IQVIA INSTITUTE FOR HUMAN DATA SCIENCE



Measuring Returns on Investment in Biopharmaceutical Innovation

The Changing Economics of Developing New Medicines 1991–2020

NOVEMBER
2026

Introduction

The biopharmaceutical industry has long been the focus of significant scrutiny, amplified in recent years by policies in multiple countries focused on drug pricing and by concerns over individual medicines that have achieved large financial returns. Sustaining drug development requires continued investment, funded both by revenues from today's medicines, which pay for research into future therapies, and by investors who expect a reasonable chance of a positive return. Because biopharmaceutical firms incur R&D costs years before they earn any sales revenue, credible evaluations of economic profitability and returns on investment must weigh lifetime revenues against lifetime costs.

This report measures lifetime returns for cohorts of drugs launched over 30 years. The analysis finds that innovation is becoming increasingly concentrated and difficult to sustain financially. While 44% of medicines generated less than $1 billion in lifetime revenue, only about 10% generated more than $10 billion and accounted for more than half of total industry revenue. The R&D costs to develop a new drug have risen to $3.2 billion in the most recent cohort, when 90% of drugs don't make back average development costs. Over the entire 30-year period 28% of drugs had a positive lifetime economic return, reflecting 50% in the early 1990s and only 10% in the most recent 5-year period.

The findings also highlight the importance of long-term product lifecycles. A substantial share of value is generated more than a decade after launch, even as development costs continue to rise and periods of effective exclusivity shorten. Together, these trends suggest that biopharmaceutical innovation increasingly depends on a small number of successful medicines to sustain investment across the broader research ecosystem.

The analysis draws on IQVIA data, net sales reporting from public companies, and peer-reviewed literature on operating costs, taxes, and R&D expenditures. It applies an updated and improved method for modeling lifetime sales relative to our 2015 paper[1], together with a novel combination of peer-reviewed estimates of R&D cost per new drug.

The study was produced independently by the IQVIA Institute for Human Data Science as a public service, with funding in part from the Pharmaceutical Research and Manufacturers of America (PhRMA). The contributions of Professor Ernst Berndt were funded by the IQVIA Institute and are gratefully acknowledged, as both a lead author of the original 2015 paper and this updated version. Additional thanks to Jamie Pritchett of the IQVIA Institute for analytical and editorial support.

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REFERENCING THIS REPORT
Please use this format when referencing content from this report:
Source: IQVIA Institute for Human Data Science. Measuring Returns on Investment in Biopharmaceutical Innovation: The Changing Economics of Developing New Medicines 1991–2020. November 2026. Available from www.iqviainstitute.org

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Overview

The U.S. biopharmaceutical industry has long been the focus of significant scrutiny and public controversy, going back at least to the Kefauver U.S. Senate Hearings in the late 1950s.[2] A common focus has been the economic profitability of the industry. Debate has evolved recently as public policy across multiple countries has turned to drug pricing, often framing the discussion around a few high-impact drugs that have achieved large financial returns.

Sustainability of drug development depends on investor perceptions of potential positive returns compared to returns in other sectors such as technology, including artificial intelligence. Historic probabilities of positive returns at the sector level are a useful way to measure the likelihood of those positive returns. Because biopharmaceutical firms incur R&D costs sometimes decades before they might benefit from sales revenues, credible evaluations of economic profitability and return on investment must incorporate lifetime revenues and all relevant costs. These include operating costs as well as R&D costs, and the R&D total must also reflect the costs of failures during development. Academic estimates of the cost to develop a new drug typically take a sector-wide view of the cost of capital and the cost of failures, enabling a comparison with the industry's overall output. While there is a common focus on headline-grabbing medicines, the thousands of drugs that are never approved also accrue costs but never achieve any revenue return. Projecting future sales enables a more timely assessment of a drug's lifetime revenue than limiting analysis to medicines with a complete lifetime, which would delay any assessment of lifetime returns for years. In addition, the level and time-distribution of lifetime revenues are extremely hard to predict, further complicating investor decision-making.[3]

Over 30 years of launches from 1991 to 2020, 825 medicines are estimated to generate $3.177 trillion in lifetime net present value of revenue, but operating costs and estimated cost of R&D total $3.331 trillion, a projected loss of $154 billion over the lives of these medicines.

Over the last 30 years there have been significant periods of innovation in the biopharmaceutical industry, including the "blockbuster" era of the late 1990s and early 2000s, as well as significant clusters of breakthrough medicines in the last decade. At the same time, the operational and R&D costs incurred by companies have continued to escalate. Analyzing the last 30 years, for both revenues and costs, provides a useful frame of reference to assess the economic returns being achieved and whether positive returns are plentiful and distributed sufficiently to support sustained innovation.

This study updates and extends a 2015 analysis of the lifetime economic returns of novel medicines, including small molecules, biologics and cell and gene therapies.[1] Using a substantially expanded dataset of 825 novel active substances (NASs) launched in the United States between 1991 and 2020, together with audited global sales data through 2023, the analysis incorporates major methodological enhancements that reflect changes in biopharmaceutical markets, improvements in data availability, and advances in the literature on drug development costs. These enhancements include product-level global revenue modeling, improved estimates of net manufacturer revenues, refined lifecycle projections, and an approach to estimating research and development (R&D) costs that reflects rising costs over time in a novel way. Together, they provide a more comprehensive assessment of the economics of biopharmaceutical innovation over three decades.

The findings reveal an industry characterized by extraordinary variability in commercial performance. While public attention often focuses on blockbuster

therapies and transformative scientific breakthroughs, most medicines generate relatively modest lifetime revenues. Approximately 44% of medicines launched during the study period generated less than $1 billion in lifetime net present value (NPV) revenue and collectively accounted for only 4% of total industry revenues. By contrast, only about 10% of medicines generated more than $10 billion in lifetime revenues, yet these medicines accounted for more than half (56%) of all industry revenue. Across the full cohort, roughly three-quarters of total lifetime revenue was generated by only 174 medicines. Biopharmaceutical innovation therefore remains highly dependent on a comparatively small number of commercially successful medicines.

This concentration of commercial success has intensified over time. Although average lifetime revenues have remained relatively stable when grouped into five-year cohorts, median revenues have declined across successive launch cohorts, and year-by-year analysis shows large fluctuations. Both views illustrate the widening gap between typical medicines and the small number of exceptional successes. The findings suggest that commercialization success is becoming increasingly concentrated among fewer medicines, making overall industry performance more dependent on achieving a limited number of extraordinary outcomes.

The study also finds that medicine lifecycles continue to play a critical role in determining economic performance. Average commercial lifetimes have shortened, particularly for biologic medicines, reflecting the emergence and maturation of biosimilar competition in the United States and Europe. Despite these shorter lifecycles, a substantial share of a medicine's economic value is generated well beyond the first decade of commercialization. Approximately 33% of lifetime NPV revenue is realized after nine years for small molecules and after thirteen years for biologics, timeframes selected for their relevance to the introduction of the Medicare Drug Price Negotiation Program under the Inflation Reduction Act. At the same time, medicines are taking longer to achieve peak sales, with median time-to-peak approaching ten years for small molecules and fourteen years for biologics. These findings underscore the importance of long-duration revenue streams in supporting innovation investments.

While aggregate revenues remain substantial, economic returns have deteriorated significantly over time. After accounting for operating costs, taxes, capitalized R&D expenditures, and the time value of money, the proportion of medicines generating positive lifetime economic returns has declined steadily across successive launch cohorts. Approximately half of medicines launched in the early 1990s generated positive lifetime returns, compared with fewer than one in ten among medicines launched between 2016 and 2020. Across the entire thirty-year period, only 28% of launches generated positive lifetime returns under the study's base-case assumptions.

Across the full cohort, about three-quarters of total lifetime revenue was generated by only 174 medicines. Pharmaceutical innovation therefore remains highly dependent on a comparatively small number of commercially successful medicines.

The decline in economic returns reflects several converging pressures. Industry R&D investment has continued to grow even as the number of novel medicines reaching the market has increased at a slower pace. Rising development costs, increasing clinical complexity, healthcare inflation, shortening periods of effective market exclusivity, and growing commercial competition have all contributed to declining returns on investment. The widely used approach to estimating R&D cost per new drug treats it as a capitalized cost that includes the cost of capital, the

Overview

cost of R&D failures, and post-approval R&D costs.[4,5] Under base-case assumptions, the analysis estimates that capitalized R&D costs increased from approximately $366 million per drug in 1991 to more than $3.2 billion by 2020. Although estimates vary across published studies, all reasonable scenarios suggest significantly higher development costs than were assumed in earlier analyses.

Sensitivity analyses reinforce the importance of long-term commercial performance in determining innovation economics. Because of signficant revenue heterogeneity, very few medicines are close to the break-even point. Extending medicine lifetimes would enable only a limited number of currently unprofitable medicines to achieve positive returns, suggesting that commercialization challenges are not solely attributable to insufficient time in market. The analysis also highlights the growing concentration of lifetime value within the first years of commercialization. For medicines launched in the early 1990s, approximately half of lifetime NPV was generated after the first nine years for small molecules and thirteen years for biologics. For launches between 2016 and 2020, roughly two-thirds of lifetime NPV of revenue is projected to be realized within those same periods. Nevertheless, those initial periods remain insufficient, on average, to offset development costs.

These findings have important implications for policymakers evaluating the sustainability of biopharmaceutical innovation. Because development costs represent the largest and most volatile investment required to bring new medicines to patients, accurate estimation of R&D costs is essential to understanding industry economics. It is notable that while most research estimates R&D costs at the aggregate industry level, some researchers have estimated costs within specific therapy areas and demonstrated wide variation. Because any individual developer may have much lower or higher direct R&D costs, estimates that attempt to be more specific by therapy area or drug type, such as biologics, do not adequately account for the cost of capital and the cost of failures and are challenging to compare with total industry estimates.[4,5]

When assessing biopharmaceutical revenue and returns, this analysis also highlights the importance of accounting for evolving market dynamics, including biosimilar competition, changing pricing structures, and differences between gross and net revenues. While some analysts have simplified their methods by capping a drug's lifetime at a set period,[3] this analysis applies longer or shorter lifetimes based on actual and expected events for patent protection and the market entry of generic or biosimilar competition.

Fewer than 10% of compounds entering development successfully reach the market, and in the most recent periods only about 10% of those launched achieve a positive return. The combined result is that only about 1% of compounds entering human trials achieve a positive financial return whose proceeds can help fund other innovations.

Finally, the study raises important questions about the relationship between innovation incentives and policies that affect commercial lifecycles. As the economics of biopharmaceutical innovation become increasingly dependent on a small number of highly successful medicines, policies that reduce revenues during periods that remain important for cost recovery may have implications for future investment decisions. While exceptional commercial successes continue to occur, the broader trend suggests that innovation is becoming more costly, more concentrated, and increasingly reliant on a limited number of medicines to sustain the broader research ecosystem. The results underscore the growing importance of understanding the long-term economics of innovation as stakeholders seek to balance patient access, affordability, and the continued development of new therapies.

Background and methodology

+ **Assessing the economic returns for biopharmaceuticals is critically important to policymakers, innovators, investors and the public**
+ **The market environment has shifted considerably since the last time robust assessments of industry returns have been estimated**
+ **Lifetime returns is calculated based on a robust estimation of lifetime revenue, reasonable estimates of development costs, and appropriate normalization to reflect inflation and costs of capital over time**
+ **The analysis measures global net lifetime revenue for 825 novel drugs launched in the U.S. from 991 to 2020, including both U.S. and ex-U.S. sales after discounts and rebates and projected for future sales for medicines with a future end of lifetime**
+ **Operating cost assumptions for cost of goods sold (COGS), sales and general administrative (SG&A), and tax on operating income (TAX) are estimated based on peer-reviewed literature and collectively these account for roughly 45% of net revenue**
+ **R&D investment costs are based on a novel combination of peer-reviewed literature where multiple researchers' findings have been combined and trended to create an estimate for each launch year of novel drugs, rising from about $366 million in 1991 to more than $3.2 billion in 2020**
+ **Lifetime returns are calculated as the net present value of global net sales in 2020$ minus the adjustments for COGS, SG&A and TAX, and the estimated cost per novel drug from the launch year of that drug.**

REVISITING THE ECONOMICS OF PHARMACEUTICAL INNOVATION

About a decade ago, members of what is now the IQVIA Institute were co-authors with an academic researcher on an analysis of the lifetime economic returns of newly launched medicines covering launches from 1991 through 2009.[1] That work found that the average lifetime profitability of novel active substances (NAS) appeared to enjoy a "golden age" in the late 1990s, but that average economic profits then fell steadily and sharply, turning negative in the most recent five-year cohort. The intervening years have brought major changes to biopharmaceutical markets, to the data available to study them, and to the research literature on development costs. Together these developments warrant a full update of the earlier analysis, and they suggest that such an update may need to be repeated more regularly.

THE MARKET ENVIRONMENT HAS CHANGED MATERIALLY SINCE 2009

In the United States, the legislative landscape shifted with the Affordable Care Act of 2010, the Biologics Price Competition and Innovation Act of 2010, and the Generic Drug User Fee Act of 2012, which has since been renewed every five years. Although several of these laws were already in force when the previous paper appeared, their full effects had not yet become visible. More recently, a wave of drug pricing policies has emerged across many countries, including the U.S. Inflation Reduction Act of 2022, alongside tariffs and executive orders relating to international reference pricing. These measures may materially affect both existing and future medicines for years to come.

The medicines themselves have also changed. Large numbers of specialty medicines, and oncology agents in particular, have launched in the United States and globally. Major advances in areas such as hepatitis C and COVID-19 produced transient "boom and bust" revenue

episodes, and the pandemic disrupted normal patterns of life and medicine use for several years. At the same time, the relative importance of U.S. versus ex-U.S. markets, changing patient populations, the growing scale of off-invoice discounts and rebates, the pace of generic erosion, and the emergence of biosimilars have all reshaped the commercial environment.

Payer dynamics have shifted in parallel. Delays in reimbursement after launch in the U.S. and gaps in insurance coverage have coincided with significant consolidation among pharmacy purchasing organizations, including pharmacy benefit managers, wholesalers, and retail pharmacy chains, while the frequency and size of rebates and off-invoice discounts have grown sharply. Some developments were expected, most notably the large number of branded medicines that lost exclusivity during the 2011 to 2012 patent cliff, an effect amplified in later years as the biosimilar pathway matured. Taken together, these forces make medicines launched between 2016 and 2020, and their resulting revenue, substantially different from those launched decades earlier.

A FRAMEWORK FOR ASSESSING LIFETIME RETURNS

A drug's lifetime is defined as the period from launch through the period after patent protection when the material portion of erosion has occurred (exhibit 6). Because operating costs accrue throughout a product's commercial life while R&D investment begins before approval and often continues, a credible assessment of financial returns must compare lifetime revenues with lifetime costs. Most analyses consider the same core operating cost categories: cost of goods sold (COGS), selling, general and administrative expenses (SG&A), and applicable taxes on operating income (TAX). These categories are reported consistently in the financial statements of public companies, which also underpin the peer-reviewed studies cited here.

R&D costs require a broader definition. Because long-term success rates from discovery to launch average below 10%, the cost of failed programs forms a large share of a company's lifetime R&D expenditure, even where the direct cost of a single successful drug is lower. R&D cost is therefore best understood as a "capitalized" cost that combines the direct cost of research and development with the cost of failures and the cost of capital, and as a sector-wide estimate reflecting that the successes and failures may accrue to different investors in innovation. Because these costs begin to accrue a decade or more before launch and continue with post-approval indication expansions and evidence generation, through a commercial life that may span 10 to 20 years, an adjustment for the cost of capital, expressed as a discount rate, places lifetime revenues and lifetime costs on a common basis. Each product's lifetime return is expressed as a net present value anchored to its launch year, and all monetary values are reported in constant 2020 U.S. dollars to allow comparison across the full 30-year launch cohort (Exhibit 6).

Within this framework, operating costs have remained a stable share of revenue. No new peer-reviewed estimates have appeared since the 2015 analysis, and a review of company income statements confirms that these ratios are broadly unchanged. R&D costs, by contrast, have continued to rise, and their treatment is the most important methodological advance in this update.

STUDY DATA AND SAMPLE

The analysis draws on IQVIA audited sales data, measured before discounts and rebates, collated for 1991 to 2023 for medicines launched between 1991 and 2020. Novel active substance (NAS) launches were identified, and revenue included only for the originator or their licensing partners in order to exclude generics, biosimilars or other non-original versions of each medicine from the analysis. Of the 1,123 NAS with a U.S. launch in this window, 825 remained after excluding medicines which were not able to be accurately analyzed. This 30-year cohort spans both small molecules and biologics and includes ex-U.S. sales and any line extensions.

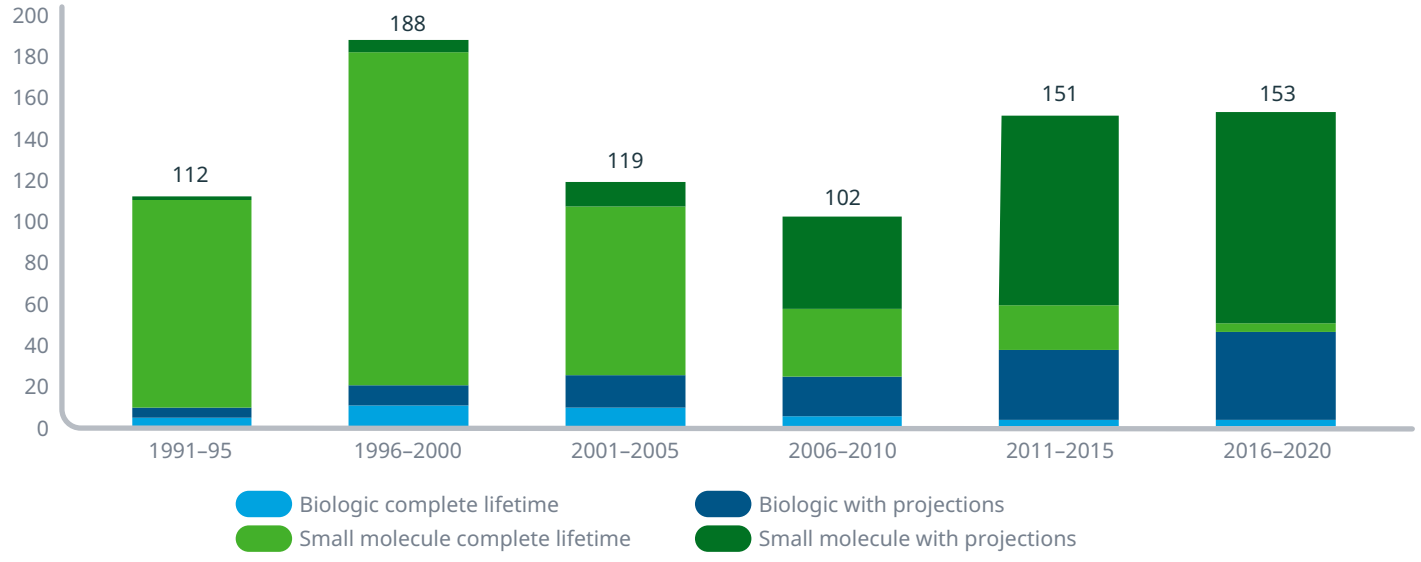
Exclusions due to concerns for accuracy were broadly even across product types, with 27% of both specialty and traditional drugs removed for these reasons. Orphan drugs, defined here as medicines launched with a rare disease approved use either at launch or added later, made up 28% of the initial list but 37% of the excluded group and 25% of the final cohort, which suggests the findings should be extrapolated to those excluded medicines more cautiously. Across the period, exclusions averaged 27% but ranged from 9.4% in 2001 (3 of 32) to 45.3% in 2020 (24 of 53). The therapy areas with the most exclusions were imaging (22 of 34), other alimentary medicines (19 of 25), neuromuscular (9 of 10); pain (15 of 45) and other cardiovascular (10 of 25). Notable high-profile medicines, such as the first vaccines, antibody-based treatments, and antiviral small molecules for COVID-19 were approved and received emergency-use authorizations during the analysis period in 2020, but were excluded from the analysis due to incomplete data associated with their unique distribution during their first several years on the market.

The final analysis cohort is described in Exhibit 1, which shows the number of analyzed launches in each five-year cohort split by product type and by whether a complete lifetime was observed. Of the 825 NAS, 438 have a complete lifetime in the data, comprising 34 biologics and 404 small molecules, while the remaining 387, comprising 127 biologics and 260 small molecules, required projection of future sales. In total, the cohort contains 161 biologics and 664 small molecules. Specialty medicines are those which treat chronic, complex or rare conditions and which have complex characteristics affecting distribution, payment or patient treatment. Specialty medicines have become a growing share of launches, rising from 27 of 112 (24%) in 1991–1995 to 342 (41%) across the full 30 years. Oncology is the single largest therapy area, accounting for 157 NAS, or 19% of the cohort.

MODELING NET MANUFACTURER REVENUE AND PRODUCT LIFETIMES

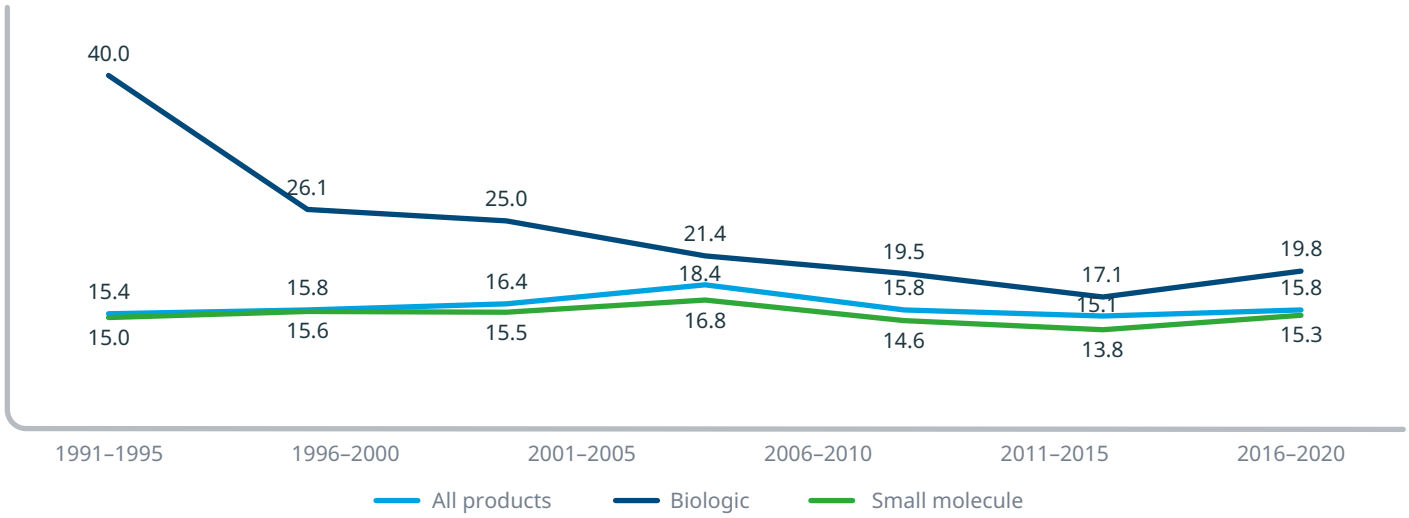
The analysis estimates the net manufacturer revenue each product earns over its lifetime. Because not every public company reports every product or year, U.S. and ex-U.S. invoice-level nominal sales were collected from launch to the end of each product's defined lifetime and then adjusted to a net basis, informed by public company

Exhibit 1: Number of analyzed novel active substance launches per cohort by status



Notes: The number of medicines in the analysis cohort segmented by biologic or small molecule and whether the defined lifetime in the analysis is complete or required projection to include future time periods for revenue.

Exhibit 2: Median defined lifetime by launch cohort



Notes: The median defined lifetime duration within the 5-year cohort refers to the median specific medicine in that cohort.

net sales where available and otherwise estimated using the methods described in the IQVIA Institute series The Use of Medicines in the U.S. (2011 to 2024).[6]

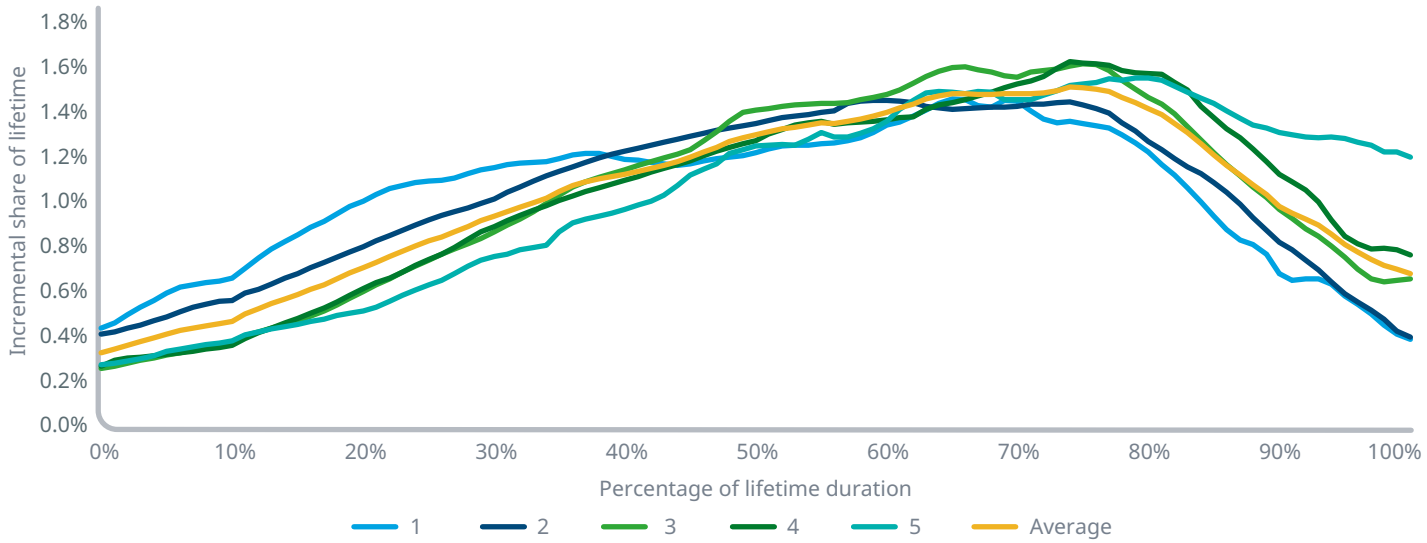
Each product's defined lifetime runs from launch to the U.S. patent expiry date plus two years for small molecules and five years for biologics, reflecting a post loss-of-exclusivity (LOE) erosion period. Patent expiry dates were adjusted to reflect actual or expected loss of exclusivity, and where an expiry is not yet accompanied by generics or biosimilars in development, typical development and regulatory timeframes were added to the current date to estimate when competitors could enter. As shown in Exhibit 2, the median defined lifetime across the cohort was 15.8 years, comprising 15.3 years for small molecules and 19.8 years for biologics. Earlier cohorts had longer lifetimes for biologics because they largely predated the biosimilar pathway. In contrast to studies that apply a single fixed lifetime duration, this analysis uses each product's actual or estimated lifetime. (Note that other studies, which define lifetime as time between brand launch and generic entry, find small molecule lifetimes to be 13-14 years on average.)[7]

PROJECTING LIFETIME REVENUE

For medicines whose commercial life is still in progress, lifetime revenue was projected using the observed trajectories of medicines with complete lifetimes. Complete lifetime medicines were sorted into quintiles based on their sales in the first five years, and these early rankings were used to project the remainder of life for medicines with future sales still to be accrued. Exhibit 3 shows the incremental share of lifetime revenue earned at each stage of lifetime progress, tracing the familiar product lifecycle of rising early sales, a plateau, and a decline near end of life as generic or biosimilar competition arrives. Exhibit 4 presents the same modeling on a cumulative basis. Medicines with the strongest early sales tended to plateau sooner and then decline more steeply than medicines with weaker early sales.

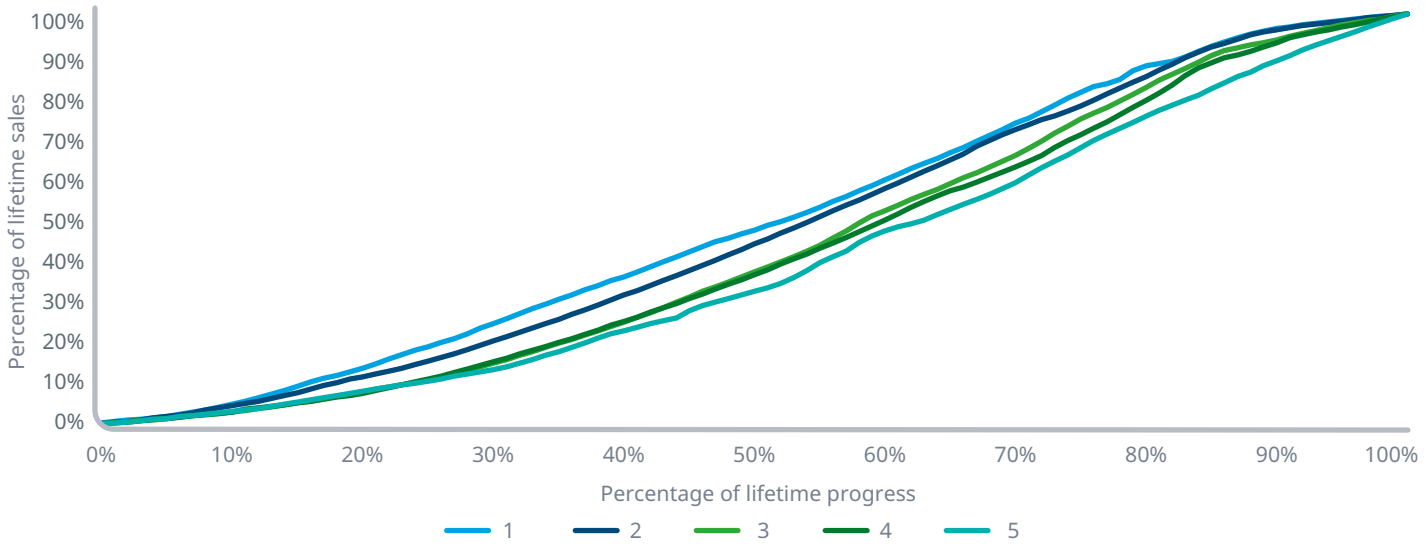
Seventeen medicines that were discontinued or withdrawn were excluded when building these projection curves but were retained, using their actual lifetime revenue, in the final analysis. To gauge accuracy, the projected curves were compared with the actual curves of complete-lifetime medicines; they differed by an average of 12 to 15% of the predicted share of lifetime net revenue, with more variation in mid-life than near the end (Exhibit 5). Because revenue during a product's life remains volatile and uncertain, this residual difference was carried through into the sensitivity analyses.

Exhibit 3: Drugs' incremental share of cumulative lifetime sales by quintile



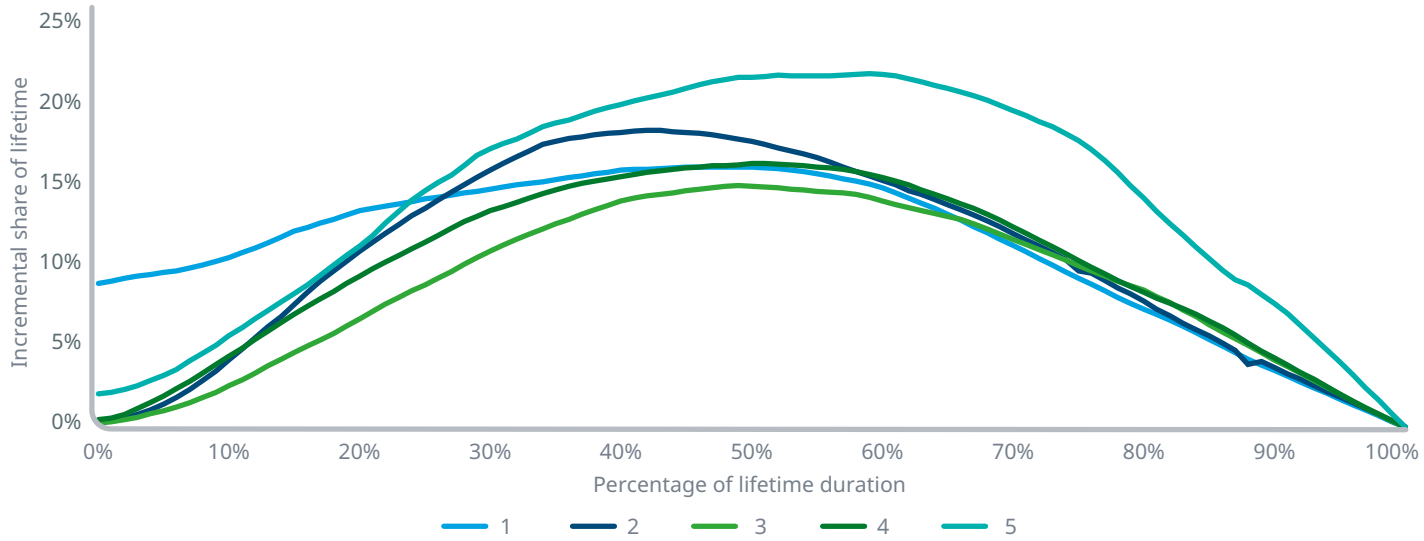
Notes: Products were assigned to quintiles in the first five years after launch with the highest selling medicines in quintile 1 and the lowest selling medicines in quintile 5. For those with complete lifetimes their incremental contribution to lifetime revenue per%age of the duration of lifetime is plotted.

Exhibit 4: Drugs' median quintile share of cumulative lifetime sales



Notes: The same quintiles are plotted on a cumulative basis.

Exhibit 5: Complete lifetime drugs, standard deviation of quintile sales distribution



Notes: The standard deviation of included products from the median at each%age of lifetime progress (x-axis) is plotted. The variations from the median in each quintile cohort are greatest in the middle of defined lifetime.

COST ASSUMPTIONS

Operating cost assumptions were drawn from averages in the peer-reviewed literature for COGS, SG&A, and applicable taxes, all of which companies typically report in aggregate. Exhibit 6 illustrates the sequence of adjustments from top to bottom of the table, applied

Exhibit 6: Analytical terms defined with assumptions

CATEGORIES	TERMS	BACKGROUND
Revenue	Global Net Nominal Lifetime Sales	Cumulative sales reflecting estimated net manufacturer revenue over the life of the medicine, defined as from launch to loss of exclusivity (LOE) + 2 years for small molecules and + 5 years for biologics
Economic Adjustments	GDP deflation	Conversion to real 2020 dollars to adjust for inflation over the 50+ years included in the analysis period
	Net present value	Adjustment of revenue to the net present value at launch reflecting discounted value of future revenues relative to the cost of capital (10.5% discount rate)
Operating Costs	COGS	Cost of Goods Sold including manufacturing and supply costs as reflected in company financial statements calculated as a%age of adjusted revenue (30% small molecule, 21% biologic)
	SG&A	Sales and general administrative costs reflecting commercialization and operational expenses as included in company financial statements calculated as a%age of adjusted revenue. (29% small molecule, 23.5% biologic)
Operating Income	Operating Income	Adjusted revenue minus operating costs
Tax	Taxes on operating income	Estimated 30% taxes on operating income (estimated tax rate applied to adjusted revenue after deducting operating costs)
R&D	R&D Investment	Estimated capitalized development costs per novel substance estimated for the launch year of the specific novel medicine (exhibit 7)
Returns	Net Returns	Economic profit/(loss)

to an NAS, from global nominal sales through deflation to 2020 dollars, the NPV adjustment, the operating cost deductions, and finally R&D, to calculate the lifetime returns for a product.

All values were converted to constant 2020 dollars and evaluated on a net present value basis at launch using a 10.5% annual discount rate, consistent with the most recent peer-reviewed estimates of development costs and slightly below the rates used in the original study. The COGS, SG&A, and TAX assumptions are carried over unchanged because the published evidence has not materially expanded.

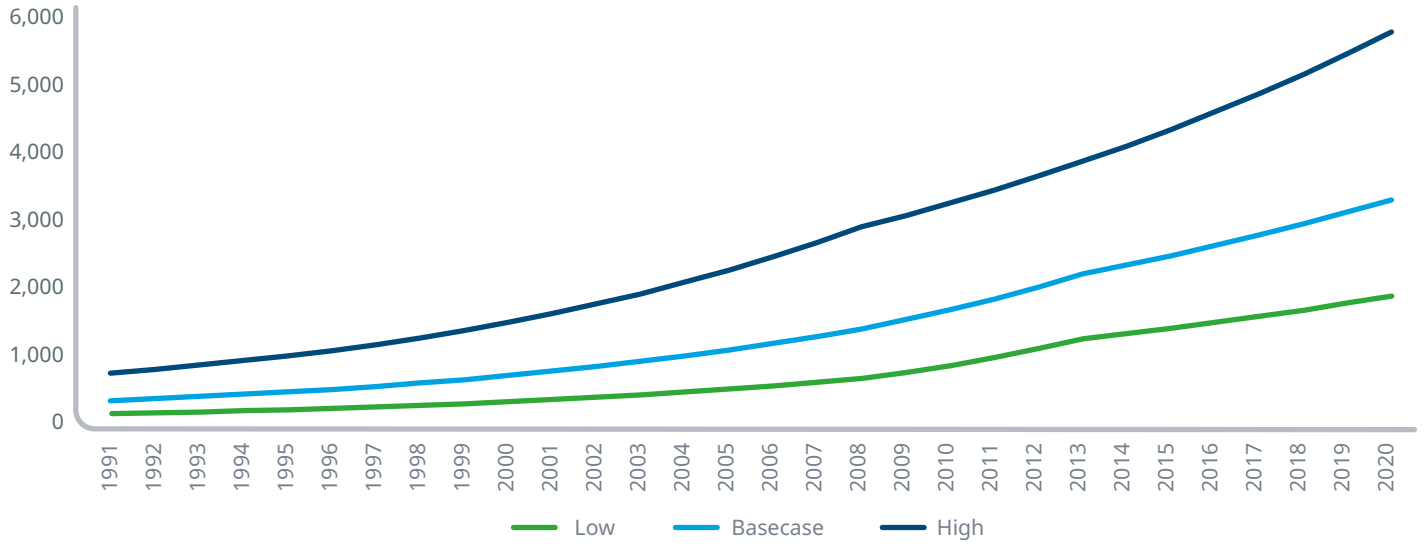
UPDATED R&D COST ESTIMATES

The treatment of R&D cost in the original study relied chiefly on the work of DiMasi and Grabowski[8–11] and used only two broad assumptions, one for the 1990s and one for the 2000s. That approach reflected the best evidence at the time but could not capture year-to-year change, though the authors noted in the DiMasi, Vernon, and Grabowski papers that costs are understood to rise over time within each study cohort.

The current analysis synthesizes a wider body of peer-reviewed evidence, including the meta-analyses by Rennane et al and by Schlander et al,[4] together with the long-running research program of DiMasi, Vernon, and Grabowski[8–15] and explicitly includes the change over time noted in these papers. Each cited estimate reflects a specific study period and includes the cost of failures and the cost of capital. Because the differing timeframes would otherwise make the estimates incompatible, the internally consistent trend published by the DiMasi group was used as a growth rate to link estimates into a single time series, producing an annual, capitalized R&D cost per novel medicine with a high and low range. These estimates are made at the whole-industry level and while the literature does include some studies focused on specific therapy areas or drug types, these don't reflect cost of capital or failures in a compatible way, and are difficult to compare directly with industry-wide figures.

As shown in Exhibit 7, base-case capitalized R&D cost per new drug rises from about $366 million in 1991 to more than $3.2 billion in 2020, with the low and high scenarios roughly 50% below or nearly double those figures.

Exhibit 7: Capitalized R&D cost by launch year, 2020$Mn



Notes: Author's analysis of published research of industry-wide estimated capitalized costs to develop a novel active substance. Published estimates have been combined and a time-series created to provide year-by-year estimates of R&D costs which no published estimates include.

This is the first time a year-by-year trend in R&D cost per novel drug has been presented. These estimates include cost of capital and cost of failure where the direct out-of-pocket cost for the innovator are typically 50% lower. The increase in costs over time reflects rising investigator costs that track wider healthcare inflation, declining R&D success rates, and growing clinical complexity, alongside the cost of capital adjustment.

CALCULATING LIFETIME RETURNS

Lifetime returns are calculated as the net present value of lifetime revenue, less COGS and SG&A, with a 30% tax applied to the resulting operating income, and then offsetting R&D costs. Returns are examined by year of launch, by five-year cohort, by mean and median, and by grouping medicines into%iles to show how many achieve a positive return. Exhibit 27 in the appendix sets out how each element of the methodology has changed since the 2015 paper.

LIMITATIONS

To avoid waiting until medicines' lifecycles have completed, or truncating to a fixed period as in some studies3, and to assess lifetime economic performance, this analysis relies on projections of some medicines' future revenues. Projections are inherently unreliable and introduce some potential error and bias to the analysis but are, on balance, helpful.

Operating costs are generally accrued and reported at a firm level by public companies, without granularity or linkage to specific medicines. As a result, in order to include these costs, the analysis relies on assumptions from the literature. Issues related to medicines' market exclusivity, generic and biosimilar competition have been based on the most current and robust information available at the time of analysis, including IQVIA reference databases. As these aspects are extremely dynamic and often litigated, this is an area where future reality may diverge from analysts' contemporaneous estimates. Further issues related to drug pricing dynamics during a product's lifetime or across countries are intertwined with potential future policy changes. And lastly, while estimates of a drug's future revenue are based on historic patterns, it is possible for adoption of newer therapies or withdrawal due to safety issues to dramatically curtail a drug's revenue in unexpected ways. This analysis assumes that evolving patterns of medical practice over the past thirty years are representative of expected degree of frequency and magnitude of those events in the future. Overall, the methodology in this study captures average industry experience but cannot predict uncommon events such as safety-related withdrawals, unexpected obsolescence, or future technological shifts, including the still-uncertain impact of digital health and AI tools.

After product sales, R&D cost assumptions remain the second most variable element of the analysis. R&D costs are estimated using a novel composite of multiple previously published studies, all of which are limited by the opacity of company reporting on R&D spending. Cost of R&D studies were all targeting the cost to develop a novel drug and included costs of capital and costs of failures, which generally make them similar enough to compare to each other. It is still notable that analysts have widely varying estimates of R&D costs. A further limitation is that, as a sector-level analysis that includes the cost of failures and cost of capital, the findings describe industry-wide dynamics and cannot be compared directly with firm- or product-level results.

Lifetime revenue for novel drugs

+ **The 825 novel drugs launched over 30 years are estimated to generate $3.177 trillion in lifetime revenue, led by oncology, cardiovascular and immunology drugs**
+ **Lifetime Revenue varies widely by modality and therapy area, and the difference between high outliers and the average performance has been expanding over time**
+ **Lifetime revenue is highly concentrated, with 10% of medicines achieving very high lifetime revenues above $10 billion representing 56% of overall revenue**
+ **Most medicines generate relatively low sales, a pattern that has been consistent over time with44% of all drugs generating total lifetime revenue below $1 billion, and contributing to 4% of overall industry revenue.**

Grouped by launch years, the aggregate total net present value of lifetime revenue ranged from $31 billion to $251 billion, with large variations in the numbers of drugs as well as the lifetime revenue they have or are projected to achieve. Some years had significantly more launches and large variations in aggregate NPV of revenue while median lifetime NPV of revenue has been within a narrower range. There are relatively few highly successful medicines and they have generally occurred intermittent across the three decades, illustrated with peaks in total revenue. Peak revenue years are not closely correlated with periods with more drugs, as reflected in the large variation between median and mean NPV of lifetime revenue.

Grouped by launch years, the aggregate total net present value of lifetime revenue ranged from $31 billion to $251 billion, with large variations in the numbers of drugs as well as the lifetime revenue they have or are projected to achieve.

Exhibit 8: Aggregate NPV of lifetime revenue by launch year, 2020$ Billions

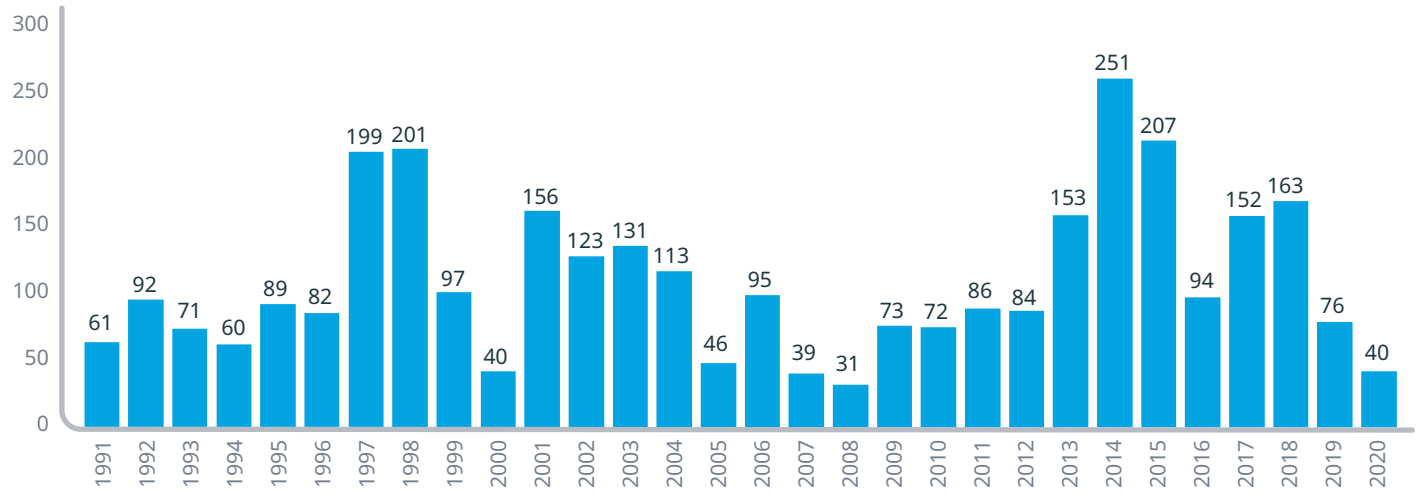


Exhibit 9: Number of analyzed NAS per launch year

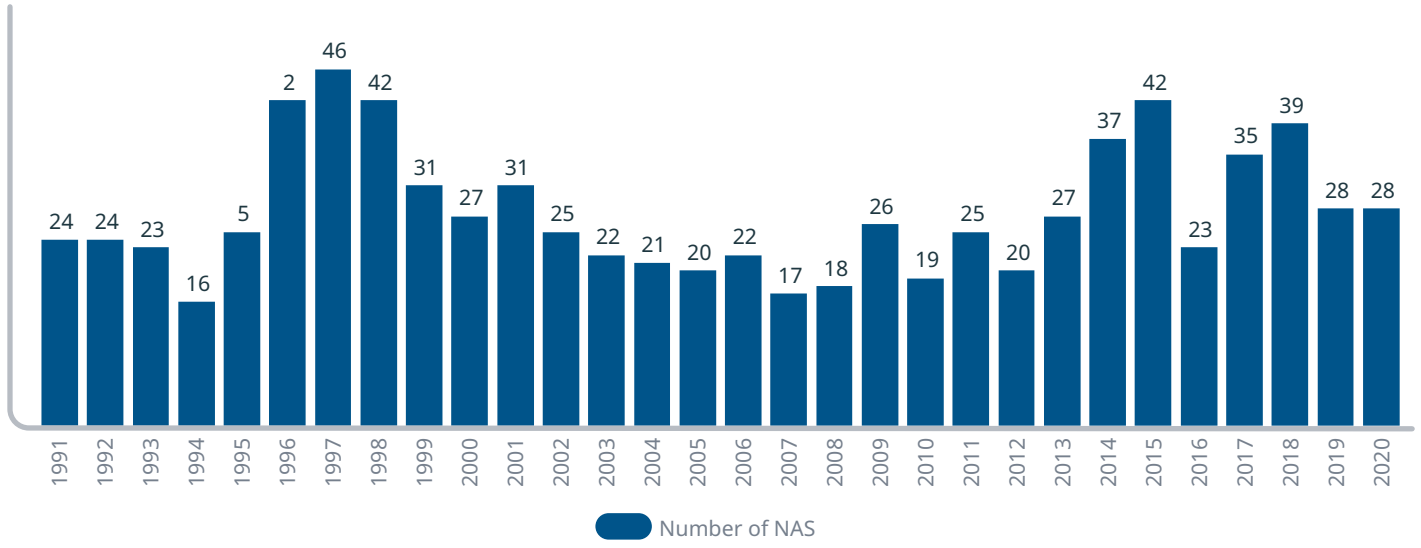
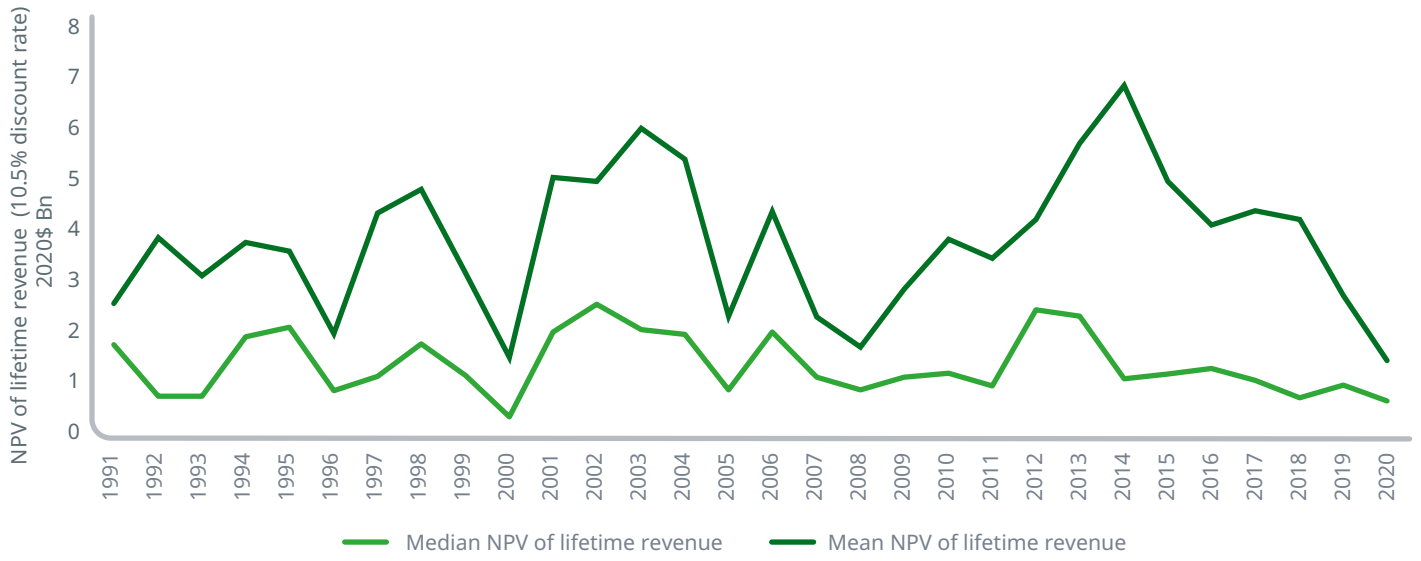


Exhibit 10: Mean and Median NPV of lifetime revenue by launch year, $Bn



The 825 novel drugs launched over 30 years are estimated to generate $3.177 trillion in lifetime revenue, led by oncology, cardiovascular and immunology drugs.

LIFETIME REVENUE IS LARGE IN AGGREGATE BUT CONCENTRATED IN A FEW MEDICINES

In aggregate, the 825 medicines included in the analysis are estimated to generate lifetime revenue NPV of approximately $3.2 trillion ($3,177 billion) when they reach the end of their defined lifetimes, led by oncology, cardiovascular, and immunology medicines. The 157 oncology drugs alone totaled $760 billion in lifetime revenue, nearly 24% of all revenue across three decades.

This aggregate total masks extraordinary variability in commercial performance. While industry discussions often focus on blockbuster medicines, most new branded drugs generate relatively modest lifetime revenues and only a limited number achieve exceptional success with lifetime net present value of revenues above $10 billion. Approximately 44% (371) of the 825 NAS generated less than $1 billion in lifetime net present value (NPV) revenue and together accounted for only 4% of aggregate industry lifetime revenues. By contrast, only about 10% of launches achieved lifetime revenues exceeding $10 billion, yet these medicines contributed 56% all industry lifetime revenues. This is consistent with other published research on the inherent risks in drug development and commercialization with the variability of lifetime revenue and the difficulty of predicting it.

Roughly 75% of total lifetime revenue NPV was generated by only 174 (21%) medicines with lifetime revenues exceeding $5 billion.[3] More than half (56%) of all launches exceeded the $1 billion threshold, and collectively these medicines accounted for 96% of total lifetime revenue value. These findings underscore the extent to which industry economics depend on a relatively small set of commercially successful therapies

The total lifetime revenue of drugs launched in a single year exceeded $200 billion in 1998, 2014, and 2015, and exceeded $100 billion in seven other years. In most years a small number of leading drugs contribute a large share of the total.

This concentration has important implications for how industry performance is evaluated. Average lifetime revenues across the study period exceeded $3 billion per product, but these averages mask a highly skewed distribution. Across every launch cohort, median lifetime revenues were substantially lower than mean revenues, with median values for all NAS declining from approximately $1.5 billion in the earliest cohort to roughly $1.0 billion among 2016–2020 launches.

Exhibit 11: NPV of lifetime by revenue band — share of drugs vs. share of revenue

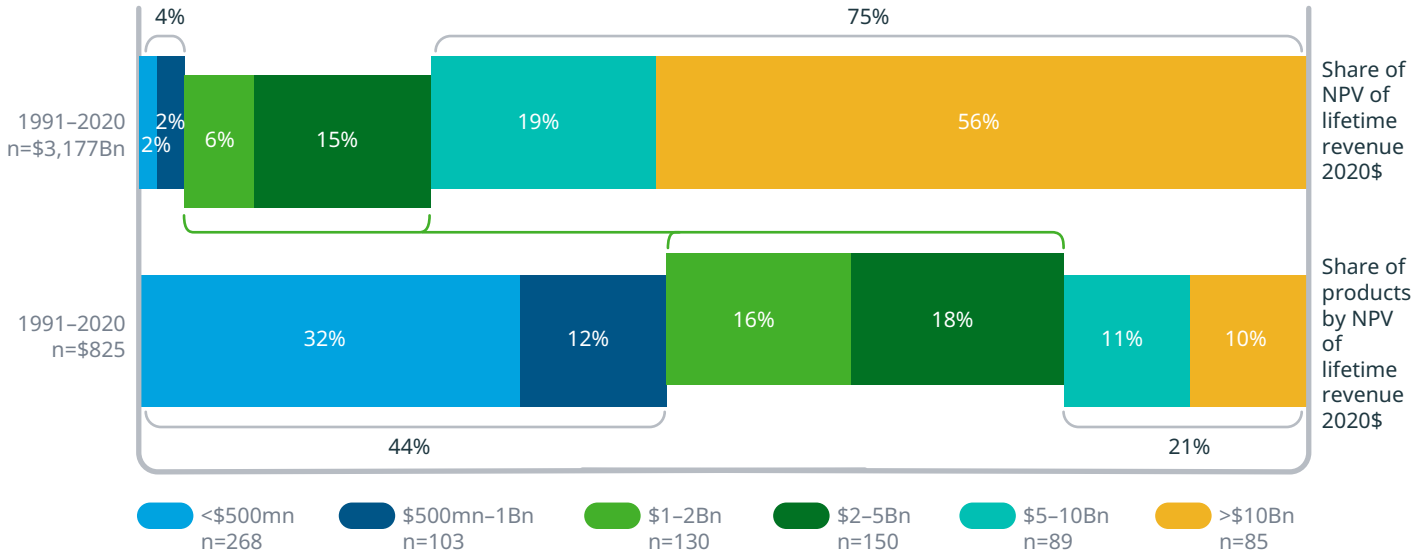
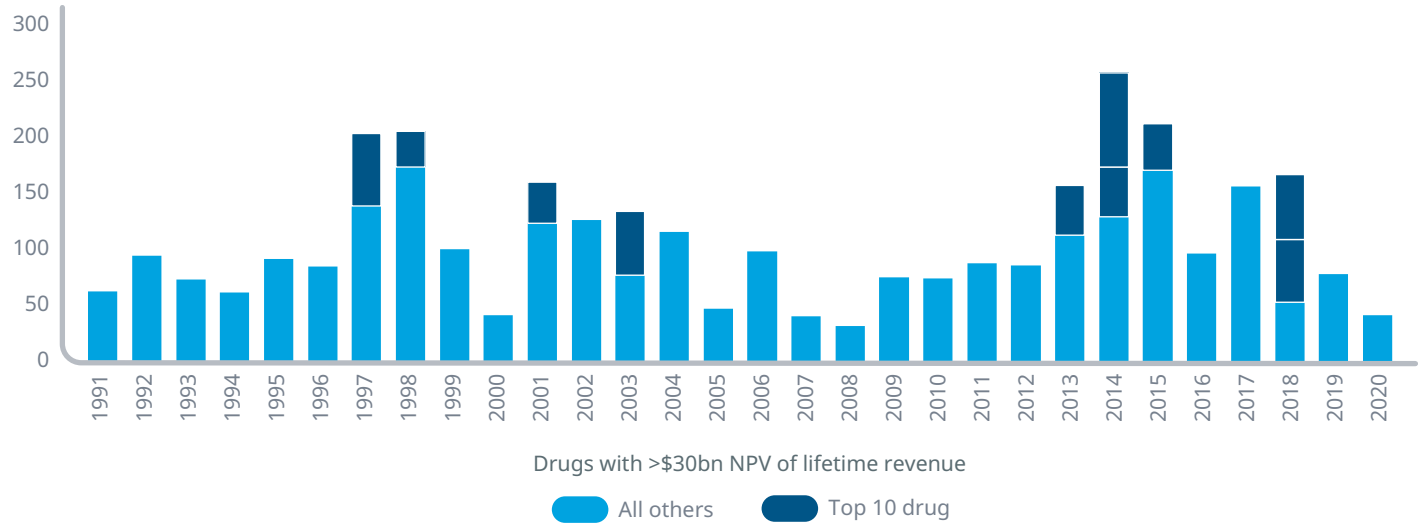


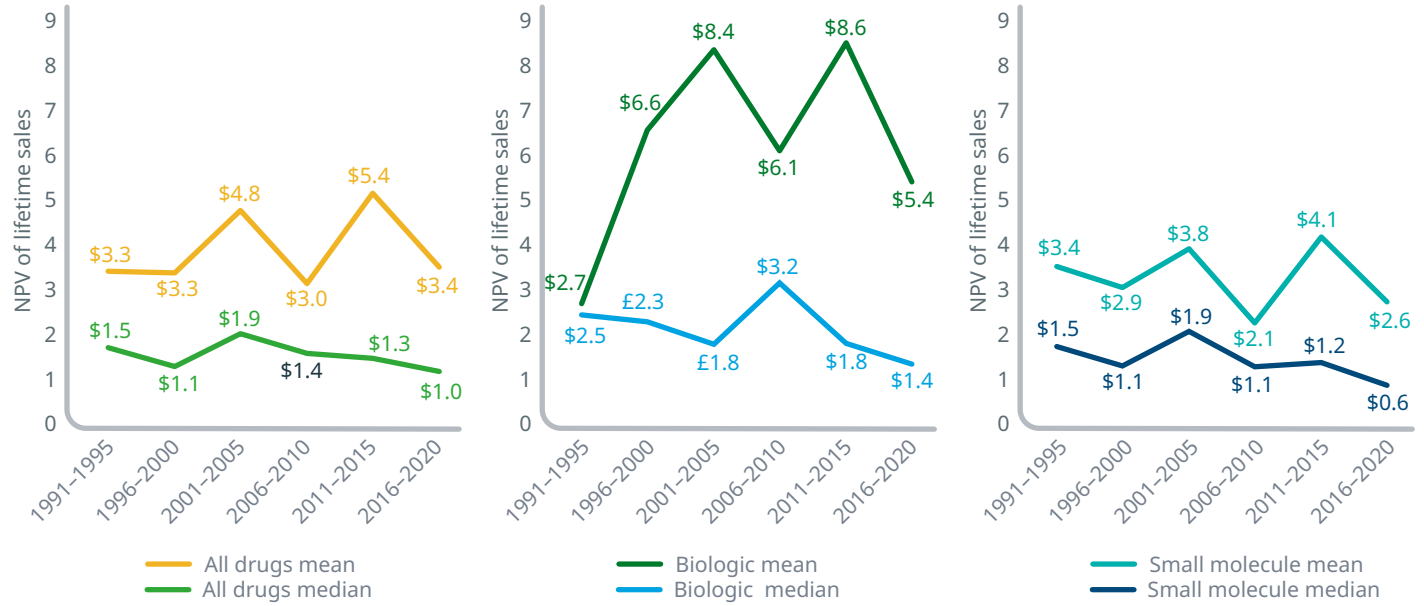
Exhibit 12: Aggregate NPV of lifetime revenue by launch year, top 10 vs. total others, $Bn



The gap between mean and median was particularly pronounced for biologics, where a small number of outlier medicines generated outsized revenues, though similar patterns were also observed among small molecules. Reliance on average revenue measures alone can therefore present a misleading picture of expected commercial success.

Recent launch cohorts demonstrate even greater revenue concentration than earlier cohorts, suggesting that commercial success is increasingly limited to a smaller number of medicines and that volatility and uncertainty are present throughout development and commercialization stages.

Exhibit 13: NPV of lifetime revenue by cohort and product type (mean vs. median), 2020$ Bn



REVENUE VARIES WIDELY BY MODALITY AND THERAPY AREA

Analysis by modality highlights important differences between biologics and small molecules. Small-molecule revenues fluctuated considerably, reflecting waves of success in areas such as hepatitis C, diabetes, oncology, and immunology. Biologics achieved substantially higher average lifetime revenues throughout most of the study period, averaging approximately twice the lifetime revenue per launch. However, the emergence of biosimilar competition significantly reduced this advantage in more recent cohorts, narrowing the gap between modalities.

Revenue also varies widely across therapy areas. Oncology was the most common therapy area with new launches, with 157 novel launches over 30 years. Its median lifetime revenue was $1.5 billion, peaking in 2011–15 at $2.5 billion. Earlier launch cohorts were more focused on larger-population primary care diseases in cardiovascular, endocrinology, respiratory, and mental health that typified the original blockbuster era. Median lifetime revenue for these drugs peaked at $2.2 billion in the 2001–05 cohort, with nine of 40 primary care blockbusters exceeding $10 billion.

Revenue also varies widely across therapy areas. Oncology was the most common therapy area with new launches, with 157 novel launches over 30 years. Its median lifetime revenue was $1.5 billion, peaking in 2011–15 at $2.5 billion.

Exhibit 14: Share of number of NAS and aggregate NPV of lifetime revenue by therapy area 1991–2020, 2020$ Bn

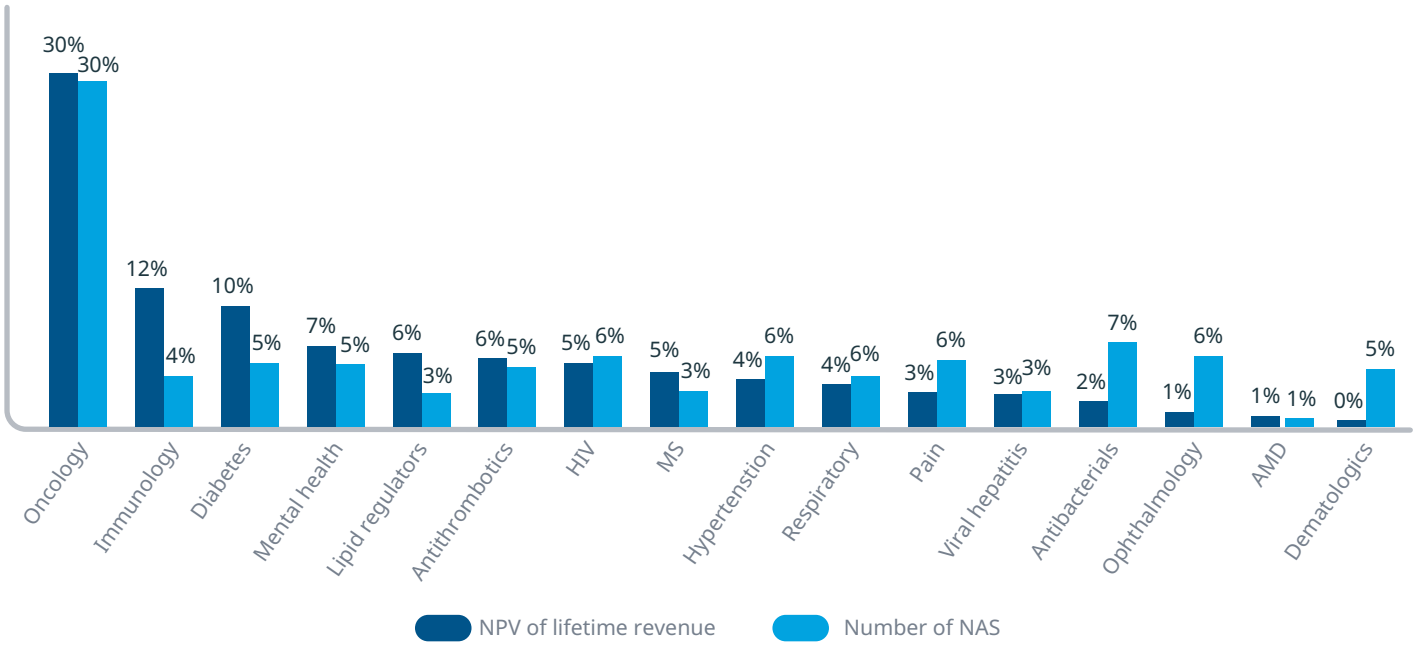
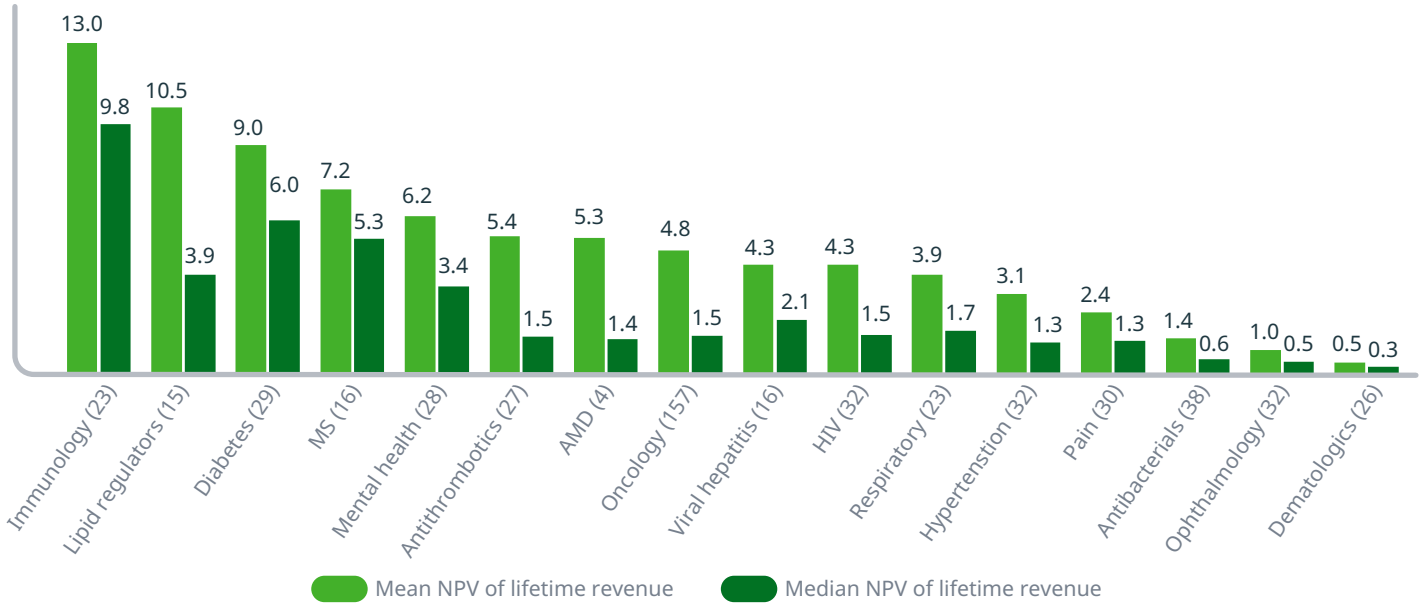


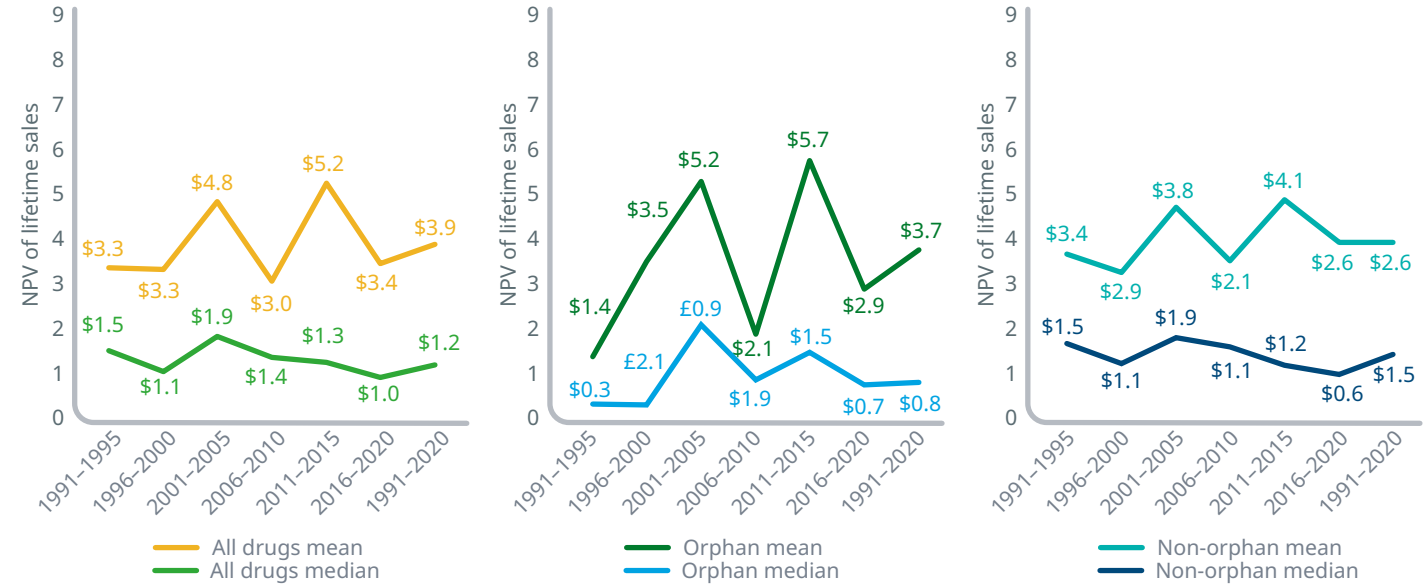
Exhibit 15: Mean and Median NPV of lifetime revenue by therapy area, real 2020$ Bn



For rare diseases, attention often focuses on unit costs without reflecting that very few patients use these drugs. Over 30 years, 236 of the NAS were approved for rare diseases (orphan drugs) at launch or later as an additional indication. The median rare disease lifetime revenue was $794 million, again heterogeneously distributed as the mean was $3.7 billion.

Fifty-four percent (127) of rare disease drugs achieved lifetime revenues below $1 billion, while 8.5% (20) exceeded $10 billion. This distribution is consistently more skewed to lower sales than non-orphan drugs, of which 41% (244) were below $1 billion and 11% (65) above $10 billion.

Exhibit 16: Mean and median NPV of lifetime revenue by launch year and orphan status, 2020$ Bn



Shifts in product lifecycles

+ **The duration of a drug lifetime has been becoming shorter over time, primarily through the introduction of the biosimilar pathway**
+ **Over 30 years, 33% of all drug lifetime revenue is accrued after 9 years for small molecule drugs or 13 years for biologics, contributing a meaningful share of lifetime NPV of revenue late in life**
+ **The share of NPV of revenue accrued after 9 or 13 years varies by therapy area, ranging from 11% for viral hepatitis to 40% for hypertension**
+ **The time from launch to peak sales has been slowing over the 30 year timespan, contributing less to lifetime NPV due to discount rate effects.**

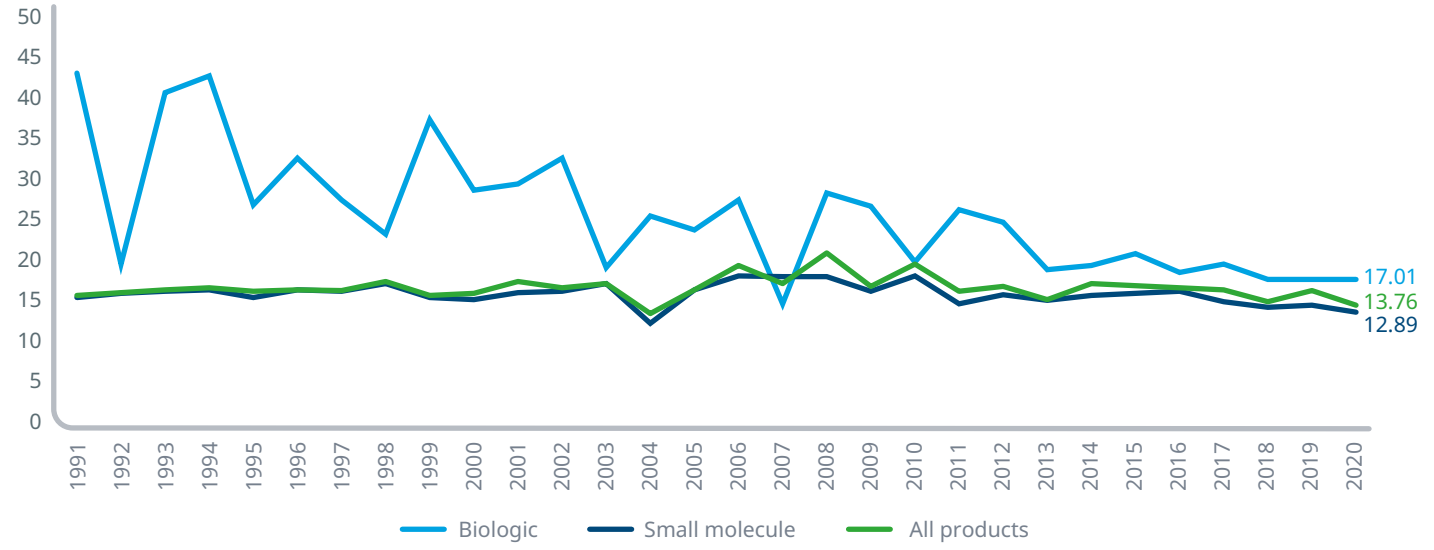
LIFETIMES ARE CONTRACTING, DRIVEN LARGELY BY BIOSIMILAR COMPETITION

Product lifecycles have evolved significantly over the past three decades, particularly for biologics. Median lifetime duration for biologics has declined from approximately 40 years in the 1991–1995 cohort to 17.1 years among launches from 2016–2020 (see Exhibit 2). This shortening has occurred as many biologics now face biosimilar competition that did not exist for earlier cohorts. While small-molecule lifecycles have remained relatively stable, biologic lifetimes have contracted substantially, increasing competitive pressure on originators and on remaining brands in the same therapy areas.

A MEANINGFUL SHARE OF VALUE IS STILL EARNED LATE IN THE LIFECYCLE

Despite shorter lifecycles, a significant share of lifetime value continues to be realized late in a product's commercial life. Approximately 33% of lifetime NPV of revenue is generated after nine years on the market for small molecules and after thirteen years for biologics. These findings are particularly relevant given policy initiatives that introduce pricing interventions at similar product ages. When assessed before applying the net present value discount rate, 39% of global net revenue in real 2020$ is accrued after 9 or 13 years, with some therapy areas much higher and others lower. Although discounting reduces the economic weight of later sales, revenues generated during the second decade of a product's lifecycle remain a substantial component of overall commercial value, and contribute meaningfully to companies' operating income and cashflows.

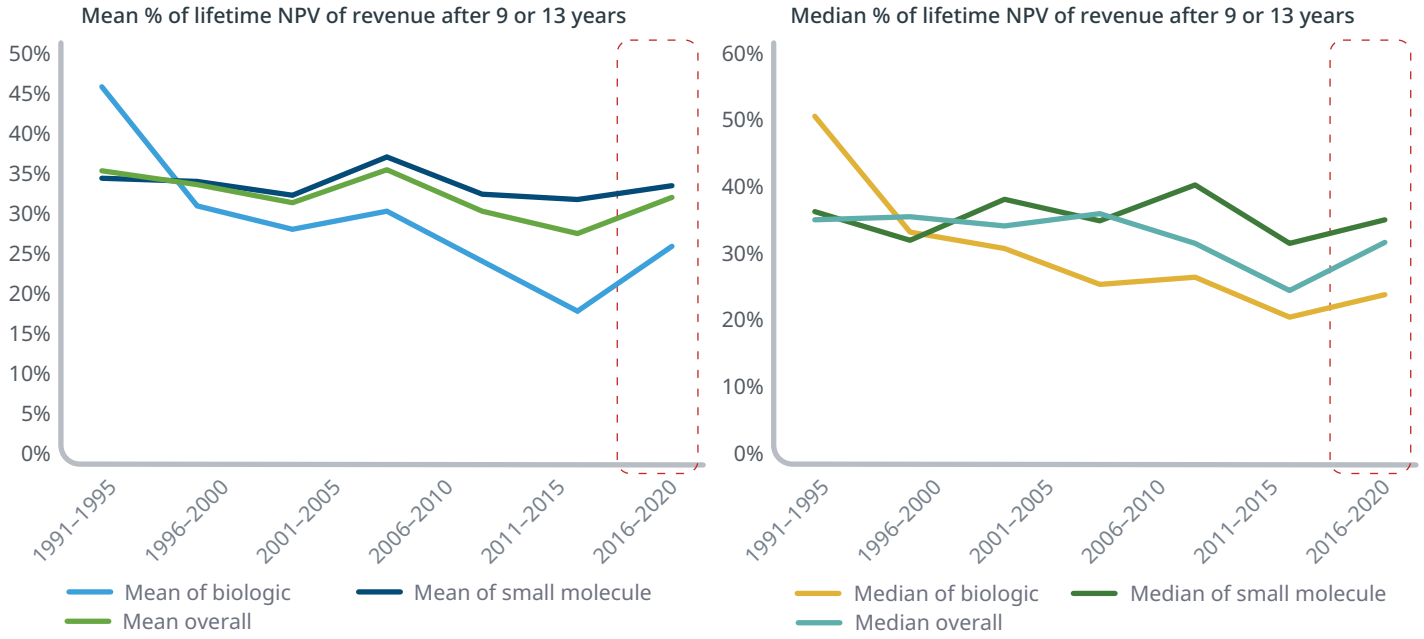
Exhibit 17: Median defined lifetime by launch year



Notes: Defined lifetime in this analysis is from launch to the loss of exclusivity plus 2 years for small molecules and 5 years for biologics, reflecting typical revenue erosion patterns following loss of exclusivity for these types of products.

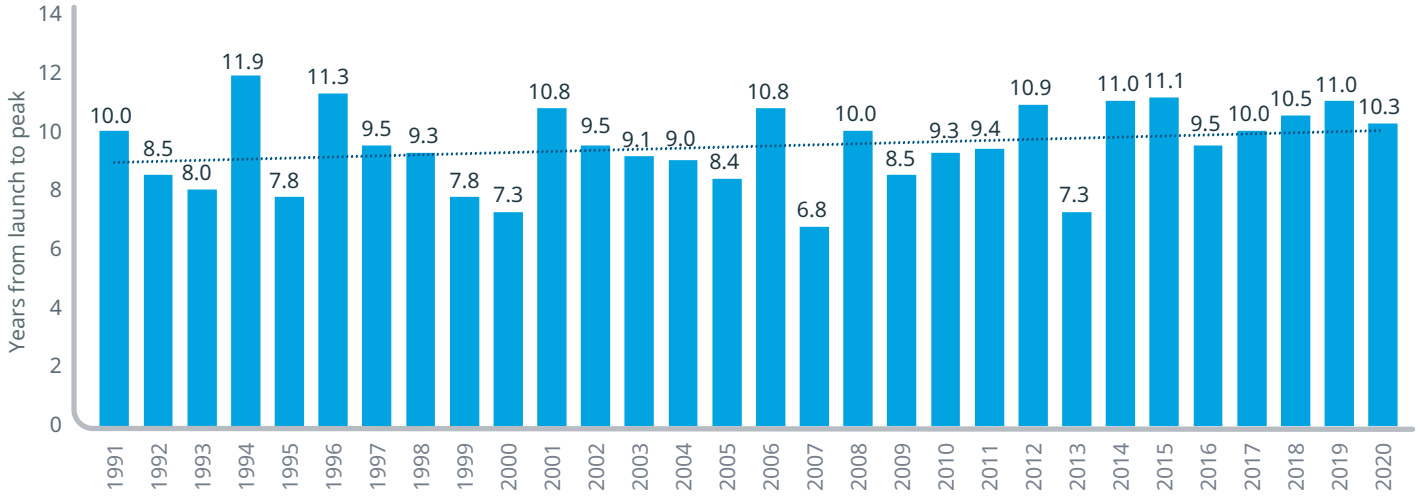
The time required to reach peak sales has also increased. Across all medicines, median time to peak global net sales was approximately 9.8 years after launch, including 9.0 years for small molecules and 14.0 years for biologics. Because later sales are discounted, this lengthening period to peak contributes less to lifetime NPV even as it underlines the importance of long-duration commercial performance.

Exhibit 18: Global NPV of lifetime revenue by launch year, late-life share, 2020$ Bn



Notes: Net present value of lifetime revenue was calculated per period and then aggregated to those before and after the 9 and 13 year timeframes for small molecules and biologics. These timeframes were selected to align to the periods when medicines in the U.S. may now be subject to price negotiation in relation to the Inflation Reduction Act. This analysis serves as a guide to the scale of lifetime revenue potentially impacted by these dynamics but the analysis has not modeled the impact of those policies on projected lifetime revenue.

Exhibit 19: Median time to peak by launch year



Notes: Time to peak is based on the specific quarterly time-period after launch with the highest estimated revenue in the life of the product, then analyzed by launch cohort to calculate the median.

Lifetime returns for novel drugs

+ **The aggregate lifetime returns for the full cohort of 825 medicines over 30 years was below lifetime NPV of revenue by $155Bn**
+ **Lifetime economic returns have been declining over 30 years while some outlier medicines continue to generate significant returns**
+ **Only 1 in 10 drugs have a positive return in the latest 5-year cohort of drug launches (2016–2020) and there were none among the launches in 2020**
+ **Returns vary by modality, therapy area, and orphan status, with 65% of immunology drugs achieving a positive lifetime return while the average for all medicines over 30 years was 28%, and other important classes lagged including oncology (25%), antibacterials (18%), and orphan drugs (16%)**
+ **Shortening lifecycles, stable operating costs, rising R&D costs and falling success rates, have combined to raise the bar to achieve a positive return from $1.4 billion in 1991-1995 to $11.9 billion in 2016–2020**

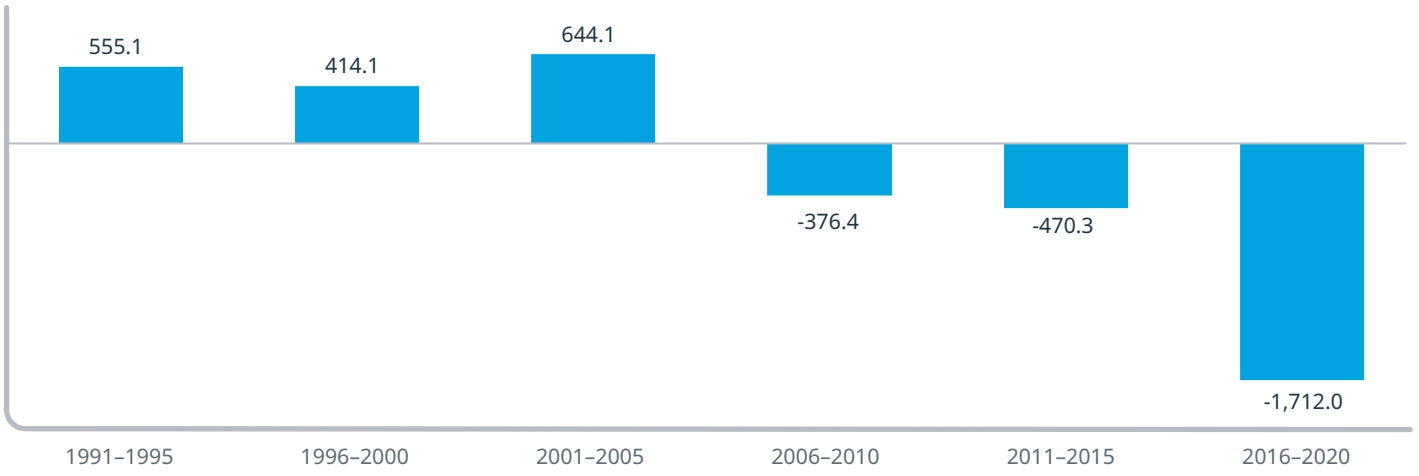
POSITIVE RETURNS HAVE DECLINED STEADILY ACROSS LAUNCH COHORTS

While lifetime revenues remain substantial in aggregate, economic returns have declined steadily across launch cohorts. The proportion of medicines generating positive lifetime economic returns fell from approximately half of launches in the early 1990s to fewer than one in ten among medicines launched between 2016 and 2020. Across the full 30-year study period, only 28.2% of launches generated positive lifetime returns after accounting for estimated R&D investment, operating costs, taxes, and the time value of money.

Because the share of revenue offset by operating costs is modeled to be quite consistent, the largest variable other than lifetime revenue is the expected cost of R&D, which is also the biggest change over the 30-year period.

The average return for launches in the earliest cohort from 1991 to 1995 was $555 million, and since the 2001–2005 cohort it has fallen steadily. The average normalized and discounted lifetime revenue for 153 medicines launched in the most recent cohort is below the total operating and R&D investment costs to develop them by an average $1.7 billion.

Exhibit 20: Average NAS NPV of lifetime returns by launch cohort 1991–2020, 2020$ Bn



For context, R&D costs were from $2.5 billion in 2016, rising to 3.2 billion in 2020.While it is widely reported that biopharmaceutical companies are striving to improve R&D efficiency industry-wide, with focus on biomarkers, electronic data management, AI, and other initiatives, R&D costs continue to rise.

While average revenues have varied, R&D costs have risen considerably and are the largest factor in the overall average negative returns.

Segmenting each cohort into deciles shows that fewer deciles have a positive lifetime return over time. In the 1991–95 cohort, 5 of 10 deciles have a positive lifetime return; in the most recent cohort, only the top decile does. Notably, the older cohorts' higher levels of positive returns rest largely on actual sales data, whereas the newest cohort relies more heavily on projections and could differ if those projections are not realized.

Exhibit 21: Average NAS NPV of lifetime revenue, COGS, SG&A, tax and R&D costs 1991–2020

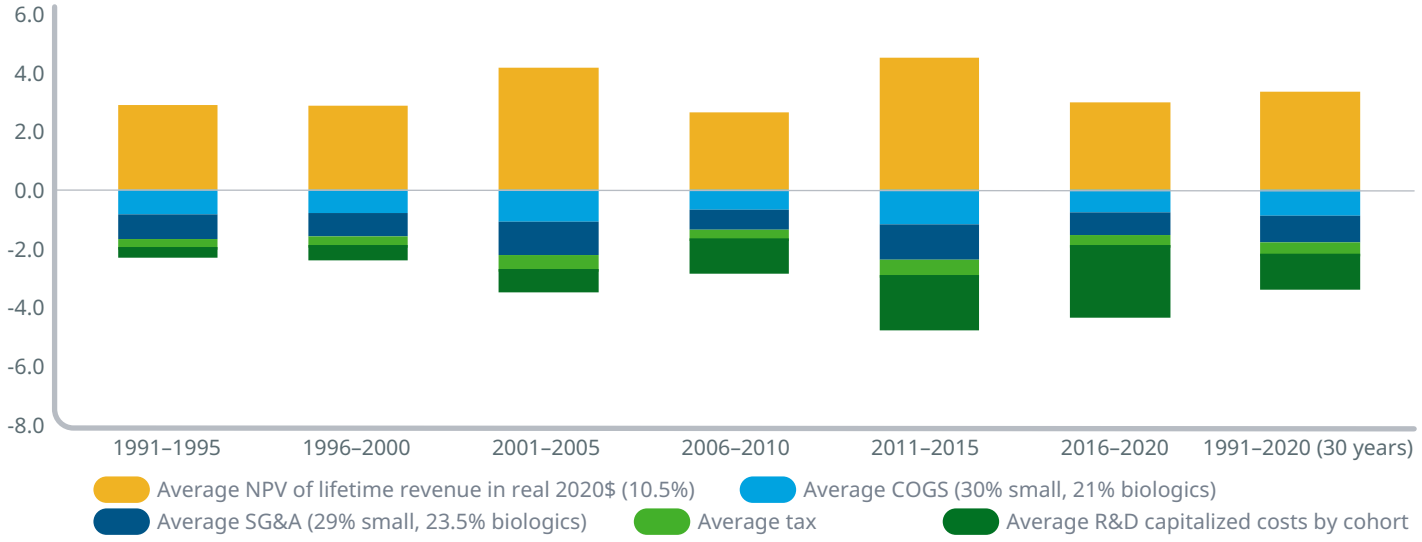
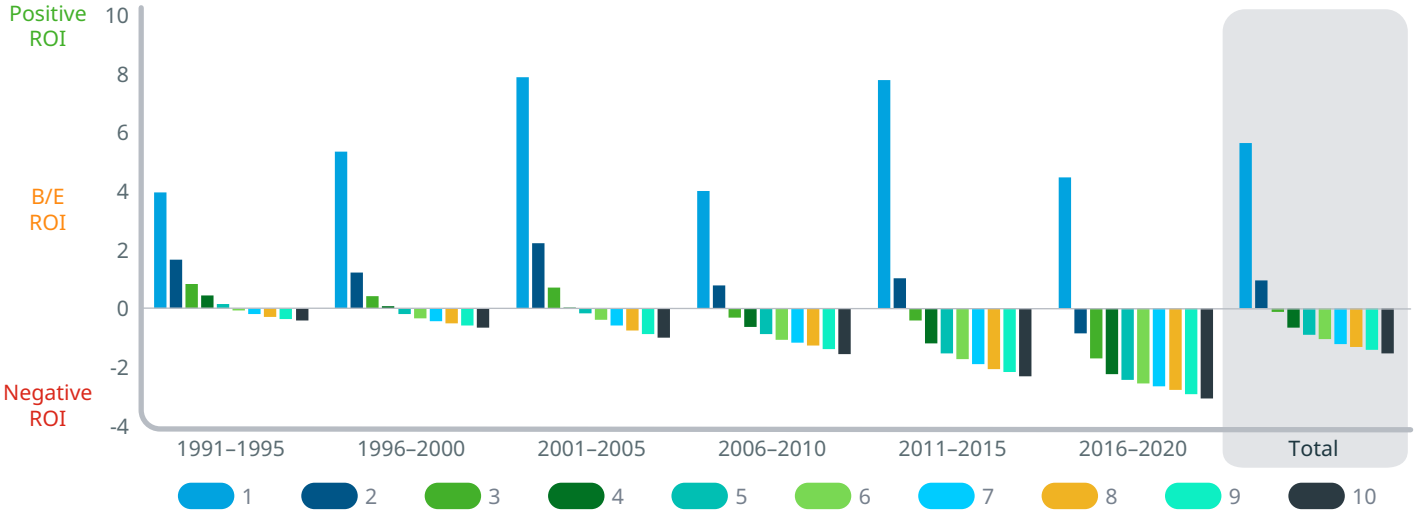


Exhibit 22: Average NPV of lifetime returns by launch cohort and decile, real 2020 US$ NPV Bn



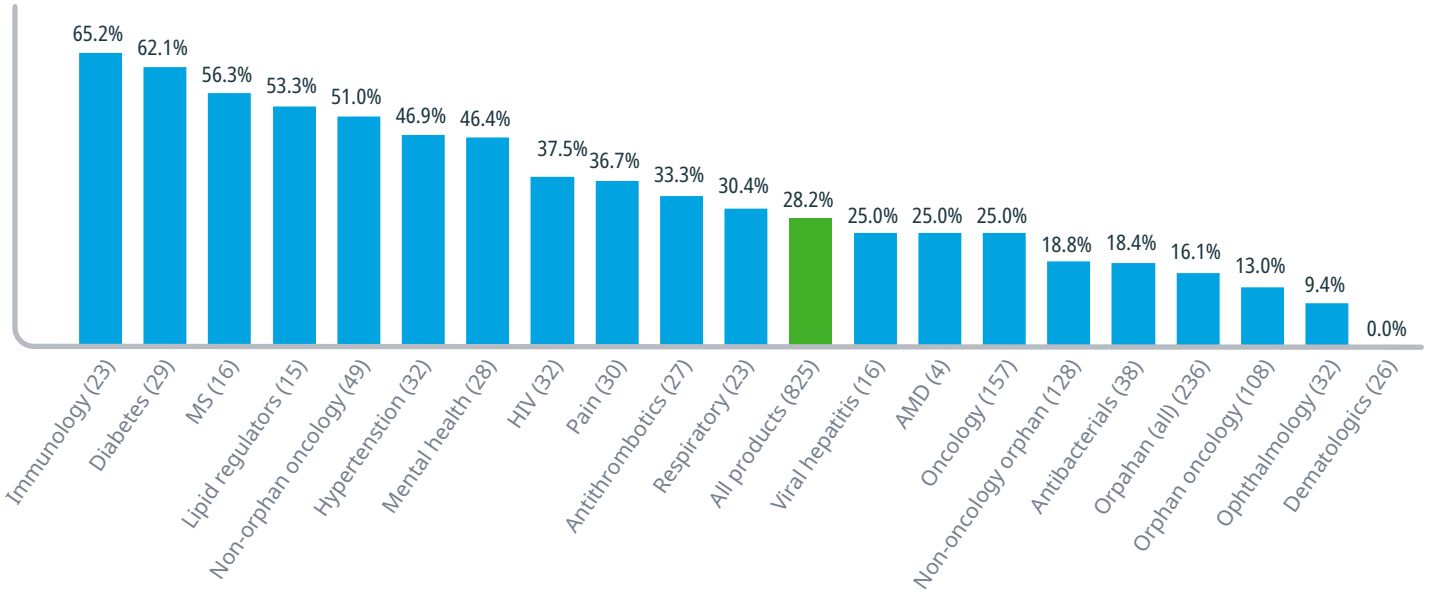
The declining rate of positive returns reflects a combination of factors, including rising R&D costs, shortening effective protected lifespans, increasing competition, and shifts in the composition of launches. Specialty medicines have grown from approximately one-quarter of launches in the early 1990s to nearly two-thirds in recent cohorts. Although specialty therapies increasingly account for a larger share of successful medicines, positive returns have nonetheless become rarer across both specialty and traditional medicines.

RETURNS VARY BY MODALITY, THERAPY AREA, AND ORPHAN STATUS

Returns vary considerably across segments of the market. Differences by modality are examined below in the context of the biosimilar pathway, while therapy area and orphan status show wide variation in the share of medicines that achieve a positive lifetime return. Some therapies like immunology encompass medicines with wide usage in multiple diseases, likely a key factor in their commercial success. Antibacterials had 18.4% of drugs with a positive return, while no small molecule dermatology therapies had positive returns (dermatologically acting immunology drugs are included in immunology). Oncology therapies, while the most numerous therapy area with 157 drugs in the analysis over 30 years, have only 25% with a positive return. Orphan drugs generate a positive return only 16.1% of the time, consistent with the regulatory framing of related incentives which reference a lower likelihood of an economic return.

Therapeutic area performance also varies substantially. The highest rates of positive returns were observed in immunology, diabetes, multiple sclerosis, and lipid regulation. By contrast, oncology overall produced below-average success rates despite substantial clinical innovation and investment. Antibacterials, ophthalmology, and dermatology also exhibited low rates of positive returns. Because the R&D cost assumption is applied uniformly across every drug in every therapy area, these comparisons reflect differences in revenue and operating economics rather than differences in development cost.

Exhibit 23: %age of NAS with positive lifetime returns by therapy area, 1991–2020



Therapy areas (Total NAS 1991–2020)

THE SHARE OF POSITIVE-RETURN MEDICINES HAS FALLEN OVER TIME

The year-by-year%age of novel drugs with a positive return has been declining, with some variation, especially for biologics, which remained above 50% in many years through 2008 but have declined since, coinciding with the introduction of the biosimilar regulatory pathway in the U.S. in 2009 and the effective shortening of biologic lifetimes.

DRIVERS OF SHIFTING LIFETIME RETURN DYNAMICS

Rising R&D costs and falling success rates. Rising R&D costs are the single most important driver of the decline in positive returns. The year-by-year trend in R&D cost per novel drug rises from about $366 million in 1991 to more than $3.2 billion in 2020. Indexing subsequent cohorts to the 1991–1995 value of 100, capitalized R&D costs per novel drug have risen steadily to 677, while lifetime NPV of revenue reached only 103 in the 2016–2020 cohort. R&D composite success rates — the share of drugs entering human trials that reach the market — have declined from an index value of 100 (equivalent to 15%) to 9% in the most recent cohort. The combination of worsening success rates and rising costs is outpacing the revenue achieved by most medicines, and only 1% of drugs entering trials are achieving a positive lifetime return.

Rising R&D costs and falling success rates. Rising R&D costs are the single most important driver of the decline in positive returns. The year-by-year trend in R&D cost per novel drug, presented here for the first time, rises from about $366Mn in 1991 to more than $3.2Bn in 2020. Indexing subsequent cohorts to the 1991–1995 value of 100, capitalized R&D costs per novel drug have risen steadily to 677, while lifetime NPV of revenue reached only 103 in the 2016–2020 cohort. R&D composite success rates — the share of drugs entering human trials that reach the market — have declined from an index value of 100 (equivalent to 15%) to 9% in the most recent cohort. The combination of worsening success rates and rising costs is outpacing the revenue achieved by most medicines.

A rising revenue bar. Medicines with seemingly large revenue may not offset these costs to achieve a positive return. With costs rising consistently through the analysis period, the lowest revenue product to achieve a positive return has higher revenue over time. The smallest revenue product with a positive return in 2016–20 had $11.9 billion in revenue, which after operating costs was $3.4 billion in operating income, and the applicable R&D costs in its launch year were $2.6 billion, leaving an estimated lifetime return of $731 million when its protected and post-protection period ends in the 2040s. The smallest drug with a positive return has roughly doubled every ten years, from $1.4 billion in 1991–1995.

Exhibit 24: %age of NAS with positive lifetime returns by small molecule/biologic

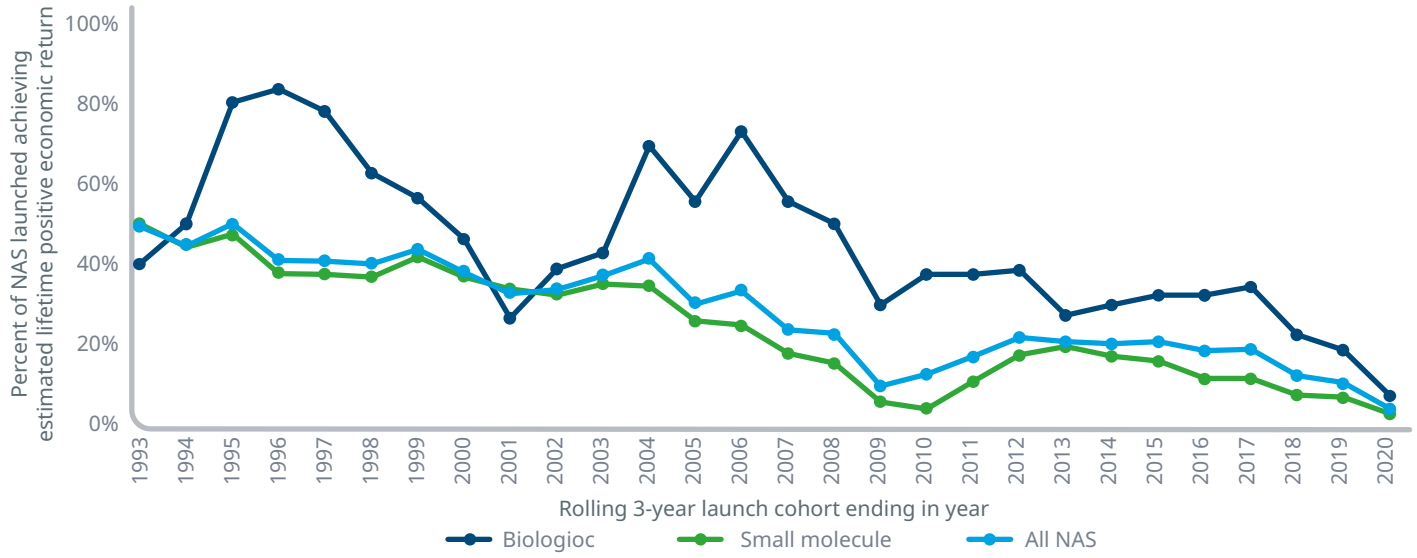
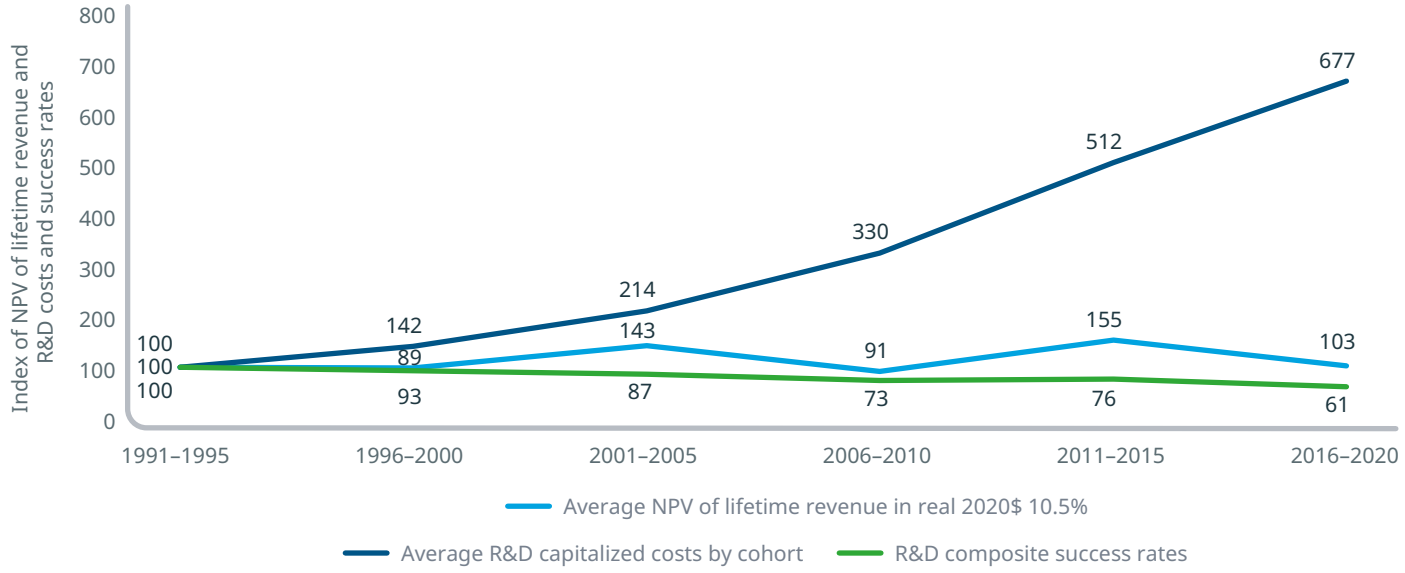
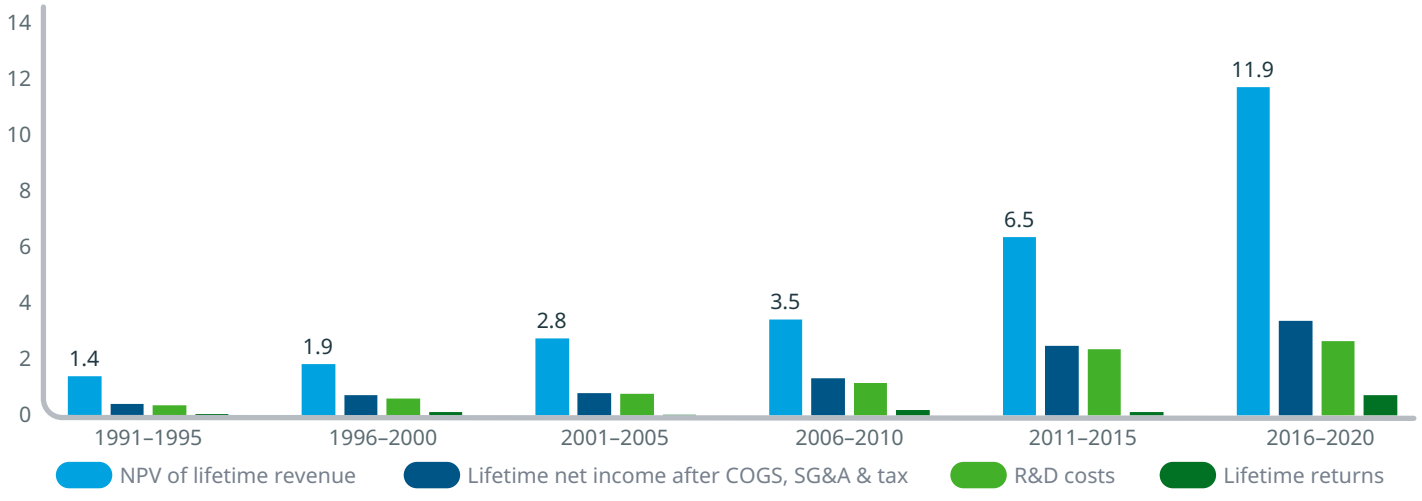


Exhibit 25: Average NAS lifetime NPV, costs and R&D success rates by launch cohort 1991–2020



Taken together, the%age of products with a positive return declining to 10% is converging toward the industry's opportunity cost of capital of 10.5%. Economists identify this kind of equilibrium of risk and return to indicate that there are not excessive returns. Historically the robust flow of novel drugs, including breakthroughs were funded when returns were more common above the opportunity cost of capital. These findings suggest that although market exclusivity provides the potential for substantial rewards, competitive pressures and rising development costs have increasingly eroded average profitability. High-profile successes such as hepatitis C therapies, COVID-19 vaccines, and GLP-1-based obesity treatments demonstrate that exceptional returns remain possible, but they are increasingly the exception rather than the rule. The rarity of positive economic returns may result in changes in investment decisions where returns for products in the market are one part of the decisions investors make.

Exhibit 26: Revenue and cost details for the medicine with a positive return and the lowest lifetime NPV revenue in the 5-year cohort, 2020$ Bn



Discussion and policy implications for sustaining innovation

+ **Assessment of industry-wide return on investment is an important indicator of whether incentives for innovation and innovators are functioning as intended**
+ **For 90% of drugs launched in 2016–2020, operating costs and R&D costs are expected to exceed lifetime revenue, up from 50% in 1991-1995, meaning only 1 in 10 drugs generate a positive return**
+ **Only about 10% of drugs entering human trials successfully reach the market**
+ **Combined R&D success and positive returns mean that only 1% of medicines entering human trials result in a positive economic return for the sponsors**
+ **A small number of successful medicines are disproportionately contributing to investments in research**

AN INNOVATION SYSTEM INCREASINGLY RELIANT ON A FEW SUCCESSES

Using a revised and more robust methodology, this analysis confirms and extends the findings of the original 2015 study, describing a biopharmaceutical innovation ecosystem increasingly dependent on a small number of exceptionally successful medicines. Industry returns are becoming more concentrated among the top-performing 5 to 10% of medicines.

Contrary to expectations that industry R&D spending had begun to plateau in the late 2000s, total investment has continued to rise. While the number of novel medicines emerging from research has also increased, growth in revenues has not kept pace with escalating development costs. The findings suggest that periods characterized by multiple blockbuster medicines, such as the late 1990s and early 2000s and, arguably, the current era, represent intermittent phases of the innovation cycle rather than a persistent norm. During periods with fewer high-performing medicines, average revenues and financial returns are substantially lower.

Although highly visible breakthroughs in areas such as viral hepatitis, oncology, diabetes, and obesity attract considerable attention, they can obscure the broader reality that most medicines generate comparatively modest lifetime revenues. Across the study period, average economic returns demonstrate a continued deterioration over time. Medicines with negative returns are generating larger average deficits, while medicines with positive returns are producing increasingly concentrated gains. In effect, a relatively small number of successful medicines are subsidizing a much larger pool of research activity.

POLICY IMPLICATIONS

The findings highlight several considerations for policymakers assessing the economic environment for biopharmaceutical innovation. Continued growth in industry R&D spending, coupled with a slower increase in the number of novel medicines reaching the market, underscores the importance of understanding the drivers of development costs. As development expenditures continue to outpace gains in productivity, the financial requirements for sustaining biomedical innovation are increasing.

The first nine years of a small-molecule product's life, or the first thirteen years for a biologic, are generally insufficient to recover development costs.

These timeframes are notable because they correspond to the provisions of the Medicare Drug Price Negotiation Program established under the U.S. Inflation Reduction Act (IRA). The distribution of lifetime value has also shifted: for medicines launched in the early 1990s, roughly half of lifetime NPV was realized after the first nine or thirteen years, whereas for medicines launched between 2016 and 2020, roughly two-thirds is expected to be realized within those same periods. To the extent this reflects a genuine compression of value into earlier years rather than only the truncation of later years, policies that further shorten a product's commercial lifetime could have a meaningful effect on innovation economics. With chances of positive returns already historically low, additional pressures on expected returns will further deteriorate incentives for drug development.

Accurately estimating R&D costs is central to evaluating these economics because development spending is the largest cost component in the innovation ecosystem and one of the areas with the greatest variability across published estimates. While company-specific returns cannot be directly measured through industry-wide analyses of this type, incorporating R&D cost estimates into assessments of lifetime returns provides valuable insight into the sustainability of innovation at the industry level.

The evolving competitive landscape must also be reflected in analytical approaches. The maturation of biosimilar markets in the United States and Europe has significantly shortened the effective commercial lifetime of many biologics over the past fifteen years, and assessments of product value must account for the timing and magnitude of biosimilar competition.

Continued growth in industry R&D spending, coupled with a slower increase in the number of novel medicines reaching the market, underscores the importance of understanding the drivers of development costs.

THE ROLE OF ADVANCING TECHNOLOGY

Advancing technology including artificial intelligence (AI) is impacting drug discovery, development and commercialization in a myriad of ways.

As personalized medicine continues to develop, the costs to develop a targeted therapy have the potential to shrink considerably, or drive a greater chance of clinical success. New types of precision therapy have emerged in years instead of decades, with a direct link to the cost of development. Expanding use of AI is enabling more rapid and efficient data handling, evidence development and dissemination and has the potential to improve and shorten clinical trials, again with a link to costs. The use of digital health tools for patient interactions and monitoring are impacting clinical trial operations as well as engagement with patients receiving marketed drugs. If these tools improve the cost basis for existing activities they could have a meaningful impact on the kinds of calculations estimated in this study[16]. Technology may also result in product performance advantages for some compared to others.

Additionally, precision diagnostics are evolving in parallel with advanced therapies, and with access to both expanding across countries, potentially contributing to shifts in medical practice that raises

some costs (for the diagnostics themselves) but lowers overall costs by avoiding wasted ineffective therapies for non-responding patients. Expanded access to medicines, diagnostics, imaging and other technology in low and middle income countries will bring medicines to more patients who can benefit from them, and contribute to drug's lifetime revenue from funding sources which have previously made lesser contributions.

These same technology questions may be more relevant to future innovations and instead contribute to changes in risk, cost or revenue results for medicines and a reshaping of the overall patterns for return on investment. As the current trend appears to show worsening lifetime revenues, and rising policy pressures, changes in costs or risks will have meaningful impacts in the coming decades.

CONCLUSION

As fewer than 10% of compounds entering development successfully reach the market, and in the most recent periods only about 10% of those launched achieve a positive return, the combined result is that only about 1% of compounds entering human trials achieve a positive financial return whose proceeds can help fund other innovations. Exceptional successes still occur, but the broader trend is that innovation is becoming more costly, more concentrated, and more dependent on a few medicines to sustain the wider research system. Understanding the long-term economics of innovation is therefore increasingly important as stakeholders seek to balance patient access, affordability, and the continued development of new therapies that can deliver on the promise of expanded health spans.

As fewer than 10% of compounds entering development successfully reach the market, and in the most recent periods only about 10% of those launched achieve a positive return, the combined result is that only about 1% of compounds entering human trials achieve a positive financial return whose proceeds can help fund other innovations.

Notes on sources

THIS REPORT IS BASED ON THE IQVIA SERVICES DETAILED BELOW

IQVIA MIDAS™ is a unique data platform for assessing worldwide healthcare markets. It integrates IQVIA national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and providing estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history, which when combined over multiple historic archives results in data covering 1991–2023 in this analysis.

ARK PATENT INTELLIGENCE is a database of biopharmaceutical patents or equivalents worldwide and including over 3,000 molecules. Research covers approved patent extensions in 52 countries, and covers all types of patents including product, process, method of use and others.

IQVIA Analytics Link is a unique interactive platform linking together IQVIA's proprietary data with company reported net sales, R&D pipelines, patent information and related forecasts. It includes historic and forecast data from IQVIA and analyst consensus forecasts at product and disease level for both volume and sales.

IQVIA Institute Net Sales Database is a comprehensive, product level view of the U.S. pharmaceutical market at net manufacturer prices, integrating proprietary IQVIA audits with publicly reported company net sales. The database enhances our existing market measurement by systematically incorporating off invoice discounts, rebates, non audited channels, and limited public disclosure. By combining audited list and invoice price data with curated company reported net sales — deduplicated and normalized — the Institute delivers a consistent and analytically robust view of market size, growth, pricing dynamics, and competitive performance.

Appendix

Exhibit 27: Key elements of methodology, 2015 paper compared to current analysis

ELEMENT	2015 PAPER	CURRENT ANALYSIS
Novel drug launch years	1991–2009	1991–2020
# of drugs included	466	825
# of drugs with complete lifetime	153	438
# of drugs with incomplete lifetime to be projected	313	387
Historic data periods	1991–2013	1991–2023
Country data	U.S. data only with single adjustment to estimate global	U.S. and ex-U.S. data per product collated
Net sales estimates	U.S. data adjusted from invoice to net revenue, a single ex-US invoice level share used for global gross-up for all medicines	U.S. data adjusted to net by product. Ex-U.S. gross to net analysis for 100 companies used to modify U.S. gross-to-net assumptions
Lifetime duration	Launch to LOE + 2 years small molecule and +5 years biologic	Launch to LOE + 2 years small molecule and +5 years biologic
LOE dates	IQVIA MIDAS reported estimated LOE dates used	IQVIA MIDAS reported estimated LOE dates further adjusted based on additional desk research per product, including extensions, litigation and settlements, and expected entry based on presence of pipeline of future generics or biosimilars
Lifetime sales projections	Medicines grouped into quintiles in first 5 years after launch, and lifetime cumulative revenue for complete life medicines compared to elapsed time to generate expected sales time distribution, and applied to drugs with incomplete life. Biologics projected based on most recent period trending to expiry, and estimated erosion curves.	Quintile projection approach applied to all medicines (small molecule and biologics), as example biologic medicines with an 'end of life' after biosimilar entry were able to be included.
Exchange rates	Constant exchange rate 2013 Q4 convert local countries to U.S.	Constant exchange rate 2023 Q4 convert local countries to U.S.
GDP deflation chain year	2005$	2020$
NPV discount rate	11.0% small molecule, 11.5% biologic	10.5% for all medicines
COGS	30% small / 21% biologic	30% small / 21% biologic
SG&A	29% small / 23.5% biologic	29% small / 23.5% biologic
Operating income	(100% = COGS + SG&A) 41% small / 55.5% biologic	(100% = COGS + SG&A) 41% small / 55.5% biologic
TAX	30% of operating income	30% of operating income
R&D costs	Small molecules: 1990s $698.6mn (2005$); 2000s $1,032mn (2005$) Biologics: 1990s $657.9mn (2005$); 2000s $971.7mn (2005$)	No distinction small molecule/biologics but year-by-year costs with low/base/high ranges used and selected years shown here: 1991: $179mn/$366mn/$748mn 2000: $381mn/$717mn/$1465mn 2010: $858mn/$1,644mn/$3,510mn 2020: $1,837/$3,195mn/$5,559mn

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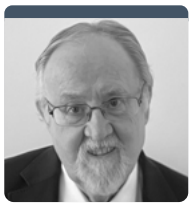
As head of the IQVIA Institute for Human Data Science, Murray Aitken provides policy setters and decision-makers in the global health sector with evidence, analysis, and insights that contribute to the advancement of Human Data Science to improve human health outcomes. He is tasked with creating and managing a research agenda that leaders in global governments, payers, providers, academia, and the life sciences industry use to accelerate the understanding of global trends in disease patterns, data science, and technology. This research is used to foster innovation critical to evidence-based decision-making and the advancement of human health.

Murray has held various roles throughout his nearly 25-year tenure at IQVIA within healthcare insights, corporate strategy, consulting, and services. Prior to IQVIA, Aitken was a partner at McKinsey & Company in the U.S. and in South Korea, covering a broad range of industries, including life sciences and consumer goods. He holds an MBA, with distinction, from Harvard University and a Master of Commerce from the University of Auckland in New Zealand. In addition to his duties at the IQVIA Institute, Murray is Visiting Professor in Practice, The London School of Economics and Political Science.



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Michael Kleinrock serves as Research Director for the IQVIA Institute for Human Data Science, setting the research agenda for the Institute, leading the development of reports and projects focused on the current and future role of human data science in healthcare in the United States and globally. Michael leads the research development included in Institute reports published throughout the year. The research is focused on advancing the understanding of healthcare and the complex systems and markets around the world that deliver it. Throughout his tenure at IMS Health, which began in 1999, he has held roles in customer service, marketing, product management, and in 2006 joined the Market Insights team, which is now the IQVIA Institute for Human Data Science. He holds a B.A. degree in History and Political Science from the University of Essex, Colchester, UK, and an M.A. in Journalism and Radio Production from Goldsmiths College, University of London, UK.



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Ernst R. Berndt is the Louis E. Seley Professor Emeritus of Applied Economics at the MIT Sloan School of Management and a Research Associate at the National Bureau of Economic Research (NBER). His research focuses on the economics of healthcare, biopharmaceutical markets, innovation, productivity measurement, and the development of economic statistics. Over the course of his career, he has examined the impact of medical innovation on healthcare costs and outcomes, the economics of biopharmaceutical research and development, generic and biosimilar competition, regulatory policy, and the measurement of quality-adjusted prices in healthcare and technology markets.

Professor Berndt served as Director of NBER's Program on Technological Progress and Productivity Measurement until 2011 and has been affiliated with NBER since 1980. His broader research contributions have advanced understanding of productivity growth, technological innovation, healthcare economics, and the measurement of economic performance.
He has published extensively on healthcare markets, biopharmaceutical pricing, direct-to-consumer drug marketing, clinical trial globalization, and policies affecting biomedical innovation.

Throughout his academic career at MIT, Professor Berndt has held leading roles in initiatives focused on healthcare innovation and biomedical enterprise. His contributions to economic measurement and applied economics have been recognized through numerous honors, including the 2020 Julius Shiskin Memorial Award for Economic Statistics, awarded for influential research on productivity measurement and quality-adjusted price change. He has also received honorary doctorates from Uppsala University in Sweden and the University of Basel in Switzerland.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research agenda

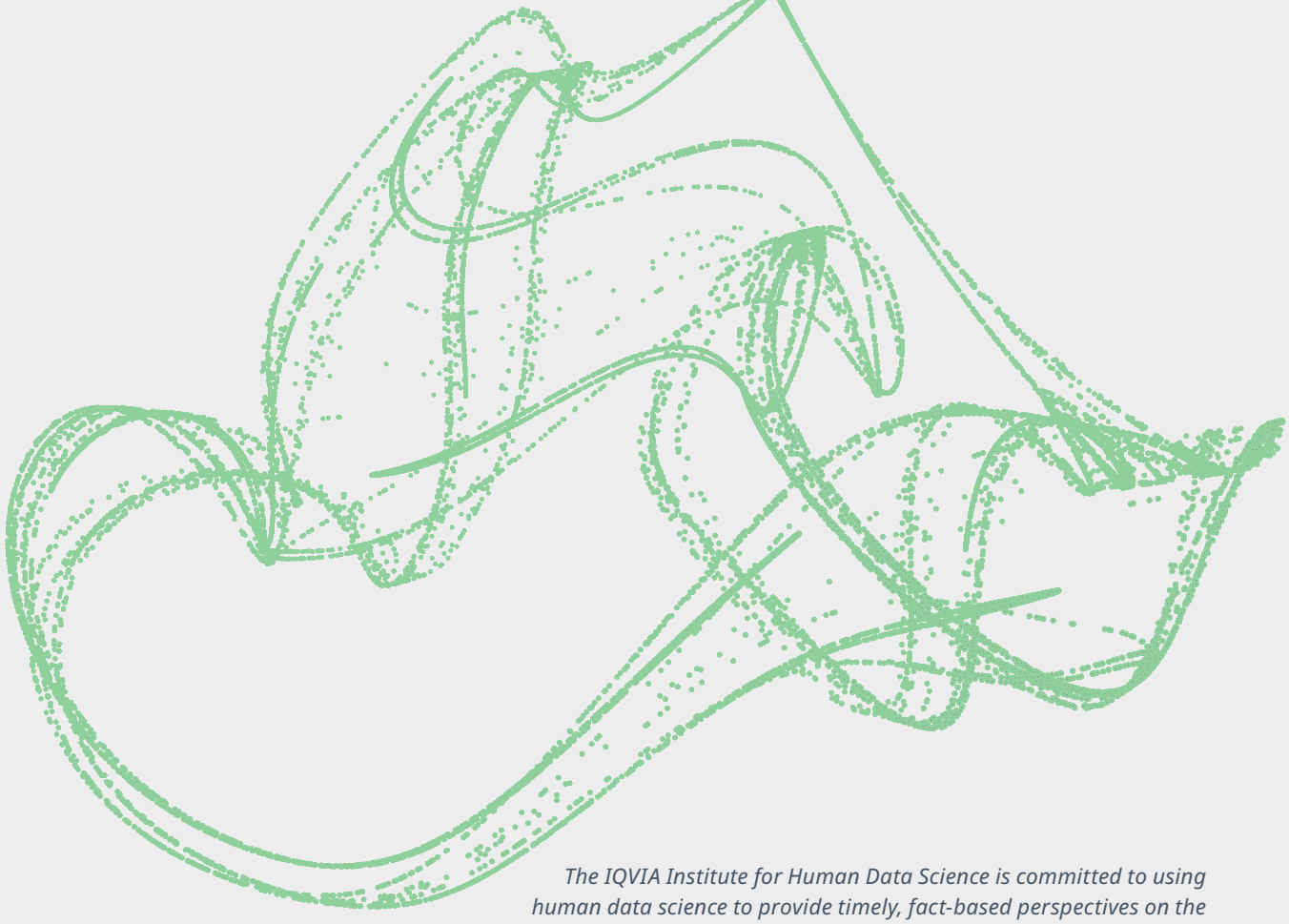
The research agenda for the Institute centers on five areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.



The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

The art is based on the analytical database used in the report showing the novel drugs grouped by therapy area and small molecule or recombinant. The numeric values represent the lifetime global net nominal sales, adjusted for GDP to 2020$, the net present value at launch of those drugs' lifetime real 2020$ revenues using a 10.5% discount rate. The values also include the estimated operating expenses, R&D costs and estimated lifetime returns modeled in the analysis.

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