CBO data show remains close to 10 years regardless of how a candidate was originally identified.

McKinsey's independent analysis adds both a quantitative economic estimate and a note of caution about how much of the pipeline AI can realistically touch. The firm finds that "less than 0.1 percent of candidate molecules pass from screening to Phase I" under conventional discovery (Source: www.mckinsey.com), underscoring just how much of total R&D cost is consumed by discovery-stage attrition long before a compound ever reaches a clinical trial cost line item. McKinsey estimates that with process optimization, companies can cut the time to reach a first-in-human application "by 40 percent or more" (Source: www.mckinsey.com), and separately projects generative AI specifically "could generate $60 billion to $110 billion a year in economic value for the pharma and medical-product industries" (Source: www.mckinsey.com). Yet the firm's own 2025 research strikes a more cautious note on realized progress, observing that despite these gains, drug development "still takes about a decade on average" from candidate nomination to launch, and that "study and application costs for investigational new drugs (INDs) have soared in recent years by 20-30 percent" (Source: www.mckinsey.com), a reminder that discovery-stage AI gains have not yet visibly reduced the overall clinical-and-regulatory cost burden this report has otherwise documented as rising.

One named example illustrates both the promise and the pace of AI-driven development. Insilico Medicine's AI-designed candidate ISM001-055 (rentosertib), targeting a novel mechanism for idiopathic pulmonary fibrosis, showed a "98.4 mL mean improvement in FVC [forced vital capacity] compared to baseline, versus a mean decline of -62.3 mL" in the untreated comparison in a Phase 2a trial reported by trade press (Source: www.fiercebiotech.com). Insilico's own chief executive has claimed the company's AI platform reached developmental-candidate stage for this program in "9-18 months to go from zero to this developmental candidate" (Source: www.clinicalresearchnewsonline.com), a figure that, as a vendor claim rather than an independently audited timeline, should be read alongside, not in place of, the independent success-rate data cited above. IntuitionLabs, a life-sciences and AI consultancy that works with pharmaceutical companies on data and analytics infrastructure rather than as a drug developer itself, similarly notes in its own public materials that "AI-enhanced drug discovery and development can accelerate timelines by up to 60%, according to recent research by Deloitte," and separately that "McKinsey estimated AI could generate $100B+ in annual value for the pharmaceutical industry, and adoption since 2024 has tracked ahead of that curve" (Source: intuitionlabs.ai) (Source: intuitionlabs.ai). Such figures are best treated as directional signals of where the industry expects value to accrue rather than settled measurements of realized savings, since, as the McKinsey and Deloitte data above show, aggregate development cost and timeline metrics have not yet meaningfully declined industry-wide.

Regulators are adapting in parallel. On January 7, 2025, the FDA issued draft guidance on "considerations for the use of artificial intelligence to support regulatory decision-making for drug and biological products" (Source: www.hhs.gov). The draft guidance describes a risk-based credibility assessment framework that may be used for AI models supporting regulatory decision-making (Source: www.fda.gov); it remains nonbinding and is marked "Not for implementation." It does not address AI models used solely in drug discovery (Source: www.dlapiper.com). Separately, the FDA maintains guidance on "Conducting Clinical Trials With Decentralized Elements" covering telehealth visits, in-home assessments, and other remote trial activities (Source: www.fda.gov), an approach a peer-reviewed Tufts CSDD and Medable study found adds roughly "$20 million per drug that enters phase II, with a seven-fold ROI" in expected net present value, driven partly by measurably lower screen-failure rates: "a screen failure rate reduction of 23.5% for phase II trials and a 32.8% reduction for phase III" (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov). Real-world evidence is also expanding as a regulatory input: IQVIA found "real world evidence contributed to seven FDA approvals" in 2025, concentrated in rare disease and oncology (Source: www.iqvia.com). None of these mechanisms is likely to single-handedly resolve the cost debate documented in this report, but collectively they represent the clearest near-term path toward narrowing the gap between the roughly $2.6 billion industry figure and the sub-$1 billion academic and government estimates, by reducing the attrition and time-cost components that account for the largest share of the disputed total.

Frequently Asked Questions (FAQs)

What is the average cost to develop a new drug in 2026? There is no single agreed figure. The most commonly cited industry estimate, from Tufts CSDD, is approximately $2.6 billion ($2,558 million in 2013 dollars, $2,870 million including post-approval R&D) (Source: pubmed.ncbi.nlm.nih.gov). Deloitte's most recent (2025-data) report gives $2.671 billion as an average cost-per-asset figure for its late-stage pipeline cohort, so it is not directly comparable with a per-approved-drug estimate (Source: www.deloitte.com). Academic studies using different methods report lower per-drug figures, from $172.7 million (Source: jamanetwork.com) to $1.14 billion (Source: jamanetwork.com).

Why does drug development cost so much? Because the headline figures divide total spending, including spending on every drug that fails, by the small number that succeed. The CBO finds only about 12% of drugs entering clinical trials are ultimately approved (Source: www.cbo.gov), and Deloitte found its tracked companies spent $7.7 billion on trials for candidates terminated in a single year, 2024 (Source: www.fiercebiotech.com). Many estimates also add a cost-of-capital component reflecting years of forgone investment returns during the roughly decade-long development period (Source: www.globenewswire.com).

What does the Tufts CSDD drug development cost study actually say? Tufts CSDD's most recent full study, published in 2016 in the *Journal of Health Economics*, found a capitalized cost per approved new drug of $2,558 million (2013 dollars), based on a survey of 106 drugs from 10 companies (Source: www.globenewswire.com). As of this writing, Tufts has not published a full successor study and is still collecting data for its next iteration (Source: csdd.tufts.edu).

What does the Deloitte cost-per-asset R&D study show for 2025? Deloitte's 16th annual report found the average cost per late-stage biopharma asset reached $2.671 billion in 2025, up from $2.229 billion in 2024 (Source: www.deloitte.com), while projected R&D internal rate of return rose to 7.0%, though it falls to just 2.9% once GLP-1 obesity and diabetes drugs are excluded (Source: www.deloitte.com).

How much does each phase of a clinical trial cost? In 2019 dollars, CBO estimates spending of $28 million in Phase 1, $65 million in Phase 2, and $282 million in Phase 3 per drug completing all three clinical phases (Source: www.cbo.gov), while a peer-reviewed study of pivotal trials specifically found a median cost of $19.0 million per trial (Source: pubmed.ncbi.nlm.nih.gov).

Does the cost figure include the drugs that fail? It depends on the estimate. Tufts CSDD's methodology explicitly divides "cost per investigational drug by the" clinical success rate to arrive at cost per approved drug (Source: keionline.org), so its $2.6 billion figure includes failures. In the HHS/ASPE analysis, the $172.7 million mean is an out-of-pocket cost; the expected cost including failures is $515.8 million, and the expected capitalized cost including failures and capital costs is $879.3 million (Source: jamanetwork.com).

Why do estimates vary so much between studies? Because researchers make three different choices: which drugs to include in the sample, whether to add a cost-of-capital adjustment, and whether the underlying company data is public or confidential. The Wouters JAMA study explicitly notes prior estimates ranged "from $314 million to $2.8 billion" even before its own contribution (Source: jamanetwork.com), and critics have specifically challenged Tufts CSDD's reliance on undisclosed, industry-supplied data (Source: researchonline.lse.ac.uk).

Can AI meaningfully reduce the cost of drug development? Early evidence is promising but not yet conclusive at the industry level. IQVIA found AI-enabled biopharma programs had a 75% Phase 1 success rate (Source: www.iqvia.com), and McKinsey projects generative AI could add $60 billion to $110 billion a year in industry economic value (Source: www.mckinsey.com), yet the same firm's 2025 analysis found overall development still takes about a decade and IND costs have risen 20 to 30 percent in recent years (Source: www.mckinsey.com).

Conclusion

There is no single number that captures "the cost to bring a drug to market," and any answer that offers only one figure without its methodology is incomplete. The published measures must be kept distinct: HHS/ASPE estimates $172.7 million in mean out-of-pocket cost, $515.8 million in expected cost including failures, and $879.3 million in expected capitalized cost including failures and capital costs (2018 dollars). Tufts CSDD estimates $2.558 billion in capitalized **pre-approval** cost per approved drug (2013 dollars), while its $2.870 billion figure is a lifecycle estimate that adds post-approval R&D. The most industry-influential initial-approval estimate is therefore the roughly $2.6 billion Tufts figure, not a $172.7 million-to-$2.87 billion range. Deloitte's $2.671 billion figure is a separate late-stage-pipeline cost-per-asset metric, not its successor or corroboration, and it should likewise not be combined into a per-approved-drug range.

What is not in dispute is the underlying structure driving whichever number one accepts: roughly 88% to 93% of drug candidates that begin clinical testing never reach approval, clinical trials now average close to a decade from Phase 1 through filing, and Phase 3 is typically the most expensive clinical phase. In 2019 dollars, CBO reports $282 million in Phase III spending per drug completing all three clinical phases in its sample; that is not a

per-trial price and should be kept distinct from the $19 million median pivotal-trial estimate cited above. These structural facts, more than any single dollar figure, help explain portfolio-level R&D investment incentives and why the industry, regulators, and technology providers are separately experimenting with decentralized trials, real-world evidence, and AI-assisted discovery as levers to bend the underlying cost curve. They do not directly determine the launch price of an individual drug: once incurred, that drug's R&D costs are sunk, while pricing is forward-looking and reflects expected revenues, demand, competition, and manufacturing and distribution costs. As of mid-2026, those levers show measurable but partial progress: faster inter-trial handoffs, higher early-stage success rates for AI-originated candidates, and a modest recovery in R&D return on investment concentrated almost entirely in a single drug class. Anyone citing a cost-to-develop figure in 2026 should specify which study, which sample, and which cost components they mean, since the number that follows will otherwise mean something quite different depending on the answer.

Tags: cost to bring a drug to market, drug development cost, tufts csdd, deloitte pharma r&d, clinical trial costs by phase, pharmaceutical r&d, drug development attrition rates, ai drug discovery cost

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