



THRIVE Launch Success Code™

The THRIVE Launch Success Code™ Decoding the DNA of Drug Launches.

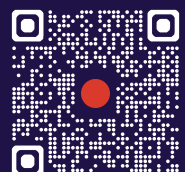
What a medicine brings to its launch before the first decision is made: 198 FDA approvals, read through their DNA.

Executive Summary



Eliette Krakora
THRIVE Consulting LLC
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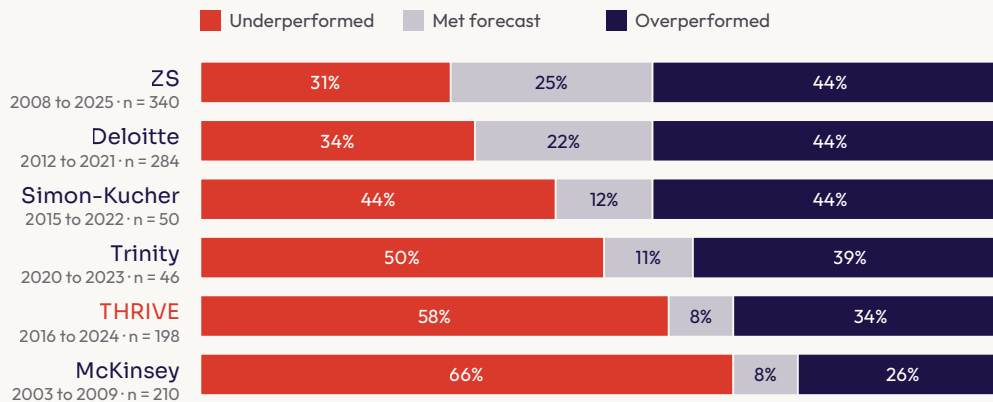
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What is well established

About half of new drug launches miss the expectations set for them before approval. That is one of the best-documented facts in our industry. Six independent studies, covering launch classes from 2003 to 2025 and samples from 46 to 340 products, put the share of launches that underperform their forecast between 31 and 66 percent. The median across the six is 47 percent. Study windows and definitions differ, and the finding does not.

Share of industry-wide launches that missed, met or beat their pre-launch forecast, by study



The chart shows industry-wide launch outcomes, not any service provider's launch portfolio.

Figure 1. Six studies, one finding. Each study defines performance slightly differently, so the rates are not directly comparable; the definition each used, and the citation, are in the endnotes. Sources: the published studies; THRIVE Launch Success Code™ research.

There is also a large body of work on why. THRIVE reviewed and analyzed more than 50 studies from 22 organizations, published between 2013 and 2026. Read together, they converge on a small number of explanations: market access secured too late, organizations that under-invest or under-commit, patient populations that were sized larger than they could be found, products that were not different enough to move prescribers. These are careful studies, and their advice is sound.

What is new

They also share a frame. Almost all of them ask what the launching company did: when it engaged payers, how much it spent, how it found patients, how it positioned the product. That is the right question for a launch team in the last eighteen months before approval. It leaves a higher-level question unasked. Before any of those decisions is made, what does the asset itself bring to the launch, and does it shift the odds?

We think about a launch the way a biologist thinks about an organism. Three layers shape what it becomes. The genome, the asset's genotype, is what it arrives with: its modality, how it is taken and how often, whether treatment is chronic or a single course, the disease it treats, the safety obligations the regulator attached to it. None of this can be changed once the product is approved, and all of it is knowable from public information, often years before approval. The second layer is expression, the epigenome: the decisions that switch those traits on or off, which is where the published literature lives, and where the launch team earns its

keep. The third is the environment the launch enters: payers, policy, competitors, the practice of medicine. It surrounds both, and it is changing fast. The launch that results is the phenotype: what the genome and its expression produce in that environment.

GENOTYPE: intrinsic product traits

Modality, ROA, efficacy, safety, etc.

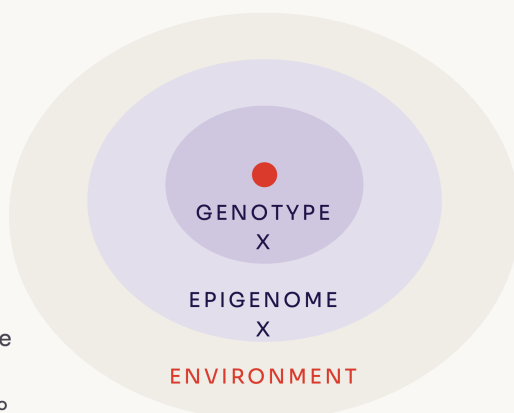
Structural drivers and barriers.

EPIGENOME: how the organization expresses it

Strategy, readiness, investment, discipline. **Launch excellence.**

ENVIRONMENT: the market the medicine enters

Who finds the patient, who decides, who pays, for what. **The fastest changing part.**



PHENOTYPE:
the physiological manifestation

Adoption, patient share, adherence, etc.; **launch “success or failure”**

Figure 2. Three layers of a launch. Genotype, epigenome and environment produce the phenotype, this launch.

This report is about the first layer. We took the question the literature had not asked and answered it with data: 198 FDA novel approvals from 2016 to 2024, 33 variables, and a statistical screen of each against how the launch performed relative to the forecast set for it before approval. Most of the 33 variables describe the asset and the situation it was born into. A handful describe the organization and its choices, so that our results could be checked against those of prior studies.

Why does the first layer need a study of its own? Because most of what the literature recommends is done in the 18 to 24 months before approval, and the decisions that matter most to a company are made years earlier, when only the genome is visible: which asset to license, how high to set the forecast, typical drivers and barriers to uptake. A company that knows the odds its asset starts with can spend its expression where it counts. And because the environment is changing, advice drawn from what other launches did needs to say which traits are exposed to that change and which are not.

The environment gets its own treatment. The biopharma industry is living through a period of disruptive change in how medicines are paid for, regulated and prescribed, and a retrospective analysis, however careful, cannot say on its own what will work next. We address that layer in our [THRIVE Futures Architecture™](#) work, and we point to it where it bears on what follows.

The question and the approach

We asked which traits of an asset, observable from public information before approval, are associated with beating or missing the sales forecast set for it at launch.

The sample is every FDA novel approval from 2016 to 2024 for which a pre-launch sell-side forecast and product-level sales could both be found: 198 launches out of roughly 460 approvals. For each launch we coded 33 variables from labels, FDA records, company disclosures and launch-price filings, then

consolidated overlapping variables into 18 for testing, with launch price tested separately. Performance was measured as reported sales against the forecast, on the forecast's own terms: a launch that beat its forecast by more than 20 percent counts as a beat, one that fell short by more than 20 percent counts as a miss, and one within that band met expectations.

Each variable was tested statistically against that outcome, with an effect-size measure and a significance screen, so that what follows reflects tested associations rather than impressions. The design is deliberately simple: one variable at a time, on a sample large enough to see moderate effects and small enough to demand humility about the rest. The method and sensitivity checks are in the appendix.

What the DNA says

First, the yardstick. We measured each launch's reported sales against the forecast set for it before approval and sorted the result into five bands: more than double the forecast; 20 to 100 percent above it; within 20 percent either way; 20 to 60 percent below; and below 40 percent of forecast, a severe miss. The three-level outcome used in the tests (beat, met, missed) folds the top two bands together and the bottom two. Figure 3 shows where the 198 launches landed, and the shape of it is the first result: launches rarely miss by a little. A third of the sample came in below 40 percent of forecast; of the 114 misses, 69 were severe. A quarter beat their forecast by more than double. The middle band, within 20 percent either way, holds 17 launches. Forecasts are less often slightly wrong than wrong in kind.

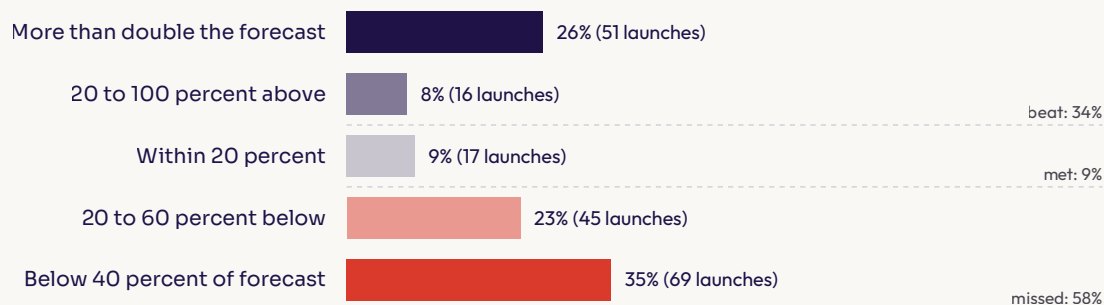


Figure 3. Where the 198 launches landed against their pre-launch forecast, in five bands.

A launch arrives with odds already attached. Overall, 58 percent missed their forecast, 34 percent beat it and 9 percent landed within the band. Those figures sit inside the range other published studies report, and they are not the finding. The finding is that the miss rate is not evenly distributed. Eleven traits, most of them fixed before approval, separate launches that tend to beat from launches that tend to miss. They fall into four groups.

MORE OFTEN BEAT FORECAST

Treatment design

genome: fixed at approval

Antibody modality

Injectable route

Monthly or quarterly dosing

Differentiation

genome: fixed at approval

Full approval and a broad label

Advantage over standard of care

Regulatory tactics and safety

genome (REMS) and a choice (voucher)

Priority Review Voucher redeemed

The organization

expression: levers the company holds

Very experienced leadership team

MORE OFTEN MISSED FORECAST

Oral, daily dosing

Accelerated approval, narrow label

REMS required

First-time launcher

One-time or finite course

Little presence in the indication

Gene, cell or RNA therapy

Figure 4. The eleven markers, in four groups, shown by the level that, in this sample, more often beat or more often missed forecast. Eight are fixed at approval; three describe the organization and are levers a company can pull. Dashed: consistent in direction with the published literature, below our screening threshold on its own.

Treatment design carries the strongest signal. How a medicine is given, and how often, showed the strongest association with launch performance among the variables tested. Launches of oral, daily therapies beat their forecast about one time in four. Launches of injectable therapies given weekly to quarterly beat it more than half the time. The same pattern shows up whichever way it is cut: antibodies beat forecast roughly twice as often as other modalities; daily dosing misses more often than any other schedule; a therapy given once, or only a few times, misses most often of all. Small molecules that are not targeted kinase inhibitors are the weakest group in the sample, and gene, cell and RNA therapies missed their forecast in more than four launches out of five.

These are not four findings. Antibodies are injectable and infrequently dosed; orals often are daily; the traits travel together, as genes do. What the data describe is one cluster: treatment design. Why it should matter this much is the question we take up in Phase II, and two mechanisms are plausible enough to name now. The first is adherence. A daily oral medicine lives or dies on whether the patient keeps taking it, and the literature on leaky funnels says fills and persistence are a common root cause of misses; a dose forgotten is a script not refilled, and the forecast assumed it would be. The second is access. Oral therapies tend to launch into crowded, price-exposed categories where payers rather than prescribers decide volume, while specialty injectables enter concentrated channels where the forecast was smaller and the funnel tighter. Both mechanisms are testable, and they are not mutually exclusive.

Regulatory tactics and safety burden move the odds in both directions. A Risk Evaluation and Mitigation Strategy is the most reliably unfavorable single marker in the sample: launches with a REMS missed their forecast nearly nine times in ten. A REMS is a fixed trait; the regulator attaches it, and the launch inherits the friction. Priority Review Voucher redemption points the other way. The ten launches for which a company spent a voucher beat their forecast seven times. Ten is a small number and we treat it as a hypothesis with a number attached. It is an interesting hypothesis, because a voucher is worth a great deal of money, and a company that redeems one has said, in public and before approval, which asset it believes in. The literature

finds organizational commitment to be the strongest single driver of overperformance; the voucher may be its first externally observable footprint.

Differentiation matters, and it matters through the evidence and the label. After commitment, clinical differentiation is the literature's strongest driver, and we coded it at approval using a THRIVE rubric based on novelty in the indication, demonstrated clinical advantage, and evidence and label strength. Differentiated launches beat forecast 39 percent of the time against 26 percent for the rest, the direction and about the size ZS reports¹; at 198 launches that difference sits just outside our screening threshold on its own. Evidence and label strength clears it comfortably: launches arriving with full approval, a broad label and no unique safety obligation beat forecast 40 percent of the time against 23, and missed 50 percent against 70. Novelty alone confers nothing; first-in-class launches beat forecast slightly less often than followers. And differentiation expresses itself only where the design lets it: among antibodies, differentiated launches beat forecast 70 percent of the time against 29 for the rest; among oral, daily therapies, differentiated and undifferentiated launches beat at the same one-in-four rate.

The organization shows up as expression. Three markers describe the launching company rather than the asset, and all three matter. First-time launchers missed their forecast about seven times in ten, against roughly half for companies that had launched before. Launches led by teams with very extensive launch experience beat their forecast noticeably more often than the rest. Companies with little presence in the indication before launch missed more often than those with some. None of this is new; McKinsey⁶ and ZS¹ have each reported versions of it, and our sample reproduces their result with a different method and an independent set of launches. What is new is seeing it next to the fixed traits. Experience is a lever a company can pull; modality is not.

As interesting as what was associated with the odds is what, in our study, was not. Some of it runs against the conventional wisdom of the industry. Oncology launches performed no differently from non-oncology launches, for all the belief that oncology is the safer bet. Fast Track and Breakthrough designations, widely read as a signal of differentiation, did not separate beats from misses, and neither did being first in class. Competition made no measurable difference: not whether a rival launched within six months of approval, not how crowded the indication already was. A Complete Response Letter on the way to approval left no mark on the launch that followed. Administration requirements short of a REMS, such as infusion or monitoring, did not matter once REMS was accounted for; the year of approval did not matter either.

Nor did price on its own. Launch price, annualized from the label and adjusted for body weight, was tested on the 133 launches priced above the Medicare Part D specialty threshold and approved from 2019 to 2024, the launches for which a filed launch price exists. It showed no association with performance on a four-way split or a three-way split. That is a bounded null: it says nothing about price below the threshold, and price travels with modality in the sample, so this method cannot separate the two. It is consistent with the one published test we know of⁷, which also found no independent price effect. Rare-disease status, finally, showed a modest unfavorable lean that did not hold up across the sensitivity samples, so we do not count it as a marker. The pattern across these nulls is the same: several badges the industry uses as proxies for a strong launch were not the traits associated with the odds in this sample.

The markers add up. Because the fixed traits travel together, a launch rarely carries just one. Launches with a predominantly favorable profile beat their forecast about two-thirds of the time and missed one time in four. Launches with a predominantly unfavorable profile showed the mirror image: one beat in four, two misses in three, and more than 40 percent came in below 40 percent of forecast. This is a description of the sample, and a validated version of the profile view is the work of Phase II. Its value now is the picture it gives of what a launch team is actually inheriting on day one.

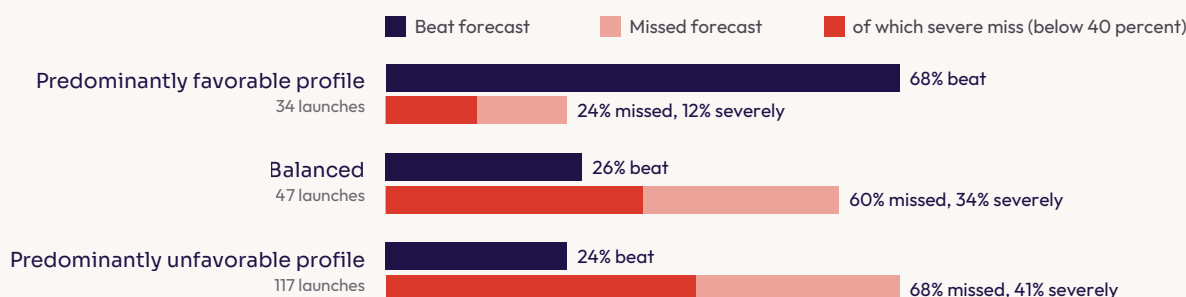


Figure 5. What a launch inherits: outcomes by fixed-marker profile, 198 launches.

Two launches, read through their DNA

Same disease, two genomes: Skyrizi and Sotyktu. Both launched into plaque psoriasis, both from large, experienced organizations with deep immunology franchises, both into the same payers and the same prescribers. Skyrizi is an antibody, injected once a quarter after loading, chronic, without a REMS, with full approval, a broad label and head-to-head superiority over two incumbents, from a very experienced team: six of the eleven markers on the favorable side and none on the unfavorable. AbbVie's own outlook, set out in January 2018 before approval, put 2025 sales at about \$5 billion; the company raised that to more than \$7.5 billion in 2022 and reported \$17.6 billion for 2025, more than three times the original figure⁸. Sotyktu is an oral, daily small molecule, chronic, without a REMS: the treatment-design cluster on the unfavorable side, with the same favorable marks on evidence, label and team. Bristol Myers Squibb's own outlook, filed before approval, put its revenue potential at more than \$4 billion by 2029; reported sales in 2025, its third full year, were \$291 million⁹. Company quality does not explain the gap; both companies know how to launch. The environment does not explain it; it was the same environment. What differed was the genome, and the difference was directionally consistent with the pattern in the sample.

One genome, expressed twice: Krystexxa. This launch sits outside our sample, approved in 2010, and we include it because it isolates the second layer. Krystexxa is an intravenous biologic infused every two weeks for chronic gout that has stopped responding to conventional therapy: a specialty infusion for a small refractory population, the same genome from the day it was approved. Its first owner launched it at the three million people with gout rather than the fifty thousand who were eligible, with a sales force still being hired, late planning and a value story payers did not accept. Sales reached \$6 million in 2011 against an \$18 million forecast and \$16 million in 2012 against \$55 million; the company sold in bankruptcy three years after approval. Horizon acquired the product at the end of 2015 and relaunched it at the refractory population, through rheumatologists, with a field force quadrupled to nearly 200, account managers built for

reimbursement, new evidence and, in 2022, a label expansion. Sales grew from about \$35 million in 2015 to more than \$1 billion by 2023. The genome never changed; the expression did, and where it could, Horizon edited the genome too, with the combination data and the new label.

Neither case is an argument that the genome decides. Skyrizi was also launched extremely well, and Krystexxa shows what expression alone can move. Genome, expression and environment produce the phenotype together, and all three matter. The cases show what the markers are for: they tell a team, well before approval, which odds it is starting with and where its expression has to work hardest.

What this means

For the launch team: read the genome before writing the plan. Every launch plan we have seen starts from the product's strengths. The markers add a second starting point: the traits the product cannot change and the odds that accompanied them in this sample. A daily oral in a crowded category is not a worse medicine than a quarterly injectable; it is a launch whose forecast, in this sample, was more likely to outrun its reality, and whose plan may therefore need to spend more, earlier, on the two places where daily orals are lost: persistence and access. The organization markers say where expression pays most. In the most unfavorable profiles in our sample, launches from experienced companies with very experienced teams missed about half the time; first-time launchers with the same profile missed three times in four. Expression matters most where the genome is hardest.

For portfolio and business development: the traits are visible years out. Modality, route, frequency, duration, orphan status and the likely safety obligations are known at the time an asset is licensed or a program is prioritized, long before a launch team exists. A portfolio carrying several unfavorable stacks may warrant closer scrutiny of its forecasts and underlying assumptions. The markers are a way to see that early and to price it into the plan, the deal or the hiring.

For forecasting: the miss has a structure. Because performance was measured against the forecast, the markers describe where expectations tend to outrun results as much as where launches go wrong. The published literature already knows that pre-launch forecasts run high on average. What it has not said is which assets get over-forecast, and by how much. One hypothesis consistent with the observed pattern is that forecasts for oral, daily therapies may overestimate persistence and access, while forecasts for specialty biologics were beaten more often in this sample. A forecast built with that in mind is a better forecast; a plan built against it is a better plan.

Limits, and what comes next

The markers are associations, tested one at a time; they are not causes, and the effect sizes are moderate. Because the traits travel together, no single one of them can be called the driver with this design. The sample is 198 launches, which is enough to see the patterns above and not enough to see the rare ones: ten voucher redemptions and seventeen REMS launches are small groups, and we have said so where it matters. Performance was measured against sell-side forecasts of varying horizon, which is the only kind that exists

before approval; we re-ran the screen on four alternative samples, dropping the youngest launches and the most extrapolated outcomes, and every marker kept its direction.

Three things follow. First, a multivariable pass to establish which markers hold an independent association once the cluster is entered as one, and a validated version of the profile view. Second, the mechanisms: why oral, daily therapies miss, why one-time regimens do, what a REMS actually costs a launch, and whether the voucher signal survives a larger sample. Third, the environment. The launches in this sample entered a market where payer rejection was climbing and breakout launches were becoming rarer, and the traits most tied to access, orals in crowded categories and high-price one-time therapies, are the ones most exposed to where that trend goes next. THRIVE's Futures Architecture™ work takes that layer up directly, and the two lines of work are meant to be read together. While it is instructive to look in the rearview mirror to learn what drove the success and failure of past launches, your next launch will happen in the future, in an environment that does not yet exist. The drivers and barriers to launch success, and what launch excellence means, will likely evolve.

READ THE DNA OF YOUR NEXT LAUNCH

THRIVE offers a complimentary Launch Success Code™ assessment: a guided conversation, about an hour, in which we compare an asset's fixed traits with the historical 198-launch sample, show how launches with similar fixed traits performed, and discuss where the launch plan may need to work hardest. Write to us at launch@thrive-co.com.

ABOUT THE AUTHOR

Eliette Krakora is the Founder and CEO of THRIVE, specializing in launch excellence and strategic decision-making under uncertainty. She brings more than twenty-five years of strategic consulting experience and has materially contributed to launch strategies for therapies that have generated over \$100B in revenue to date, several of which became leaders in their categories.

Appendix: method

Sample. FDA CDER and CBER novel approvals, 2016 to 2024 (about 460). Included: launches with a sell-side sales forecast published 6 to 24 months before approval and product-level reported sales. Excluded: launches without either. Final analysis set: 198 launches, 48 of them from companies launching for the first time.

Variables. 33 launch variables were coded for each of the 198 launches from public sources: labels, FDA approval records and designation lists, company disclosures and investor materials, and launch-price filings. Overlapping variables were consolidated to 18 for testing; launch price was tested separately.

Outcome. Reported sales against the pre-launch forecast, evaluated on the forecast's own terms (a specific year where the forecast named one, otherwise peak), using reported sales through 2024 and consensus estimates for 2025 to 2026 where the forecast year had not yet been reached. Bands: above 120 percent of forecast, beat; 80 to 120 percent, met; below 80 percent, miss; below 40 percent, severe miss.

Tests. Chi-square test of independence for each variable against the three-level outcome, Cramér's V as the effect-size measure, and relative risk of beat and of miss for each category against all other launches, with exact tests for small cells. Ten variables cleared the screening threshold; effect sizes were weak to moderate throughout. Sensitivity: the screen was repeated excluding 2024 approvals, excluding 2023 and 2024 approvals, excluding outcomes that required extrapolation to the forecast year, and excluding both; the share of launches missing forecast ranged from 54 to 63 percent across these samples and every marker kept its direction in each. These analyses identify retrospective associations in this sample; they do not establish causation or predict the outcome of any individual launch.

Pricing. Launch wholesale acquisition cost was annualized from label dosing and adjusted to a reference body weight for weight-based products. California HCAI new-drug filings, which cover launches priced above the Medicare Part D specialty threshold from 2019 onward, provided 133 of the prices; the test was run on those 133 by quartile and by tertile. Prices for the remaining launches were collected from public sources and are being completed for a full-sample test.

Differentiation. Each launch was coded at approval using a THRIVE rubric based on novelty in the indication, demonstrated clinical advantage, and evidence/label strength. Coding was blind to outcome, with an independent second coder on 40 launches (kappa 0.54 on the differentiated yes/no classification).

Provenance. Forecasts from published sell-side research (more than 80 providers); sales from Bloomberg compilations of company filings; regulatory data from FDA; prices from HCAI. Variable coding retains a written rationale per value.

Endnotes

Notes 1 to 6 are the six studies in Figure 1. Each analyzed an industry-wide sample of launches over the window shown, and each defines performance in its own way; the definitions are given here so the rates in Figure 1 can be read on their own terms. Note 7 is the published price test cited in the text; notes 8 and 9 the sources for the case-study forecast figures.

1. **ZS.** Sales against forecast; outperformance above 120 percent. 340 launches, 2008 to 2025. Gurnani, K. Why clinically differentiated assets miss market expectations in pharma launch strategy. ZS Associates; 2026. Accessed September 1, 2026. zs.com
2. **Deloitte.** Sales against consensus; within plus or minus 20 percent counts as met. 284 launches, 2012 to 2021. Deloitte Center for Health Solutions. Drug Launches Reflect Overall Company Performance. Deloitte; 2023. Accessed September 1, 2026. deloitte.com
3. **Simon-Kucher.** Forecast accuracy; plus or minus 25 percent band. 50 launches, 2015 to 2022. Tritschler, J., Slusarczyk, M., Wochner, S. The Wild West of Sales Forecasting in Pharmaceuticals: When Expectation Meets Reality. Simon-Kucher; April 2024. Accessed September 1, 2026.
4. **Trinity.** Year-one sales against forecast; plus or minus 10 percent band. 46 launches, 2020 to 2023. Perry, K., Stoekl, B., Fritz, J., Gessner, S. Moving the Needle: Lessons from the 2023 Launch Class. Trinity Life Sciences; 2024. Accessed September 1, 2026. trinitylifesciences.com
5. **THRIVE.** Reported sales against the pre-launch sell-side forecast, on the forecast's own terms; plus or minus 20 percent band. 198 launches, 2016 to 2024. Krakora, E. The THRIVE Launch Success Code™: Decoding the DNA of Drug Launches. THRIVE Consulting; 2026. This report.
6. **McKinsey.** Year-one sales against consensus; plus or minus 20 percent band. 210 launches, 2003 to 2009. Ahlawat, H., Chierchia, G., van Arkel, P. The Secret of Successful Drug Launches. McKinsey & Company; March 2014. Accessed September 1, 2026. mckinsey.com
7. **L.E.K.** Tested pricing strategy among candidate drivers of launch performance across 62 launches from the ten largest pharmaceutical companies, 2015 to 2019, and did not find it among the significant drivers. L.E.K. Consulting. Variability in Large Pharma Launch Performance. Executive Insights; January 2024. Accessed September 28, 2026. lek.com
8. **AbbVie.** Presentation at the J.P. Morgan Healthcare Conference, January 2018 (risankizumab sales of approximately \$5 billion in 2025); press release of January 11, 2022 confirming 2025 risk-adjusted Skyrizi sales guidance of more than \$7.5 billion; fourth-quarter and full-year 2025 results (reported Skyrizi revenue). news.abbvie.com
9. **Bristol Myers Squibb.** Investor presentation filed on Form 8-K, February 2021 (deucravacitinib non-risk-adjusted revenue potential of more than \$4 billion in 2029), and first-quarter 2022 earnings presentation filed on Form 8-K (the same figure); fourth-quarter and full-year 2025 results, February 5, 2026 (Sotyktu worldwide revenue of \$291 million in 2025). sec.gov (2021); sec.gov (2022); sec.gov (2026)

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