White Paper

Accelerating Drug Development: Insights from 2020–2024 Rapid Approvals

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Introduction

Bringing a new therapy from first-in-human trials to regulatory approval is typically a lengthy process — often close to a decade in development. However, a recent baseline analysis of asset-level cycle times (Phase I start to first approval) for drugs approved in 2020–2024 reveals that some programs achieved substantially shorter timelines under specific scientific, regulatory, and operational conditions.[1] This analysis, leveraging IQVIA Institute's analysis of Citeline Pharmapremia data, aimed to identify case studies of accelerated development. By examining thousands of development programs across therapeutic areas, the study highlights how a subset of drugs achieved approval years faster than their peers[1] and uncovers common factors behind these rapid timelines.

For clinical development teams and biotech executives, these findings offer more than retrospective data. They show the conditions sponsors can identify, plan for, and act on earlier to reduce avoidable delay. Understanding the characteristics of the fastest programs can inform strategies to streamline R&D, with the recognition, however, that such outcomes are far from guaranteed. In this paper, we summarize the analysis methodology, present key findings across oncology, immunology, infectious diseases, and pan-therapeutic areas, and spotlight high-speed development case studies. We also discuss how factors like rare disease focus, accelerated approval pathways, and novel modalities contributed to faster development, and how companies can apply these insights to accelerate their own pipelines while managing risks.

Methodology: Measuring asset-level cycle times

Asset-level cycle time was defined as the total elapsed time from the start of an asset's first Phase I trial to its first marketing approval (anywhere globally).[1] The analysis included all assets first approved between 2020 and 2024 (inclusive), using data prepared for the Global Trends in R&D 2025 report. These cycle times are actuals (not composite averages) for each asset's development journey,[1] tracked on a per-asset basis rather than using pooled averages. This Phase I-to-first-approval measure is complementary to broader clinical development program measures, which may include inter-phase planning, protocol development, start-up, delivery, and close-out intervals that contribute to total program duration.

To ensure robust comparisons, the study segmented results by therapeutic area and calculated distribution metrics:

- Median development time for each therapeutic area (50th percentile).
- 10th, 25th, 75th, and 90th percentiles for each area's distribution.[1]

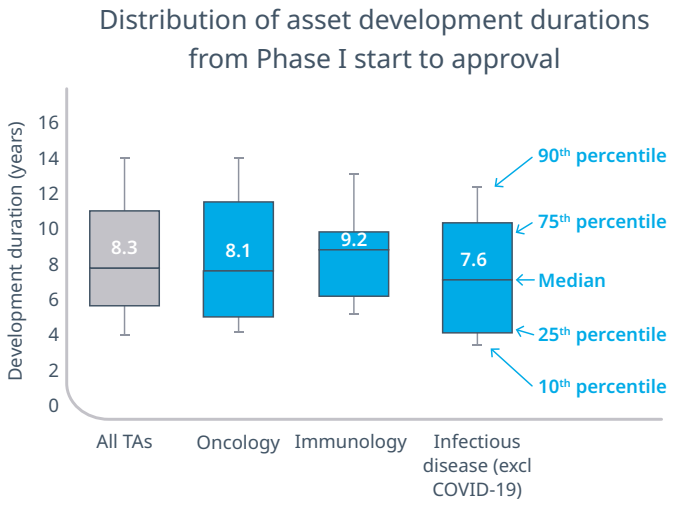
Therapeutic areas examined included Oncology, Immunology, Infectious Diseases (excluding COVID-19), as well as an aggregate across all therapy areas (pan-TA).[1] Notably, COVID-19 programs were excluded to avoid skewing the results, given the unique circumstances and accelerated timelines of pandemic-related projects.[1] The source data came from Citeline's Pharmapremia database of program success rates and cycle times, with independent IQVIA Institute calculations and an asset-centric approach applied to ensure each drug's timeline was captured accurately.[1]

Data validation: Top-line statistics were cross-checked, and implausibly short timelines were independently validated. For example, one oncology asset (Loqtorzi) initially appeared to have an exceptionally brief cycle time; further investigation revealed prior Phase I work in another country, and it was removed from the shortlist of "short duration" assets.[1] This careful vetting ensured that the identified fast-development cases truly represent accelerated R&D, not data errors or partial timelines.

Development duration variability across therapeutic areas

A key finding of the baseline analysis is how widely total development durations varied both within and across therapeutic areas.[1] Figure 1 illustrates the median Phase I-to-approval times for 2020–24 approvals in major categories, along with the interquartile range (25th to 75th percentile) for each:[1]

Figure 1. Development duration from Phase I start to approval by therapeutic area (2020-2024 approvals). Each bar spans the 25th to 75th percentile (IQR) of asset development times, with values labeled at the 25th, 50th (median), and 75th percentiles (black diamonds mark medians). Immunology programs have the longest typical timeline (median ~9.2 years), whereas Infectious Disease programs are fastest (median ~7.6 years). Oncology shows the widest variability (IQR ~5.7 to 11.8 years, a ~6.1-year span). (Source: Citeline Pharmapremia data, IQVIA Institute analysis.)



Several observations emerge from these data:

- **Typical timelines remain long**. Across all therapy areas combined, the median development time was about 8 years from Phase I to approval.[1] Many programs took substantially longer — the 75th percentile often extended into the 11-12 year range.[1] In other words, the "usual" drug project still spans close to a decade, and in many cases over a decade, reinforcing how challenging and protracted drug development is.
- **Differences by therapeutic area**. There were clear variations: Oncology programs had a median around 8.1 years, near the overall benchmark.[1] Immunology (e.g., autoimmune diseases) tended to be slower — a median ~9.2 years, the longest of the group.[1] In contrast, Infectious Disease (excluding COVID-19) had a lower median of roughly 7.6 years,[1] indicating generally faster development for anti-infectives. These differences likely reflect trial and disease characteristics: for example, infectious disease trials (e.g. for antivirals or vaccines) can often be completed more quickly due to clear endpoints and urgent medical need, whereas immunology trials (e.g. chronic autoimmune conditions) may require longer observation periods to establish efficacy.[1]
- **Wide within-area variability**. Each therapeutic area showed a broad spread between faster and slower programs. In immunology, the 25th percentile development time was ~6.8 years versus ~10.2 years at the 75th percentile1 — a difference of about 3.5 years between relatively "quick" and "slow" outcomes even within the same field. Oncology had an even wider interquartile range (about 5.7 years at the 25th percentile vs. 11.8 years at the 75th).[2] Infectious diseases had some very rapid programs at the low end (~4.8 years at the 25th percentile) but still reached ~10.7 years at the 75th percentile.[2] This means that within each area, a few assets managed to cut years off the typical timeline while others greatly exceeded the median.

In summary, while development times differ by therapy area, even the 25th percentile "fast" programs in most areas still take on the order of 5–7 years from Phase I to approval. The handful of programs beating the 5-year mark are exceptional outliers. Thus, although the fastest 10% of programs achieved remarkable speeds, most sponsors should be mindful that their projects will likely follow the longer trajectories absent specific scientific, regulatory, and execution conditions. These outliers do, however, offer valuable lessons. They show that faster development is rarely accidental; it often depends on earlier decisions, clear evidence strategies, regulatory alignment, and execution models that reduce avoidable delay.

Identifying short-duration development cases

To learn from these rare successes, the analysis focused on those successful programs that significantly outpaced typical timelines. Two tiers of unusually rapid developers were defined:

- "Short but not extreme" durations: assets with total development times roughly in the 25th to 10th percentile range for their therapeutic area. These represent the top 10–25% fastest developments in each category.[1] They are notably quick relative to peers, yet not absolute extremes, making them potentially practical case studies.
- "Sub-10th percentile" durations: the ultra-rapid outliers — about the fastest 10% of programs.[1] These cases approached development times of only ~3–4 years (from Phase I to approval), which is extraordinary and may be unique.

The study first examined the "short but not extreme" group as more instructive examples (as opposed to almost one-of-a-kind anomalies). All told, about a dozen assets across oncology, immunology, and infectious disease fell into the 10th–25th percentile speed band (after validating their timelines).[1] Figure 2 highlights some common features of this cohort:

Figure 2: Common traits among short-duration development programs (top 10-25% speed cohort). In this subset, oncology assets were highly over-represented,[1] reflecting both the volume of oncology approvals and the frequent use of expedited pathways in cancer. Rare disease status and Accelerated Approval pathways appeared in a large proportion of cases,[1] suggesting that a savvy regulatory strategy is a key contributor to speed. Additionally, many programs involved breakthrough modalities (like CAR-T cells, antibody–drug conjugates, or RNA therapies), which often yielded dramatic efficacy and thus faster routes to approval.[1]

Regulatory strategy

Frequent use of expedited regulatory pathways
Early and iterative regulatory engagement
Acceptance of post-approval confirmatory study obligations

Scientific and clinical

Design traits
Molecularly defined patient populations
Clear biological rationale and target validation
High unmet medical need

Indication and population characteristics

Over-representation of oncology programs
Rare disease or niche subpopulation focus
Small, well characterized patient populations

Trial design and evidence generation

Early-phase trials designed as registrational
Multi-cohort or basket trial structures
Use of surrogate or intermediate endpoints
Single pivotal study supporting initial approval

Modality and technology enablers novel or differentiated therapeutic modalities

Mechanisms capable of producing rapid and measurable clinical responses
Operational and execution factors
Aggressive timelines with parallel activities
At-risk investment in manufacturing or scale-up
Lean, focused development programs

How fast is "fast" in context? The exact 10th percentile cut-offs differed by area. In oncology, any program completing development in under roughly 5 years was in the top decile (the 10th percentile ~4.9 years).[1] In infectious diseases, the 10th percentile was even lower (~4.3 years) given a few lightning-fast antiviral or antibody projects.[1] In immunology, the threshold for the top 10% was higher (~6.2 years) due to generally longer timelines in that therapeutic area.[1]

Only a handful of programs met these extreme benchmarks. By design, the "short but not extreme" cohort captures slightly more of the curve — those in roughly the 10th–25th percentile range, which still translates to just a few years faster than median. For example, a drug that took 5 years in an indication where the median is 8 qualifies as short-duration, even if it's not the single fastest. A few examples from this group illustrate what was achievable (and under what conditions):

- **Oncology**: *Rybrevant* (amivantamab) — Janssen's bispecific antibody targeting EGFR/MET for lung cancer — went from first patient in Phase I to FDA approval in ~4.9 years[2] (2016 start to 2021 approval). This is remarkably fast for a first-in-class NSCLC therapy. Rybrevant's development made use of an Accelerated Approval (based on strong early-phase results) and had striking efficacy in a molecularly defined population, even though the disease (metastatic lung cancer) itself is not rare.

- **Oncology**: *Retevmo* (selpercatinib) — Eli Lilly's RET inhibitor progressed from first-in-human dosing to initial FDA approval in approximately 4–5 years, placing it firmly within the short-duration oncology cohort. Selpercatinib received Accelerated Approval in 2020 for RET fusion–positive NSCLC and RET-altered thyroid cancers based on robust response rates observed in the Phase I/II LIBRETTO-001 trial, a global, multi-cohort study designed to enroll molecularly defined populations across tumor types.[3,4] The program exemplifies how precision oncology, basket-style early development, and early regulatory engagement can compress timelines even in non-rare solid tumors. Notably, selpercatinib's development leveraged a single, well-designed registrational study spanning multiple indications, enabling rapid expansion of the label while deferring confirmatory evidence generation post-approval.

- **Immunology**: *Vyvgart* (efgartigimod alfa) — Argenx's antibody fragment for myasthenia gravis — reached approval in ~6.2 years[5] (Phase I in 2015 to approval in late 2021). This neuromuscular disease is rare (orphan), and the drug's mechanism (targeting FcRn to reduce pathogenic antibodies) delivered clear benefits. Notably, Vyvgart achieved standard approval (no accelerated pathway) by running a streamlined development program with one pivotal trial, reflecting how a well-designed trial in a rare disease can suffice.

- **Infectious Diseases**: *Inmazeb* (atoltivimab + maftivimab + odesivimab) — Regeneron's antibody cocktail for Ebola — went from initial Phase I to approval in only ~4.3 years[6] (2016 to 2020). This timeline was aided by the urgent public health context (Ebola outbreaks) and robust efficacy observed during an epidemic trial. Inmazeb received Priority Review (but not accelerated approval, since its approval was supported by direct clinical outcome data) and exemplifies how crisis situations can compress development, albeit under unique conditions.

Even these "short" cases depended on aligning multiple favorable factors (scientific, regulatory, and operational). It's clear that sub-5-year development cycles are possible but exceedingly rare. The next section delves into a broader set of case studies — including some sub-10th percentile extreme cases — to extract patterns from those successes, while keeping in mind that each benefited from specific circumstances.

Case study highlights: Fast-track development in action

Several drugs approved in 2020–2024 stand out as exemplars of accelerated development. We profile a selection of these rapid developers below, noting key metrics for each. These case studies span different therapeutic areas and modalities, showing various pathways to a shorter timeline. It must be emphasized that each example achieved speed under particular conditions; attempting to replicate their approach without similar conditions may not yield the same results. Nonetheless, they provide valuable insights.

Table 1: Selected Rapid Development Case Studies (2020–2024 approvals) — Attributes of drugs with notably short development durations. Each listed asset progressed from Phase I to first approval significantly faster than the norm for its field. (Rare disease and accelerated approval status are indicated.)

DRUG (GENERIC)	LEAD COMPANY	THERAPEUTIC AREA	DEV TIME (YRS)	RARE DISEASE	ACCELERATED APPROVAL	MODALITY
Lumakras (sotorasib)	Amgen	Oncology (NSCLC)	~2.8	No	Yes	Small molecule inhibitor (KRAS G12C)
Jemperli (dostarlimab)	GlaxoSmithKline (GSK)	Oncology (Endometrial)	~5.1	Yes	Yes	Monoclonal antibody (PD-1 inhibitor)
Abecma (idecabtagene vicleucel)	Bristol Myers Squibb (BMS)	Oncology (Multiple Myeloma)	~5.1	Yes	No	CAR-T cell therapy
Zynlonta (loncastuximab tesirine)	ADC Therapeutics	Oncology (B-cell Lymphoma)	~5.1	Yes	Yes	Antibody–drug conjugate (CD19-targeted)
Retevmo (selpercatinib)	Eli Lilly	Oncology	~4–5	Yes	Yes	Small molecule targeted kinase inhibitor (RET)
Hemgenix (etranacogene dezaparvovec)	CSL Behring	Hematology (Hemophilia B)	~5.1	Yes	No	Gene therapy (AAV vector)
Oxlumo (lumasiran)	Alnylam	Renal (Primary Hyperoxaluria)	~4.7	Yes	No	RNA interference therapy (siRNA)
Vyvgart (efgartigimod alfa)	argenx	Immunology (Myasthenia Gravis)	~6.2	Yes	No	Antibody fragment (FcRn inhibitor)

Sources: IQVIA Institute analysis of Citeline Pharmapremia data (unpublished).

This table underscores the diverse routes to a faster finish line. For instance, Lumakras (Amgen) was the first FDA-approved KRAS inhibitor, a novel targeted small molecule, which famously went from first human dose to market in under 3 years. Amgen concentrated on a specific patient subset (KRAS G12C-mutant lung cancer) and secured an Accelerated Approval by demonstrating tumor responses in Phase II[7] in a population with unmet need. In contrast, Abecma (BMS) is a CAR-T cell therapy for multiple myeloma; it took ~5.1 years, not via accelerated approval but through being a breakthrough therapy in a rare cancer and running certain development steps in parallel plus outstanding efficacy (e.g., manufacturing scale-up alongside clinical trials).[6]

A brief look at two of these cases highlights different mechanisms of acceleration:

- Lumakras (sotorasib): *Target*: KRAS mutant oncoprotein in NSCLC. Phase I Start: 2018. Approval: May 2021 (US). *Approach*: Seamless Phase I/II design — the Phase I trial rolled directly into an expanded cohort once early efficacy emerged, yielding pivotal results in ~1.2 years. The FDA granted Accelerated Approval based on the Phase II data (objective response rate ~36%).[7] From first patient dosed to NDA submission was only ~2.5 years; FDA review took ~0.4 years, bringing total Phase I-to-approval time to ~2.8 years. *Enablers*: A clearly defined and well known molecular target linked to an unmet clinical need, use of surrogate endpoints (tumor response) for early approval, and strong collaboration with FDA on trial design allowed Lumakras to set a new speed record in oncology. *Caveats*: Post-approval confirmatory trials were required and are ongoing. Not every program will see such striking early data or regulator willingness to expedite.
- Abecma (ide-cel): *Target*: BCMA antigen on myeloma cells (CAR-T therapy). Phase I Start: early 2016. *Approval*: March 2021 (US). Approach: An academic Phase I (CRB-401 study) gave preliminary safety signals by 2015; by 2017, Celgene/BMS launched pivotal trials (KarMMa-1) quickly on the heels of Phase I, minimizing the gap between early and late-stage testing.[8] Pivotal evidence came from a single-arm Phase II (given the unmet need in refractory myeloma), and manufacturing of this complex cell therapy was scaled up during trials. Total time was ~5.1 years. *Enablers*: Orphan drug status and Breakthrough designation facilitated regulatory interactions, and the therapy's transformative efficacy (deep, durable responses in heavily pre-treated myeloma) secured Priority Review (6-month FDA review). Caveats: CAR-T trials are resource-intensive and involved substantial at-risk investment. If efficacy had been less dramatic, this aggressive timeline might not have paid off.

Other rapid cases followed additional patterns. Jemperli (dostarlimab, GSK) targeted a rare subset of endometrial cancer (dMMR tumors) and used accelerated approval to go from Phase I start to approval in ~5.1 years. Zynlonta (loncastuximab, ADC Therapeutics) similarly paired an orphan lymphoma indication with accelerated approval, hitting ~5 years.[9] Meanwhile, Hemgenix (CSL Behring), a gene therapy for hemophilia B, achieved a standard approval in ~5.1 years by demonstrating a curative benefit in one pivotal study (no need for acceleration)[10] — but gene therapy manufacturing had to be in place. Oxlumo (Alnylam), an siRNA for primary hyperoxaluria, was approved in ~4.7 years,[11] and Inmazeb (Regeneron), the Ebola antibody cocktail, set a record in anti-infectives at ~4.3 years in partnership with Biomedical Advanced Research and Development Authority (BARDA).[12]

It's worth noting that beyond these examples, a pan-therapeutic scan found a few fast developers in other fields as well (e.g., an RNAi cholesterol drug and a diabetes drug around 6 years each). The common thread remains: they address serious or rare conditions and often involve novel mechanisms, enabling streamlined trials. Importantly, none of these fast-track cases were "easy" projects. They required exceptional science, timely evidence, careful planning, and disciplined execution under uncertainty.

The role of Rare diseases, accelerated approvals, and novel modalities

Examining the rapid development cases, several common accelerators consistently show up — as well as implicit challenges:

- Rare Disease Focus (Orphan *d*esignation): Most ultra-fast programs target a rare disease or niche population. In Table 1, 7 of 8 drugs have orphan status. Orphan designation provides incentives (fee waivers, tax credits) and often means smaller trial size requirements, since patient populations are limited. More critically, when a condition has no existing treatments (as is often true in rare conditions or specialized oncology subsets), a drug showing clear efficacy can sometimes suffice with a single pivotal study. For example, dostarlimab's endometrial cancer indication and ide-cel's myeloma use case both had orphan status and unmet needs, allowing faster endpoints and regulatory flexibility. Biotech companies can strategically target niche indications (or stratify larger diseases into genomic subsets) to take advantage of this; success in a narrow population can later be expanded, but the initial approval comes sooner. *Caution*: Not every program can find an orphan niche, and even in rare diseases regulators still require solid evidence. Orphan focus should be a natural fit, not forced. In addition, available placebo or control data may be difficult to obtain in a rare disease or population and real-world alternative sources may not be accepted by regulatory agencies.

- Accelerated approval and other expedited pathways: Many of the oncology therapies in the fast cohort went through FDA's Accelerated Approval (AA) process or similar expedited routes (Fast Track, Breakthrough Therapy designation, Priority Review). Accelerated Approval in the U.S. allows approval based on a surrogate endpoint reasonably likely to predict clinical benefit, followed by confirmatory trials post-approval. Lumakras, Jemperli, Zynlonta, and others obtained AA on the strength of Phase I/II data. The experience with selective targeted therapies such as selpercatinib (Retevmo)[13] further reinforces how molecularly defined populations, basket style early trials, and early use of accelerated approval pathways can compress development timelines to 4–5 years even outside ultra rare diseases, while still requiring post approval confirmation of benefit.

  This shaved years off their time to market by bypassing lengthy Phase III trials pre-approval. The trade-off is the requirement to conduct Phase IV confirmatory studies, but critically, the drug reaches patients sooner. For developers, this underscores the value of identifying surrogate endpoints (e.g., tumor response rate, pathogen clearance) and engaging regulators early to validate their use. Even outside oncology, accelerated/conditional approvals were used (e.g., *Viltepso* for DMD received conditional approval in Japan based on dystrophin levels[14]). Companies should design trials with interim analyses and surrogate markers in mind, to enable applying for early approval if the data are compelling. Additionally, Priority Review (6-month review clock) and Breakthrough Therapy designation (intensive FDA guidance) were frequently seen in these cases, contributing to overall speed. *Caution*: Accelerated pathways only apply when you have compelling data. Relying on an unproven surrogate or hoping for an easy pass can lead to setbacks if the FDA isn't convinced. And an accelerated approval, once granted, still demands successful confirmatory trials to maintain the approval.

- Novel modalities and technologies: It's evident that many fast-track drugs involve innovative therapeutic modalities — CAR-T cells, gene therapies, RNAi, bispecific antibodies, etc. These modalities often tackle diseases in new ways, yielding large effect sizes. For instance, Hemgenix (gene therapy) can essentially cure hemophilia B in one dose, a paradigm-shifting outcome that made its case to regulators very strong.[10] *Oxlumo* (siRNA) directly silences a disease-driving gene, showing quick biochemical and clinical effects.[11] Tecvayli and Talvey (bispecific T-cell engagers for myeloma, in the short-duration list) produced high response rates in refractory cancers. Such profound efficacy signals can justify accelerated approvals or smaller trials. However, novel modalities also introduce CMC and manufacturing challenges — what likely helped in these cases is that companies (or their partners) invested early in manufacturing scale-up and process development, preventing CMC delays from becoming the critical path.[10] The takeaway for biotech leaders is to embrace innovative science that can deliver outsized efficacy, but also to plan early for manufacturing and scale. Regulatory agencies have shown willingness to expedite ground-breaking therapies, provided safety is managed and quality is ensured. *Caution*: Pioneering a new modality is high-reward but also high-risk. Ensuring quality (e.g., consistent cell therapy product) and safety (managing novel side effects) can be as time-consuming as the trials themselves if not anticipated early.

- Operational excellence, early decision-making, and integrated trial design: While not as quantifiable as the above factors, a qualitative review of these cases suggests that teams pursued aggressive, sometimes unconventional development strategies. Several programs used adaptive trial designs or overlapped trial phases to cut down idle time. For instance, running Phase II and Phase III in parallel (or starting Phase III at an interim Phase II readout) was done in cases like tirzepatide for diabetes. Global trials and concurrent submissions to regulators in different regions also shaved time — e.g., some assets achieved approval in Europe and the U.S. within the same year, indicating parallel regulatory filings. Companies looking to accelerate should adopt a "data-driven, risk-managed" development plan: make big decisions (like scaling up or starting pivotal trials) as soon as the data justifies, rather than waiting until avoidable delay is already built into the pathway. In these case studies, sponsors often had to invest at risk (for example, manufacturing CAR-T product at commercial scale ahead of approval) but were rewarded by being first to market. *Caution*: Compressing timelines increases risk. If interim data disappoint and you've already started the next phase, resources and time are lost. This approach demands robust early data and contingency plans in case things go awry.

Balancing ambition with realism: Strategies for sponsors

The 2020–2024 cases prove that, under the right circumstances, a drug can go from Phase I to approval in as little as 3–5 years. But for most sponsors, a more realistic target might be to shave some time off the standard timeline rather than replicate the extreme outliers. With that balanced view, here are strategic takeaways:

1. Leverage Orphan/Niche Indications (if applicable): If your asset addresses a rare disease or a stratified subset of a larger disease, consider focusing development there first. Smaller trials and strong unmet need can accelerate approval. However, ensure the indication is scientifically appropriate as regulators may sense if an orphan strategy is forced. The data shows nearly every ultra-fast program had an element of rarity/unmet need driving it.

2. Engage regulatory pathways early: Design your development plan around the possibility of expedited approval. This means identifying potential surrogate endpoints and seeking Breakthrough Therapy designation or Accelerated Approval discussions as soon as Phase I/II data show a strong signal. The fastest oncology approvals in 2020–24 all capitalized on this e.g., Amgen worked closely with FDA to align on response-based approval for sotorasib.[7] Even outside oncology, be aware of analogous mechanisms (FDA's Fast Track, EMA's PRIME, etc.) to speed regulatory review. Importantly, ensure post-approval studies are ready to launch; regulatory bodies are more amenable to early approval if you have a solid plan to confirm the benefit afterward. However, not every drug will qualify for these pathways.

3. Invest in cutting-edge modalities (eisely): If your program involves complex modalities (cell therapy, gene therapy, RNA, etc.), start laying the groundwork early. Secure manufacturing capacity and expertise during Phase I/II, rather than waiting for Phase III results.[11] The case studies show that companies which addressed CMC challenges upfront avoided bottlenecks later. Also, novel modalities often face unknown regulatory questions; engage expert consultants and schedule agency meetings early to clarify requirements. When done right, delivering a life-changing therapy (like a CAR-T or RNAi) in a high-need area can practically guarantee expedited consideration by regulators. The payoff can justify the upfront investment. Be prepared for surprises as novel modalities can have unforeseen issues (safety, manufacturability) that traditional drugs don't.

4. Design operations to reduce white space and accelerate decisions: Adopt an internal culture where time is a critical resource. This means minimizing the gap between protocol completion and first patient in, using adaptive designs to combine phases when possible, and analyzing data in real-time to accelerate decisions. For example, if early Phase II data are positive, have the Phase III protocol ready to go. Several fast programs had Phase III trials initiated while Phase II was still maturing, under the contingency that Phase II meets a certain bar, a strategy that can cut a year or more. Use of master protocols or platform trials can also speed up development for multiple indications or combinations in parallel, rather than sequential trials. Efficiency must not come at the expense of data integrity or patient safety. Implement rigorous monitoring so that speeding up doesn't lead to overlooking important signals or quality issues.

5. Ensure adequate resources and partnerships: Small biotechs should consider partnerships to leverage additional resources for fast execution. Larger firms should ensure their internal processes can support acceleration (avoiding bureaucratic slow-downs). Many rapid successes built on prior scientific knowledge: for example, Pfizer's Prevnar 20 vaccine piggybacked on the established Prevnar 13 platform, thus much of the groundwork was laid and the development time was ~4.5 years,[15] showing that re-using proven technology can significantly compress timelines. Biotechs should similarly reuse known components (delivery systems, scaffolds, etc.) when possible, to avoid reinventing the wheel. Partnerships and platform reuse are not cure-alls; they must be well-managed to actually save time.

In closing, the IQVIA analysis of 2020–2024 approvals confirms that *rapid drug development is possible* as some programs did achieve approvals in materially shorter development timelines than the median for their therapeutic area.[1] However, it also reminds us that these are exceptional cases, not the norm. The median program still takes ~8–9 years,[1] and many take longer. Sponsors should strive to learn from the outliers without assuming their project will naturally emulate them. By consciously applying the factors discussed, focusing on high-need areas, working closely with regulators, harnessing potent science, and running lean operations, companies can improve their odds of accelerating development. Even a modest reduction in timeline can translate to significant benefits for patients and a competitive advantage for the company, especially when acceleration is grounded in earlier decisions, integrated data flow, and disciplined execution.

Ultimately, speeding up development is about working smarter within the constraints of science and regulation. The case studies are inspiring, but each was enabled by aligning key pieces (science, medicine, regulation, operations). With careful planning, sufficient resources, and timely evidence, regulatory alignment, and disciplined execution, a sponsor can create the conditions for their asset to improve development speed and predictability. Still, prudence is warranted: plan for scientific uncertainty, but design development decisions, data flow, and operations to reduce avoidable delay where the evidence supports it.

Organizational and operating-model changes to accelerate development

Lilly case example key learnings

EXAMPLE — Organizational and operating-model transformational changes were implemented through creating a dedicated “Next Generation Development” organization to accelerate development, creating a repeatable operating model for speed, reducing the average development time from the previous ~10.5 years to ~8-8.5 years and cutting months from multiple transition points, sometimes exceeding 8 months per program.

The new goals: Speed and science

- Prioritizing time saving over money: Mapped and streamlined the steps of the drug development process.
- Giving scientists “permission to fail”: Created a freeing mindset that encouraged big, creative thinking about how to get around the usual development bottlenecks.
- Designing studies more thoughtfully to produce the critical data necessary to drive decisions: Transformed the organization to make purely scientific decisions overcoming people’s natural preference toward particular ideas, projects and teams.
- Demonstrated impact with the approval for tirzepatide in T2D.

Reducing white space for regulatory approvals

- Better use of analytics: Modeling the potential outcomes of a study real me using proprietary technology allowed focusing on the outcomes tha are most likely to occur shifting from reactive to proactive decision planning.
- Investment in infrastructure and digitization: Gathering patient data through advanced electronic solutions, directly from labs and connected devices.

Cutting clinical trial timelines

- Expediting patient recruitment and retention: making patient aware what trials exist for their disease in their location, enroll patients in trials where they are located and keep them on the study untill the end.
- Proactive engagement: Engage advocacy groups and consider the voice of patients and sites in the study design.
- Process improvement: Simplified consent forms to improve patient retention.

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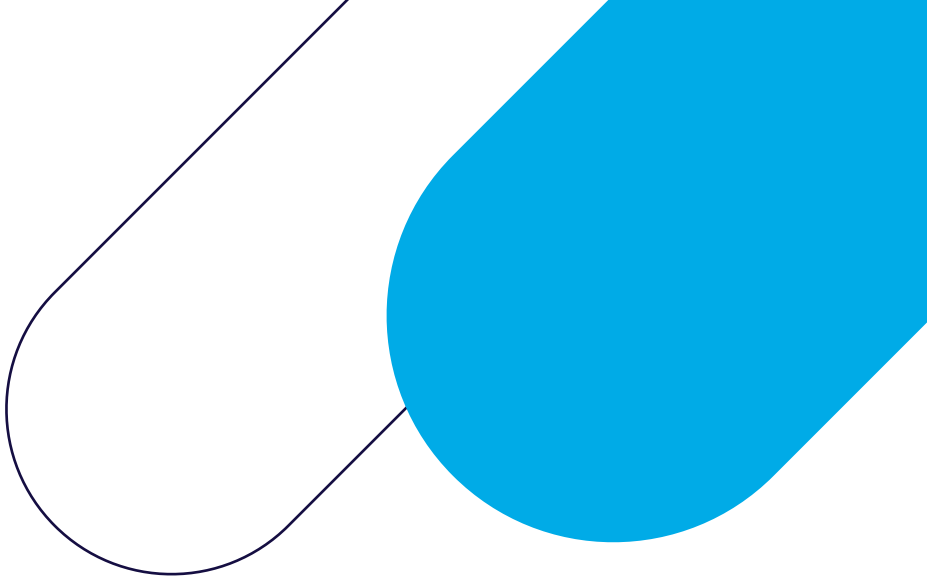

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