A BRANDLAUNCHX DISCUSSION PAPER

The Global TFPA Index

A fresh, shared way to measure launch access, built as a tool for launch leaders to advance launch excellence

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De-Risk. Accelerate. Maximize. Launch Success.

This paper describes a measure and a benchmark that are in development. Where we describe design intent rather than an existing capability, we say so. External figures are referenced, and the endpoint used for any observation is graded so that different kinds of evidence are never treated as if they were the same.

The idea, in one paragraph

Time to First Patient Access, TFPA, is the number of days between a medicine being approved and a patient actually being able to receive it, measured market-by-market. Regulatory approval and reimbursement milestones are widely reported. The day a patient is first treated is measured far less consistently, and almost never on a common basis across therapies and markets. The **Global TFPA Index** is our proposal to close that gap: a shared, transparent framework to see the wait, understand it, and act on it, with a single precise definition and a clearly defined grade attached to every observation. It is in development, and it has evolved thanks, in part, due to the input of the wider launch community. This short paper sets out what it is, the two ways it is meant to be used, and just as importantly, what it is not. It is not a scorecard for marking launch leaders down. It is a tool built to help them delver repeatable launch excellence.

Why a shared measure

Access varies enormously and lives nowhere on the launch dashboard. In EFPIA's 2025 W.A.I.T. survey, the EU27 median time from marketing authorisation to recorded availability was 532 days, with country medians ranging from 56 days in Germany to 1,201 days in Romania [1]. For most countries, availability means inclusion on a public reimbursement list, and does not necessarily indicate patient use or uptake. It is a proxy, and sometimes a flawed one. But the spread is real, and it is large. A number that big, moving that much between markets, and yet tracked on no common cross-market benchmark, is at odds with the data and evidence driven ethos that underpins good launch discipline. The oft quoted saying “What gets measured gets managed” does not account for the need for the right things to be measured in the first place. We think TFPA is a “right thing” and it exists to make the wait a variable a team can steer, rather than one it simply absorbs.

What the Global TFPA Index is

It helps to keep two things distinct. TFPA is the metric: the days from approval to the point a patient is first treated in a given market. The Global TFPA Index is the product built on top of it: a shared benchmark, designed to let a launch team see its own performance and compare it, fairly, with what comparable therapies achieve in comparable markets. To be clear, the benchmark is in development. We are not claiming a live dataset or a finished index here. We are describing how it is designed to work and inviting the field to shape it.

One definition, and an honest grade

A measure is only worth having if everyone means the same thing by it. So the endpoint is defined precisely. **Realised TFPA** is the number of calendar days from the relevant marketing authorisation, for a specified product, indication and market combination, to the first verified dispensing or administration to an eligible patient through an authorised access route in that market.

That is the true event. It cannot always be observed, and transparency about that is part of the design. Where a cleaner signal is not available, a proxy is used, but it should never be allowed to masquerade as the real thing. Every observation carries an evidence grade, so a reader always knows what was actually measured.

Grade	Endpoint observed	What it really tells you
A	First verified dispensing or administration to an eligible patient	A patient was actually treated. The true measure.
B	First hospital purchase, paid claim or recorded commercial sale	The medicine has been bought and can reach a patient. A close proxy.
C	Reimbursement listing or comparable administrative availability	A payer decision is in place. Availability, not yet treatment.
D	Announced or forecast access date	An intention, not an event. The lowest grade of TFPA evidence.

Grading lets the Index keep broad coverage without pretending that a reimbursement listing and a treated patient are the same milestone. Comparisons are made like grade with like grade, and a lower grade is a prompt to go and find better evidence, not a place to hide.

A shared measure also has to survive contact with the real world, and the method has to settle the hard cases openly: whether early-access, named-patient and compassionate-use treatment count; whether the clock starts from central approval or local authorisation; how indication extensions and new formulations are handled; whether access must be reimbursed or may be privately funded; how markets with many payers, the United States above all, are defined; and how ultra-rare diseases are treated, where the time to a first patient can reflect how rarely a patient presents rather than how well a launch was run. None of these is a reason not to measure. Each is a reason to measure carefully, and to say what was measured.

Two lenses

The Index is meant to be read through two lenses. The first is **against your own plan**. Forecast TFPA is the access timeline a team commits to before launch, market by market. Realised TFPA is what actually happens. The distance between the two could be one of the most useful management signals a launch has, and it is one that teams rarely write down. Read from day one, forecast against emerging reality, it turns access from a post mortem into something a team can observe while there is still time to act.

The second lens is **against the field**. A realised number only means something in context. Ninety days might be excellent for one asset in one market and disappointing for another. The Index is designed to compare like with like, similar therapy, similar market, similar access pathway, so that a team can see not only its own number but whether that number is good. This is the facet that lets the industry begin to define what good actually looks like, rather than each company guessing in private.

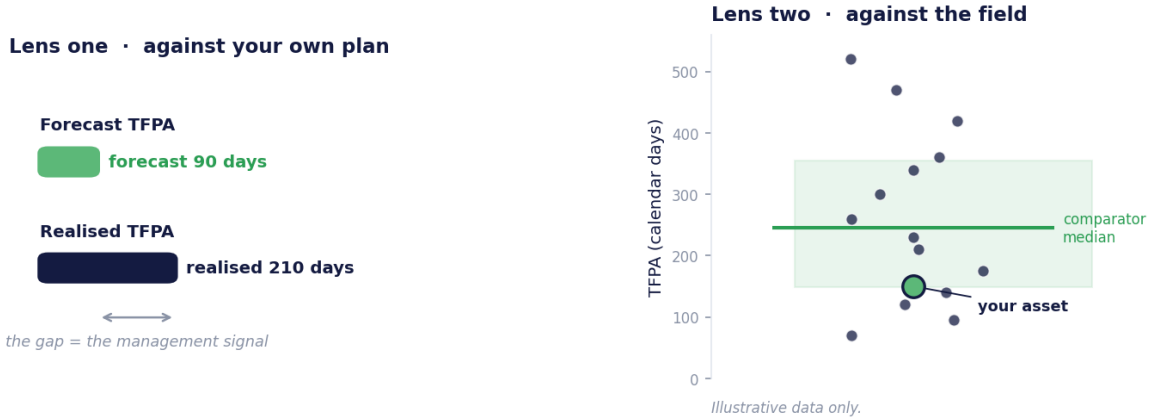

Figure 1. Illustrative. Lens one compares a team's forecast with its realised result in calendar days; lens two places that result against the distribution of comparable therapies and markets. Illustrative data only.

A tool, not a rod

The philosophy matters, so let us be blunt about it. A measure like this could easily become a stick. That is clearly not the intent, and it would be self-defeating. TFPA is designed to be objective, transparent and, above all, contextual. A launch leader inherits a system they did not design: pricing rules, external reference pricing, reimbursement queues, supply realities, compliance requirements. Some delays reflect deliberate sequencing decisions, including responses to external reference pricing, rather than poor execution. Holding a launch in a lower price market to protect a reference price elsewhere, or waiting to satisfy a legitimate compliance requirement, is a considered, reasonable constraint, not a failure. These reasons are not "excuses" but facts of life science innovation and must be factored accordingly.

So the proposed methodology will aim to stratify results by the contextual factors that matter and to distinguish, where the evidence permits, between controllable and externally driven delay. True attribution is genuinely hard, because pricing negotiations, submission timing, regulatory requirements, payer decisions, manufacturing readiness, centre accreditation and patient presentation can all overlap, and we will not pretend otherwise. Used well, the Index gives a launch leader something they rare: a defensible account of their own performance in context, that they can take to a board, an investor or a payer, and say, here is where we stand, here is why, and here is what we plan to do about it.

> *The aim is not to judge launch leaders against an unfair ideal. It is to give them a fair mirror, and then the tools to act on what it shows.*

From a shared measure to shared movement

Measurement is only the start. The goal is to define what good looks like for a given asset and market, and then to understand why the strong performers are strong. That is the forensic half of the idea: a set of discovery tools, in development, intended to help trace the contributing factors behind a fast or a slow TFPA, so that the insight can be shared rather than relearned in private each time. The ambition is deliberately collaborative. The best launch practices should not stay locked inside individual companies. A shared, transparent benchmark, paired with honest root cause discovery, is how a community examines, challenges and improves its own craft together. It is worth noting that measurement of first access is not entirely new. Published work has tracked it or close proxies, including an Italian study of advanced therapies that found an average of 340.6 days from publication of the reimbursement decision to first patient treatment [2]. What is still missing is a consistent, transparent, cross-market benchmark. That is the gap the Index is built to fill.

Figure 2 From a shared measure to shared movement

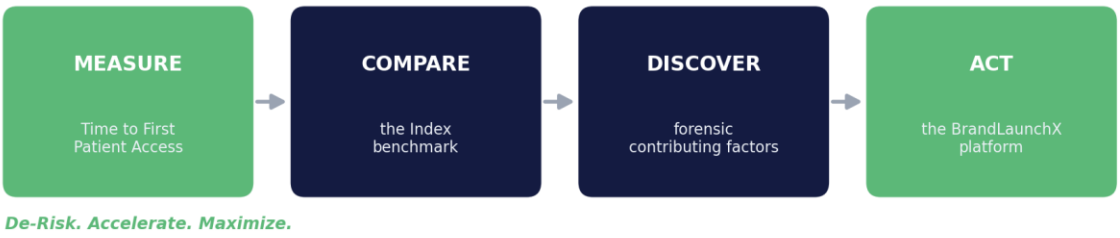

Figure 2. The intended arc: measure with TFPA, compare through the Index, discover the contributing factors, then act.

Made for a global picture

A global index cannot lean on a single common reimbursement milestone, because health systems do not share one. National single payers, regional reimbursement, hospital formulary decisions, the fragmented payer landscape of diverse markets like the United States, private-pay routes, early-access programmes and centre qualification for advanced therapies all reach a patient by different roads. The endpoint hierarchy and comparator model will be adapted to different health-system structures while preserving a common core definition. Every result will disclose the endpoint used, its evidence grade and the relevant access pathway, so that a robust comparison across very different markets is possible.

Complementary to the BrandLaunchX platform

TFPA and the BrandLaunchX platform do different jobs, by design. The Global TFPA Index is the shared, industry facing measure: it is intended to tell a team where it stands and what good looks like. The BrandLaunchX Launch Impact Navigation platform is the private toolset that helps a team act, bringing its planning, prediction, recommendation and acceleration capabilities to the orchestration and execution of a launch. In short, the Index is intended to reveal the gap; the platform is designed to help teams investigate and address it. One is the microscope, the other is the toolkit. Together they serve to de-risk, accelerate and maximize the launches that patients are waiting on.

Who it serves

Our focus has been on three main protagonists. For the launch leader, an objective, contextual read on performance, and a route to improve it rather than just be measured by it. For the investor, the ambition is to develop a potential leading indicator of launch execution quality, subject to validation against subsequent access and commercial outcomes, and read earlier than the revenue line will ever reveal it. For the patient, the point of all of it, the intended benefit is earlier identification and management of the avoidable barriers that stand between an approved medicine and dependable access to it. Put plainly, faster access to approved novel therapies in more markets. When those three interests are measured on the same clock, the hypothesis is that launch excellence drivers become more aligned.

An invitation

The Global TFPA Index is in development, and deliberately so. We would rather shape it with the people who run launches than hand it to them finished. If you carry a launch, fund one, or wait for one, we would value your view on where the endpoints should sit, on how the grades should work in your markets, and on what else launch excellence ought to measure.

A note on method

Realised TFPA is defined as the calendar days from the relevant marketing authorisation to the first verified dispensing or administration to an eligible patient through an authorised access route, for a specified product, indication and market. Where that event cannot be observed, a graded proxy is used and labelled, from grade A for a verified treated patient to grade D for an announced or forecast date. Access figures such as the EFPIA benchmark record reimbursement-list availability, not patient uptake, and are treated as a grade C proxy. The Index, its comparator model and its discovery tools are in development; no live benchmark, validated investor signal or quantified causal model is

claimed in this paper. Where we have described design intent rather than an existing capability, we have said so.

References

[1] EFPIA. Patients W.A.I.T. Indicator 2025 Survey, prepared by IQVIA; published May 2026, data current to 5 January 2026. EU27 median time from marketing authorisation to recorded availability of 532 days, ranging from 56 days in Germany to 1,201 days in Romania. Availability is defined for most countries as inclusion on a public reimbursement list and does not necessarily indicate patient use or uptake. https://www.efpia.eu/media/mnfdwzax/efpia-patients-wait-indicator-2025.pdf

[2] Jommi C, et al. Advanced Therapy Medicinal Products: Availability, Access and Expenditure in Italy. BioDrugs, 2024. Reports an average of 340.6 days from publication of the reimbursement decision to first patient treatment across authorised administration centres, an example of first-access measurement using a verified treatment endpoint. https://doi.org/10.1007/s40259-024-00683-0

[3] WHO. Substandard and falsified medical products, fact sheet, 3 December 2024. On the conditions under which limited access to affordable, quality-assured medicines is associated with greater circulation of falsified products. https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

[4] Vogler S, et al. The impact of external reference pricing on medicine prices and launch timing: evidence is associational and heterogeneous, and systematic reviews caution that the strength of the effect varies. Referenced here in support of the statement that some launch sequencing reflects deliberate responses to external reference pricing rather than execution quality.

Note: references [2] to [4] are cited to substantiate, respectively, the existence of prior first-access measurement, the distinction between reimbursement and treatment, and the role of external reference pricing in launch sequencing. Full bibliographic details are held on file and will accompany any published version.