A BRANDLAUNCHX DISCUSSION PAPER

The Unmeasured Years

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Why great launches still keep patients waiting, and the case for a common measure of Time to First Patient Access

De-Risk. Accelerate. Maximize. Launch Success.

This paper cites only published, verifiable sources. Every material figure is referenced. Where a claim is our own reading of the evidence rather than a sourced fact, we say so.

Executive Summary

A new medicine is approved. The science has been proven to work, now it's the turn of the launch professionals to deliver success. A market is accessed; a launch team celebrates. And then, in market after subsequent market, patients wait. Not days. Not weeks. Years.

This is not a story about bad drugs or ineffective teams. It is a story about the gap between approval and the first patient actually receiving a therapy, and about the fact that almost nobody measures that gap with real intent. The independent European Federation of Pharmaceutical Industries and Associations (EFPIA) benchmark now puts the median wait between marketing authorisation and patient access across Europe at **532 days**, and in the widest cases the gap runs from 56 days in Germany to 1,201 days in Romania, an 88% disparity between the fastest and slowest markets [1,2]. It is a worsening trend, supported by the fact that the share of new medicines fully available on public reimbursement lists has fallen to 28%, down from 42% in 2019 [1,2].

The cost of that wait is not hypothetical. Peer reviewed work from the Tufts Center for the Study of Drug Development, drawn from 645 launches since 2000, estimates a single day of launch delay at roughly **500,000 US dollars** in lost sales [8]. The majority of launches already miss their own commercial expectations [9]. And a patent cliff that puts an estimated 236 billion US dollars of revenue at risk by 2030 is shortening the runway on which any of that value can be earned back [10].

Meanwhile, artificial intelligence is compressing the front of the pipeline. Credible estimates put the time and cost savings in discovery to preclinical at 25% to 50% [17], and the first end-to-end AI discovered medicine has now cleared a Phase IIa readout [18]. It appears that the super-tool that is AI is actually going to exacerbate the issue of access delays. We are getting dramatically faster at inventing medicines, but no faster at getting them to patients, creating a bigger bottleneck downstream of development.

> *We measure a launch by how fast the revenue arrives. We do not measure how long the patient waits. That is the flaw this paper is about.*

Our argument is simple. The delays persist partly because the industry has no common, forward looking measure of what a good launch actually delivers for patients. What gets measured gets managed as any good Project Manager will tell you. Time to access is measured inconsistently, late, and after the fact, so it is managed the same way. We propose that we build a new, fit-for-purpose measure, and that we build the benchmark for it in the open.

1. The paradox of the celebrated launch

Trikafta, known as Kaftrio in Europe, is rightly remembered as one of the defining launches of its decade. It changed the outlook for people with cystic fibrosis, and it was approved in the United States in October 2019 [4]. That is the part everyone tells.

The part we tend to leave out is the calendar. Reimbursed access followed in Spain in November 2021 [5], on the Australian Pharmaceutical Benefits Scheme in April 2022 [6], and, under a durable deal with the NHS in England, only in June 2024* [7]. From the same approval, patients in different countries waited very different lengths of time, and in England the wait for a settled access arrangement ran to nearly half a decade.

Figure 1 One medicine, four clocks: Trikafta / Kaftrio across markets

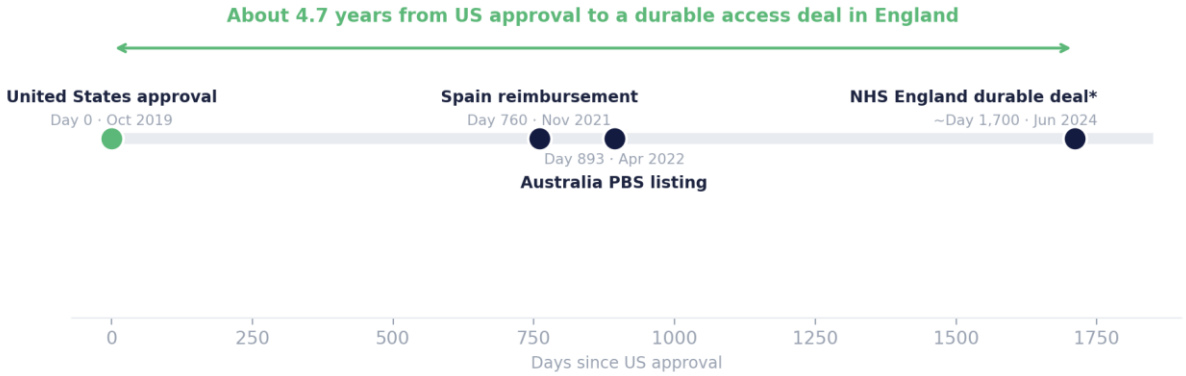

Figure 1. Dates of reimbursed access relative to US approval. Sources: Vertex and US FDA [4]; Vertex Spain [5]; Australian Government and Vertex [6]; NHS England and NICE, via FiercePharma [7]. England day count approximate to month of the deal.

Hold Trikafta up as the exception if you like. The uncomfortable truth is that it is the rule with a good publicist.

2. This is not one drug's story

If Trikafta were a one off, it would be a footnote. It is not. The EFPIA Patients W.A.I.T. Indicator, compiled by IQVIA across 168 new medicines and 36 countries, finds an average (mean) wait of 578 days from marketing authorisation to patient access. That the mean sits well above the median of 532 days is itself telling: a long tail of very slow markets is pulling the average upward. Same continent, same medicines, wildly different waits [1].

Figure 2 The same Europe, wildly different waits (EFPIA W.A.I.T. 2025, median)

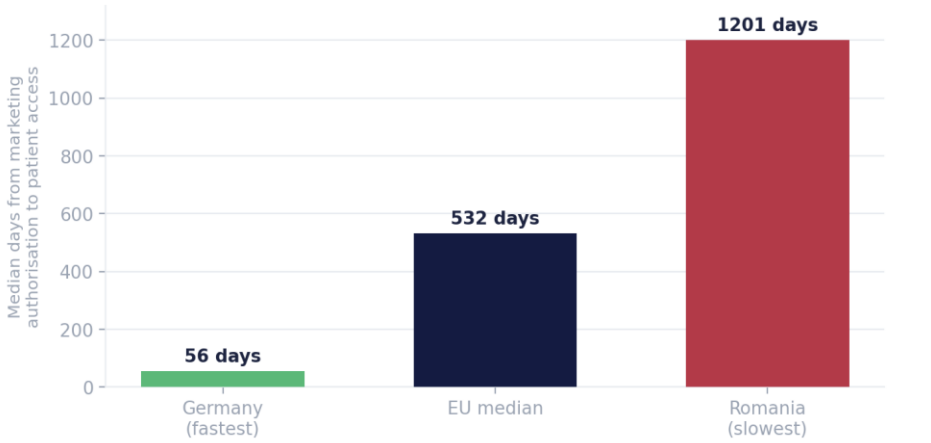

Figure 2. Median time from marketing authorisation to patient access: fastest and slowest markets against the EU median, an 88% disparity between the two extremes. Source: EFPIA Patients W.A.I.T. Indicator 2025 [1].

More troubling is the direction of travel. The share of new medicines fully available on public reimbursement lists is only part of it. It is not only the wait that is worsening but the odds of access at

all. Nearly half of these medicines, 49%, were not available to patients in Europe, up from 46% in 2019, and the share available only under restrictions has climbed to 17%, from 6% [1]. Access, in other words, is going backwards.

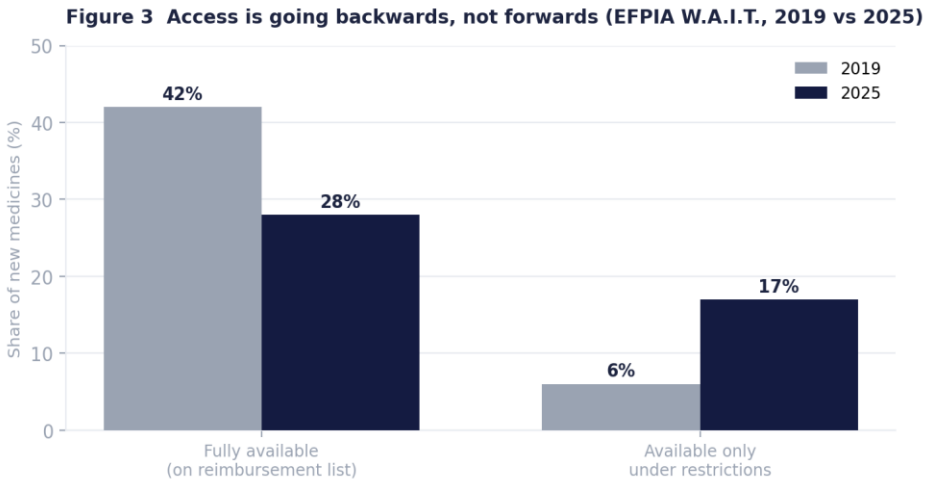

Figure 3. Availability of new medicines on public reimbursement lists. Source: EFPIA Patients W.A.I.T. Indicator, 2019 and 2025 [1].

The pattern repeats across very different therapies. When Novartis launched the gene therapy Zolgensma, it created a programme called Day One specifically to give patients access ahead of formal reimbursement, an implicit admission that the standard timeline leaves a gap worth bridging at the company's own expense [11]. When the first CAR T cell therapies, Kymriah and Yescarta, were approved by the EMA in 2018, patients in parts of Central and Eastern Europe did not receive them until late 2019 and 2020 [20]. A breakthrough, it turns out, does not arrive everywhere at once. It arrives on a rolling map drawn by payer, launch complexity and postcode.

Therapy	Condition	Access span across markets	What it shows
Trikafta / Kaftrio (Vertex)	Cystic fibrosis	US Oct 2019; Spain Nov 2021; Australia Apr 2022; England Jun 2024. About 4.7 years to a durable, long term access deal in England [4,5,6,7].*	A celebrated launch that still left patients in some markets waiting years for a medicine already reaching others.
Zolgensma (Novartis)	Spinal muscular atrophy	US May 2019; EU conditional approval May 2020, for a narrower indication than the US [11].	The maker built its own bridge, the Day One access programme, precisely because reimbursement lags approval [11].
Kymriah, Yescarta (CAR T)	Blood cancers	EMA approval 2018; first uses in parts of Central and Eastern Europe not until late 2019 and 2020 [20].	Even breakthrough therapies arrive on a rolling map, and the map is drawn by geography and payer, not by need.

Table 1. Three therapies, one pattern. Sources as cited.

3. What the wait actually costs

It is tempting to file access delay under ethics and move on. That would be a mistake, because the commercial case is just as stark. Peer reviewed research from Tufts, spanning 645 launches since 2000, estimates the cost of a single day of launch delay at approximately **500,000 US dollars in lost**

sales, a figure that scales to roughly 3.5 million a week and 15 million a month [8]. State the unit and the point makes itself.

This lands on an industry that is not, on the whole, launching brilliantly to begin with. McKinsey's analysis of drug launches found that about two thirds miss their own expectations, and that early stumbles tend to stick: of the launches that lagged in year one, most continued to lag in years two and three [9]. A slow launch is rarely a slow start followed by a strong recovery. It is usually just slow.

And the window in which to recover is narrowing. Industry analysts estimate that around 236 billion US dollars of revenue is exposed to loss of exclusivity by 2030, with some estimates higher still [10]. When the patent runway shortens, every month lost to access delay is a month subtracted from a shorter earning life. The same delay costs more in 2026 than it did in 2019, even if the delay itself has not grown. It has simply become more expensive to afford.

> *A fixed delay is no longer a fixed cost. Measured against a shorter runway, the same lost months are worth more than they used to be.*

4. Why the delays persist: the expert view

If the cost is so clear, why does the delay endure? The most credible answer is that it is not one problem but many, wired together. Charles River Associates, in work commissioned by EFPIA, documents ten interrelated factors behind unavailability and delay, and offers a line of real honesty for a benchmark describing its own field: it is not possible to untangle their impact with perfect precision [3]. The environment shapes commercial decisions, and the decisions reshape the environment.

Where the days go	The mechanism
Before marketing authorisation	Regulatory review in Europe runs slower than the US. One 2025 analysis of 152 novel oncology therapies found 94% were cleared by the FDA before the EMA [15]. Expedited pathways are used less often in the EU [3].
Starting the pricing clock	In many markets the pricing and reimbursement process does not begin automatically. External reference pricing gives a company a rational reason to launch late, or not at all, in lower priced markets, to protect prices elsewhere [3,12].
The value assessment itself	Health technology assessment bodies ask for different evidence. A 2024 study of six European agencies found material divergence in the evidence they will accept for the same oncology medicine [3,14].
Paying for the decision	Even after a positive assessment, budgets, regional approvals and local formularies add further delay. Availability, EFPIA notes, is not the same as access [3].

Table 2. Where the days go, drawn from the CRA and EFPIA root cause analysis [3] and the sources noted.

The single most illuminating strand of the academic literature concerns pricing. In a study of twenty five major markets, Danzon and colleagues [12] showed that because a low price in one country spills over to others through external referencing and parallel trade, a manufacturer may rationally prefer to delay a launch, or skip a market altogether, rather than accept a low headline price . Panos Kanavos and colleagues at the London School of Economics have since documented how widely external reference pricing is applied, and how unevenly it works in practice [13]. The delay, in short, is not always accidental. Sometimes it is the entirely predictable result of a system that rewards waiting.

Layered on top is genuine disagreement about evidence. A 2024 study of six European health technology assessment bodies found they often require different evidence to judge the very same oncology medicine [14], while regulatory review in Europe trails the United States: one 2025 analysis

of 152 novel oncology therapies found 94% reached the FDA before the EMA [15,16]. Each hurdle is defensible on its own terms. Stacked together, they produce a wait that no single actor intended and no single actor owns.

5. The accelerant: what AI does to this picture

Into this slow moving system arrives a fast moving technology. The evidence on AI in drug discovery is still maturing, and it deserves a sceptic's eye. But the direction is not in serious doubt. A joint analysis by BCG and Wellcome estimates time and cost savings of 25% to 50% in the discovery to preclinical phase [17]. Insilico Medicine has reported positive Phase IIa results for rentosertib, described as the first medicine both discovered and designed end to end with generative AI, having reached the clinic in a fraction of the usual time [18].

Prudence is warranted. Not every AI designed candidate survives contact with a patient, and at least one high profile programme was discontinued after early trials [19]. Compressing discovery does not guarantee clinical success. But even on conservative assumptions, AI shortens the front of the pipeline while leaving the back of it, the pricing, the assessment, the reimbursement, entirely untouched. The consequence is an asymmetry.

Figure 4 The compression asymmetry (conceptual)

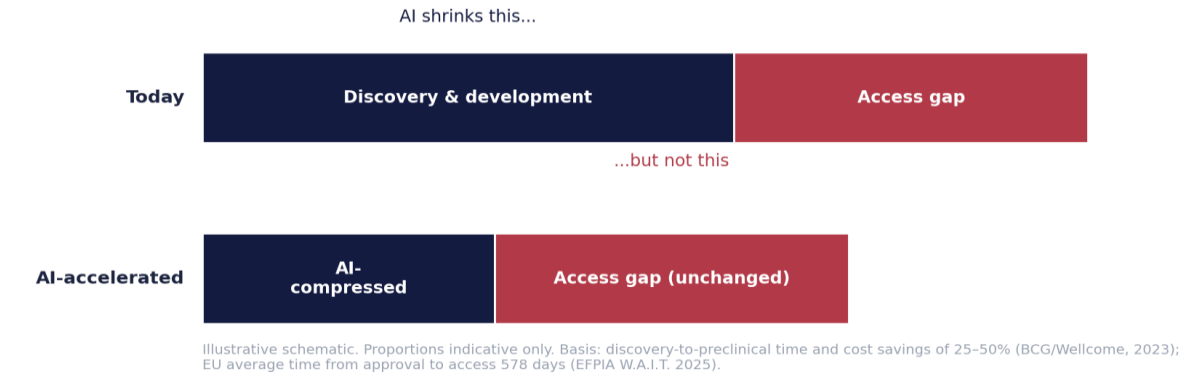

Figure 4. Conceptual only, proportions indicative. As discovery compresses, the access gap becomes the dominant share of the time between a good idea and a treated patient. Basis: discovery to preclinical savings of 25% to 50% [17]; average approval to access of 578 days [1].

The faster the industry gets at making medicines, the more conspicuous the years spent not delivering them become. AI does not create the access gap. It shines a very bright light on it, and it moves the gap to the centre of the story.

6. The missing instrument

Here is where we put the BLX™ view on the table, and label it as such. We believe a meaningful part of the problem is that the industry has no shared, robust, forward-looking measure of what a launch delivers for patients.

Consider what is measured today. Commercial success is tracked obsessively, in sales against forecast, and by that measure most launches disappoint [9]. Access is measured too, but late and inconsistently. The EFPIA indicator, valuable as it is, records availability, meaning a listing on a reimbursement schedule, and its own authors are careful to note that availability is not the same as access for an actual patient [3]. Health technology assessment bodies, as we have seen, cannot even

agree on the evidence [14]. There is no common instrument that a launch leader can point to on day one and say, this is the number we are here to move.

> *What gets measured gets managed. Time to patient access is measured late, unevenly, and after the fact. So, predictably, it is managed the same way.*

We are not claiming that a single metric would dissolve external reference pricing, or reconcile six HTA bodies, or repeal the patent cliff. We are making a narrower and, we think, defensible claim: you cannot manage well what you have chosen not to measure well, and the industry has not chosen to measure the patient's wait with anything like the rigour it applies to the quarter's revenue.

7. A modest proposal: measure the wait

The metric we propose is deliberately plain. Time to First Patient Access is the number of days between marketing authorisation and the first patient actually receiving a therapy, measured market by market, and treated as something to protect while there is still time to protect it.

It is forward looking by design. Most launch measurement is a post mortem, precise about a window that has already closed. This one is meant to be read on day one, when the sequencing decisions, the evidence dossiers and the payer conversations that determine the wait are all still live. It is also, deliberately, a shared measure. The best launch practices should not stay locked inside individual companies. A common, transparent benchmark is how a field examines, challenges and improves them together.

In the interest of the honesty this paper has tried to keep, one caveat. The benchmark for this measure, which we call the TFPA Global Index, is in development. It is not a finished product, and we think building it with the people who run launches than hand it to them complete is the only rational approach to take. This paper is part of that invitation.

8. Conclusion

The industry is on the cusp of making medicines faster than at any point in its history. That achievement will be measured, fairly, in breakthroughs. It should also be measured in something less flattering and more human: the days a patient waits after the science is already settled.

Trikafta was a triumph. It also made patients wait years for a medicine that already existed. Both statements are true, and holding them together is the beginning of a better way to judge a launch. The first step is not a new platform or a new pricing model. It is a number we agree to watch. If this paper persuades you of anything, let it be that the wait is worth counting, and that counting it is where the next chapter of launch excellence begins.

A note on method and caveats

Figures are reproduced from the cited sources and, in the case of the Trikafta timeline, calculated from published approval and reimbursement dates. Access figures follow the EFPIA definition of availability as a reimbursement listing, which, as its authors stress, can overstate real patient access. The cost of delay figure is an industry average across many therapy areas and will vary widely by asset and market; it should be read as an order of magnitude, not a promise. Figure 4 is an illustrative schematic and its proportions are indicative only. Patent cliff estimates vary by source and methodology, and we have cited a conservative figure. Where we have offered our own interpretation,

rather than a sourced fact, we have said so in the text. Our intention with this discussion paper is to open up a dialog with industry professionals so please do share your thoughts.

*** On the England milestone.** Where this paper dates England's access to Trikafta (Kaftrio) to 2024, including in Figure 1 and Table 1, we mean the point at which a durable, long term reimbursed arrangement was settled following full appraisal by NICE, not the first day a patient could receive the medicine. England moved quickly to make the therapy available: on 21 August 2020, the day the European licence was granted, an interim commercial agreement made Kaftrio immediately available to eligible patients. That agreement was, by its own terms, temporary, set to run for four years while further data was gathered and prices were reviewed. We anchor on the durable arrangement because it marks the point at which access moved from a conditional, time limited footing to a permanent one, and both stages belong in an honest account of time to dependable patient access. Sources: NHS England, 21 August 2020; Cystic Fibrosis Trust, 30 June 2020.

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