TRINITY

WHITE PAPER

Moving the Needle: Lessons from the 2023 Launch Class

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The 2023 launch class exceeded Trinity Life Sciences' expectations with only 50% underperforming their pre-launch first year forecasts while 39% overperformed, indicating an improvement from prior years (54% and 35%, respectively, for 2020–2023)[1].

This was driven by notable improvements in "Specialty and Large Market" products (36% overperformed vs. 18% average in years prior) and First Launch Companies (33% overperformed vs. 20% in years prior).

The needle is moving.

Performance of Product Launches by Company Type[2]

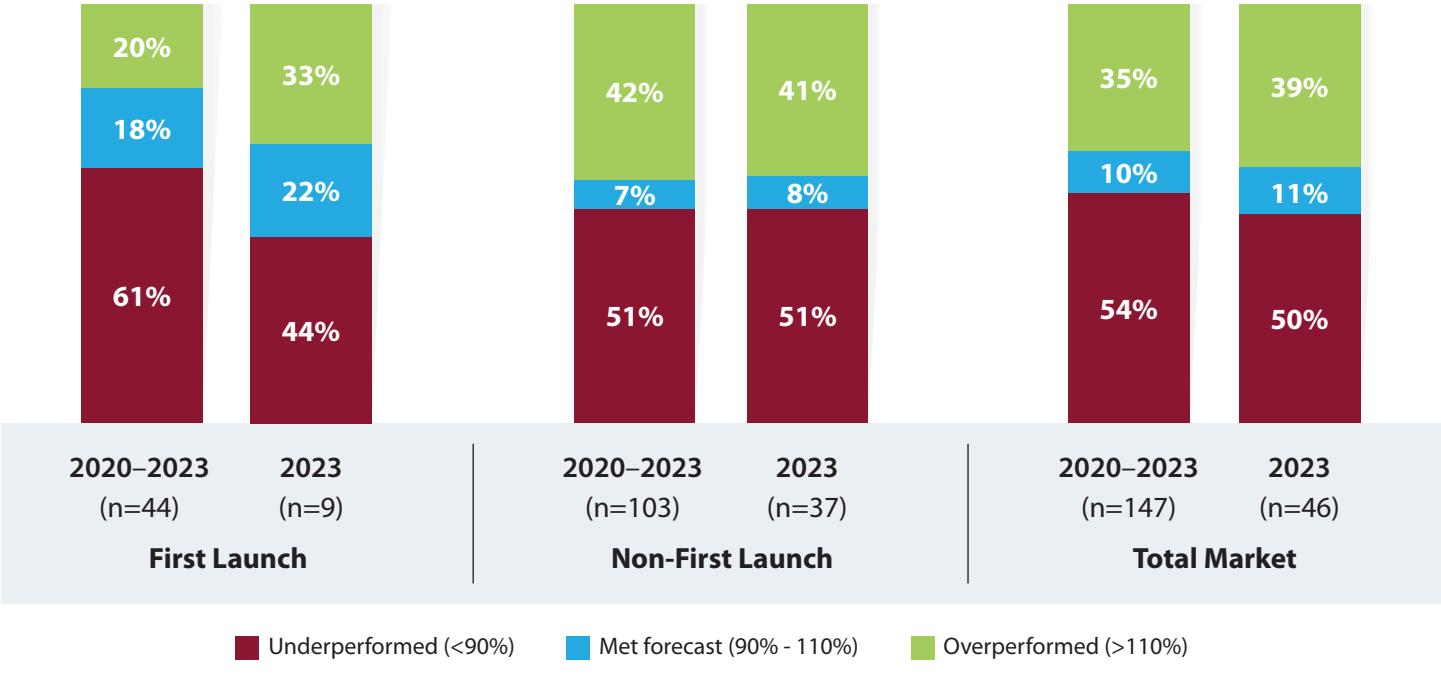


FIGURE 1 | Performance of new product launches by company type relative to first year forecast, for U.S. launches. Comparing products launched between January 2020 and December 2023 with the 2023 Launch Class (January 2023–December 2023).

[1] References Trinity's September 2023 whitepaper: What Lies Ahead for New Product Launches?

Performance of Product Launches by Category[2]

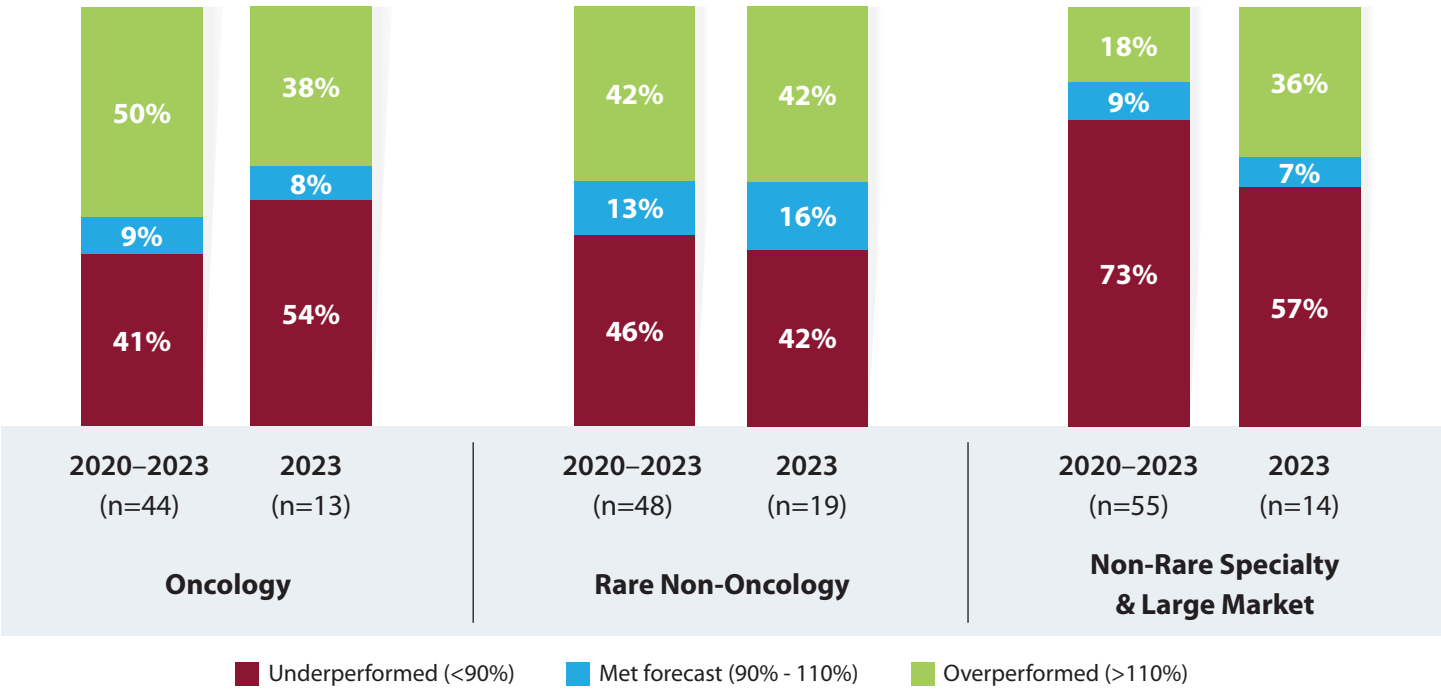


FIGURE 2 | Performance of recent product launches by category relative to first year forecast, for U.S. launches. Comparing products launched between January 2020 and December 2023 with the 2023 Launch Class (January 2023–December 2023).

We found that success in first year performance could be attributed to two main factors:

1. **Demand in high unmet need spaces**
   Treating a condition with very limited or no existing pharmacological treatments

2. **Launch experience and strong track record in more established or complex markets**
   Leveraging past launch experience to attain early success

Throughout this white paper, we will explore cases of products that achieved first year launch success thanks to these factors across various modalities and market sizes.

[2] Source: Analyst consensus forecast (reported from EvaluatePharma & Analyst Reports) & Company Reported Sales Performance is measured by comparing reported first calendar year sales against pre-launch forecasted first calendar sales from Evaluate pharma or analyst reports. Performance data are limited by the availability of full year sales in the calendar year of launch and the availability of a pre-launch forecast.

Recent Select Overperforming Launches

Asset	Company	Indication	Category	First Launch	Performance	Launch Year Revenue ($M)	Forecasted Revenue ($M)
AREXVY®	GSK	RSV infections	Specialty and Large Market	8/17/2023	1388%	$1,485	$107
ABRYSVO®	Pfizer	RSV infections	Specialty and Large Market	9/30/2023	879%	$888	$101
BEYFORTUS®	Sanofi	RSV infections	Specialty and Large Market	9/30/2023	647%	$440	$68
DAYBUE™	ACADIA Pharmaceuticals	Rett Syndrome	Rare (Non-Oncology)	4/17/2023	611%	$177	$29
IZERVAY™	Iveric Bio (Acquired by Astellas Pharma)	Geographic Atrophy	Specialty and Large Market	9/1/2023	559%	$84	$15
SYFOVRE®	Apellis	Geographic Atrophy	Specialty and Large Market	3/31/2023	500%	$275	$55
SKYCLARYS®	Reata Pharmaceuticals (Aqcuired by Biogen)	Friedreich's Ataxia	Rare (Non-Oncology)	6/27/2023	211%	$93	$44
EPKINLY™	Genmab	Adult Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)	Oncology	6/30/2023	130%	$61	$47
ELEVIDYS®	Sarepta Therapeutics	Duchenne muscular dystrophy (DMD)	Rare (Non-Oncology)	8/2/2023	125%	$200	$160
JAYPIRCA®	Eli Lilly	Adult Patients with Relapsed or Refractory Mantle Cell Lymphoma	Oncology	3/31/2023	121%	$75	$62

FIGURE 3 | Notable recent examples of companies demonstrating successful commerical performance, based on actual revenue relative to first year forecast

1 Demand in high unmet need spaces

Launches in high unmet need spaces saw the most success in their first year regardless of the type/size of the company bringing the product to market or the type/size of the market. These launches included products with strong clinical value for conditions without existing treatments, such as RSV vaccines, Friedreich's Ataxia, Geographic Atrophy, Rett Syndrome and Demodex blepharitis. For rare disease companies in particular, early market development efforts created a path to success through early patient finding/identification and rapid access attainment.

First Year of Launch Success Examples

RSV Vaccines

One of the larger unmet need spaces to see progress in 2023 was the prophylactic use of RSV vaccines, which marked a significant public health achievement after decades of research. Three vaccines—from **Pfizer (ABRYSVO®)**, **Sanofi (BEYFORTIS®)** and **GSK (AREXVY®)**—were approved for adults 60+, as well as a maternal vaccine to protect infants. Success came from advances in stabilizing the virus's prefusion F protein, a critical target for neutralizing antibodies. In addition to being launched by established players with deep experience in vaccine research and commercialization, the wide unmet need for these vaccines enabled all three products to concurrently exceed forecast. That all three were able to exceed forecast, despite competitive headwinds on all sides, shows how intense the unmet need was for preventative RSV treatments.

SKYCLARYS® (Reata Pharmaceuticals)

Reata immediately became a household name in the Rare Disease community for their launch of SKYCLARYS as the first treatment for **Friedreich's Ataxia** (FA). FA is a rare, inherited, degenerative disease that damages the nervous system, characterized by impaired coordination and walking. The strong commercial uptake and commensurate increase in stock price culminated in a successful purchase by Biogen.

Given the rare disease population, Reata invested in efforts aimed at patient identification. Prior to approval, Reata conducted mapping of the highest target physicians treating FA patients as well as the key centers of excellence, including Collaborative Care Research Network (CCRN) centers. Reata drove early engagement with CCRNs and proactively worked with them to understand needs and drive awareness, going beyond traditional practice centers to find patients where they were most likely to receive care. Reata also invested in sales support tools to identify patients and target promotional efforts on FA-treating HCPs.

Reata put a heavy emphasis on patient access and support. The company hired a patient access liaison team to engage with practices on access requirements and navigating payer criteria. Reata's REACH platform provided comprehensive patient access resources to connect patients to care navigators and served as the intake center for all SKYCLARYS start forms. In just the first two months of approval, the platform received over 500 patient start forms across 250+ HCPs.

Reata took a relatively nuanced commercial approach, launching with a streamlined group of 50 seasoned sales reps targeting 2,500 HCPs. This focused strategy helped to activate the early centers while putting HCP needs front and center, ultimately resulting in fast uptake of SKYCLARYS.

Looking ahead, Biogen's acquisition of SKYCLARYS complements their existing neurology portfolio and there will be further benefits from Biogen's expertise in patient access and support. This additional support from Biogen's existing neurology franchise will position SKYCLARYS to help more patients over its lifecycle.

SYFOVRE® (Apellis) and IZERVAY™ (Iveric)

Prior to 2023, **Geographic Atrophy** (GA), an advanced form of dry age-related macular degeneration (AMD), was an area of major unmet need in ophthalmology. 2023 saw the launch of two products: SYFOVRE from Apellis, approved in February 2023, and IZERVAY from Iveric (acquired by Astellas Pharma), coming to market just months later in August 2023. Both products far exceeded initial forecasts and are poised for greater gains throughout their respective product lifecycles.

Both SYFOVRE and IZERVAY benefited from a wide unmet need: prior to 2023, no products were approved in GA, with an estimated 1.5 million patients in the U.S. and 5 million patients globally with the disease. GA is also believed to be underdiagnosed globally, leading to early market-shaping efforts on Apellis's part to build awareness of this disease state.

Apellis began unbranded campaigns in 2022, launching both dedicated ECP (Eye Care Professional) and patient-focused campaigns to generate early understanding of the condition and foster interest in new available treatments.

Through the first year of performance data, it appears that Apellis has leveraged their first-mover advantage to outperform IZERVAY in the first year of availability. In 2023, SYFOVRE sales far outpaced initial forecasts, a trend that has continued into 2024. When evaluating quarterly sales specifically, SYFOVRE's growth has been phenomenal – compound annual growth rate from launch through Q2 2024 is 54%.

For SYFOVRE, keen early efforts in market shaping and patient finding have achieved early patient growth higher than originally expected. As additional plan coverage continues in 2024, SYFOVRE is well-positioned to use their first-in-market status and familiarity with HCPs to drive continued growth.

It's likely that Iveric's product, IZERVAY, benefited from the early market-shaping efforts from Apellis, as their immediate 2023 uptake was far above forecast, despite being second-to-market in GA.

Iveric became an Astellas company in July 2023, prior to FDA approval in August 2023. However, Iveric was still planning as a "first launch" company and indicated they would launch with the "team already in place at [...] Iveric Bio before the acquisition by Astellas."[3]

Like Reata did with SKYCLARYS, IZERVAY focused on patient support, bringing a small but experienced commercial team to field and locking in early support from key treatment centers. Iveric's strategy was to build a "focused" commercial team. Iveric deployed ~90 commercial staff (50-70 sales reps) – targeting the top 2/3 of retinal specialists that account for 80-90% of patients treated – at the point it was announced Astellas wanted to acquire the company in May 2023.

XDEMVY® (Tarsus Pharmaceuticals)

Tarsus's Demodex Blepharitis product, XDEMVY, surprised many by achieving expectations as a first launch biotech within a challenging novel ophthalmology therapeutic area. Tarsus is now poised for additional gains as they seek to expand into Part D populations later in 2024.

Tarsus has done a fantastic job of deploying scientific evidence to drive physician utilization and letting payer coverage drive commercial uptake. To that end, further commercial and government coverage wins in 2024 are setting up for a sales expansion to unlock further patient gains in 2025.

Progress has continued in 2024, with net product sales rising 65% from Q1 2024 to Q2 2024. Tarsus has been able to significantly expand their HCP footprint, with over 11,000 HCPs having now started patients on XDEMVY.

[3] https://scrip.citeline.com/SC148831/Astellas-Izervay-Joins-Geographic-Atrophy-Market-Intensifying-Competition

2 Launch experience and strong track record in more established or complex markets

For more established or competitive markets, having launch experience in the therapeutic areas and/or an existing track record of launching into challenging spaces enabled success. Established companies, particularly in oncology, leverage their size and existing relationships/infrastructure to establish themselves as "the player" in certain therapeutic areas. For example, Eli Lilly's efforts to establish a foothold in hematology/oncology enabled further success in 2023 via the launch of JAYPIRCA®. Other companies in this category, such as Sarepta, know the most important leverage points for their product and their market and aim to position themselves to activate these leverage points.

First Year of Launch Success Examples

ELEVIDYS® (Sarepta)

The long-awaited Duchenne muscular dystrophy (DMD) gene therapy treatment from Sarepta was off to a strong start in 2023 due to Sarepta's established presence within DMD. ELEVIDYS represents Sarepta's fourth marketed DMD product since EXONDYS 51® launched in 2016. Although gene therapy launches have generally struggled in recent years, Sarepta was able to achieve early uptake and position ELEVIDYS for future growth.

Sarepta's commercialization strategy focused on maintaining existing strong relationships with healthcare providers and leveraging patient advocacy groups to raise awareness. As a gene therapy, Sarepta spent generously to prepare the market and ramp up engagement with authorized treatment centers capable of administering gene therapies and ensured comprehensive training for physicians. Strong reimbursement strategies, including partnerships with payers and specialized distribution networks, were critical to ensuring access. Finally, the outputs of early access programs and strong data from clinical trials helped drive physician adoption and patient interest in the first year.

EPKINLY™ (Genmab/AbbVie)

EPKINLY is co-commercialized by Genmab and AbbVie in the U.S. for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). EPKINLY is a highly anticipated bispecific antibody with a strong efficacy profile that eliminates the hurdles and burden of cell therapies. Despite competing against COLUMVI™ (Novartis), which also received approval in 2023, EPKINLY had the first-mover and convenience advantage of a once-monthly subcutaneous route of administration (compared to COLUMVI: IV, step up dosing with QW for first 2 weeks followed by Q3W). EPKINLY has quickly secured a Category 2A preferred regimen recommendation in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guideline. The company's go-to-market strategy focused on leveraging the first-mover advantage with a focus on key accounts and customers, utilizing field medical, sales and market access teams across both Genmab and AbbVie. Genmab and AbbVie's combined experience in hematology-oncology certainly helped navigate the early diagnosis, treatment and reimbursement realities inherent in complex new therapies of this type. The results have been impressive, with strong customer engagement and rapid access, covering 99% of medical lives in the U.S. within the first 5 months of launch.

JAYPIRCA® (Eli Lilly)

As Eli Lilly continues to grow the oncology franchise, it has seen success with the launch of JAYPIRCA in relapsed or refractory mantle cell lymphoma in March 2023 and in chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in December 2023. In fact, Lilly's oncology portfolio became the second highest contributor to the company's revenue in 2023. JAYPIRCA's higher price tag of $21,000 per month is justified by its mechanism that allows for sequential use in patients who have failed on an earlier BTK, creating a clear value proposition and positioning it in later lines of therapy. JAYPIRCA's success is also supported by an extensive pipeline, with 16 indications currently in clinical trials for this asset.

The First Year Can Be a Challenge, But All is NOT Lost

Notably, first (or second) launch companies in oncology have seen more limited uptake (e.g., Gamida Cell, BioLineRx, Coherus) in their first year on market. In addition to commercial complexities, emerging oncology companies often experience challenges with manufacturing/supply. If not addressed quickly, these can serve as a cautionary tale of how operational or technical elements of commercialization can constrain an emerging biotech company's ability to achieve their ambition for these therapies.

For those manufacturers lacking the experience launching in these more established markets, we are seeing more muted uptake in launch year. If this is your situation, Trinity recommends being realistic about your uptake and thinking about defining success on a longer timeline to enable time to build/scale. It is possible to find success after starting slow. Since beginning this first launch performance analysis starting with the 2020 class, we have seen some "turnaround" success stories from products that underperformed initial launch forecasts but recovered to become longer-term successes.

ZEPOSIA® (BMS)

After a slow start in 2020, ZEPOSIA grew steadily, increasing YoY sales by 79% in 2022 and another 83% in 2023. BMS did not have a strong multiple sclerosis franchise at the time of launch in 2020, which may have muted their launch in the first months on market. After obtaining wider access in 2021, ZEPOSIA eventually took off and is now positioned for peak year sales above $900M.

EVRYSDI® (Genentech)

Despite missing their forecast in 2020, Genentech's SMA product rallied very well in 2021, achieving 581% growth from years 1 to 2. This is potentially due to the prior existence of Biogen's SPINRAZA® dampening initial EVRYSDI uptake. As HCP familiarity increased and EVRYSDI's dosing convenience story became clear, Genentech was able to leverage their wider Neurology franchise to overcome the early hurdles and achieve sustained growth.

Product	First-year U.S. Sales (vs. Forecast)	2023 U.S. Sales	Trinity Drug Index Rating / Performance[4]
ZEPOSIA®	$10M (26% of forecast)	$324M	3.1 / 5 (11th out of 58 products)
EVRYSDI®	$61M (56% of forecast)	$562M	3.5 / 5 (4th out of 58 products)

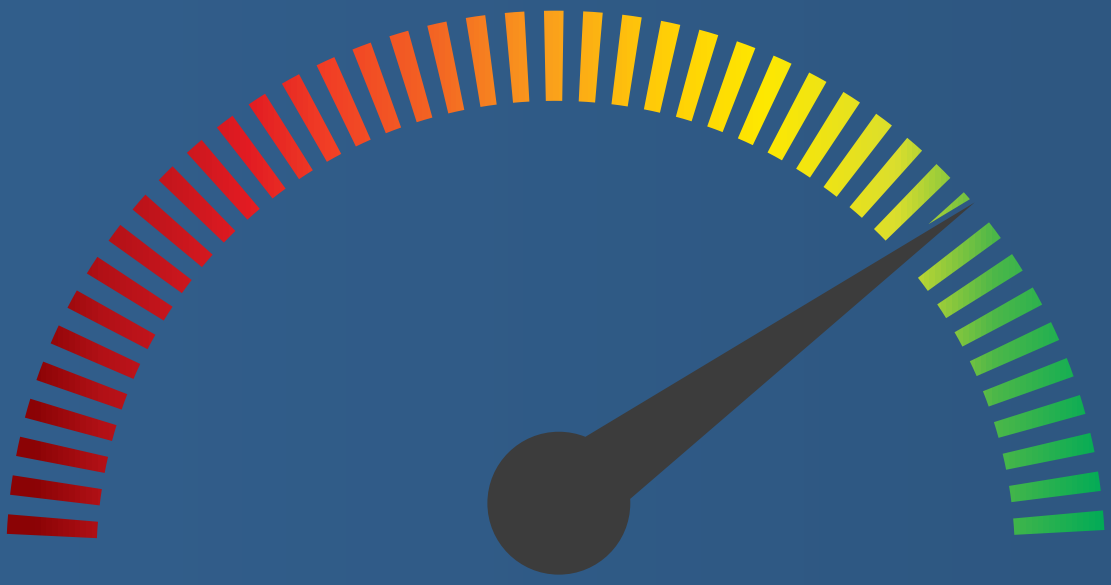
FIGURE 4 | ZEPOSIA and EVRYSDI demonstrate that it is possible to find success after starting slow.

[4] References Trinity's January 2024 whitepaper: Trinity Annual Drug Index: Evaluating the Commercial Performances of Novel Drugs Approved in 2020

Looking Ahead

Trinity's market analysis for 2023 predicted similar performance to 2022 due to the high number of non-rare specialty and large market drugs approved that year. The actual launch results exceeded expectations (with the success of RSV vaccines a notable driver), despite traditionally high underperformance rates in both the first launch and non-rare specialty and large market categories. With the advent of GLP-1 medications in larger markets throughout 2023 and 2024, we are excited to see whether this momentum outside of rare markets can be continued in future years.

In 2025 and beyond we hope to see the needle continue to move, and we will continue to track whether our thesis explored above holds true: to achieve early (first year) success a product must either treat a truly untreated disease area, or be supported by a sophisticated, well-built commercial franchise with experience in the space. Otherwise, plan for and expect a slower uptake and focus on setting an early foundation that will enable strong growth in years 2-3+.



Authors

Krista Perry | Partner & Head of Launch Excellence

Krista supports biopharma and biotech companies in their global GTM strategy, launch readiness & planning, and optimizing execution. She leads Trinity's Launch Excellence group, supporting the development and management of dozens of launches annually. Krista partners with companies focused on their first commercial launch to their 50th, bringing expertise across all types of therapeutic areas and modalities. Clients leverage Krista's experience and insights in navigating early-mid clinical stage product development opportunities and the commercial needs required to recognize their full potential, specializing in cross-functional activities that warrant communication and alignment.

Bruno Stoekl | Associate Principal

Bruno Stoekl has played numerous roles on Commercial Brand teams for over ten years experience, with a focus on brand launch. During that time, Bruno has advised clients across a wide spectrum of therapeutic areas and modalities, with an emphasis on the actions, team structures and investments required to achieve launch success. Bruno started his career at Accenture, before moving onto Vynamic. He has a B.S. in Information Sciences and Technology from Penn State University.

Jenna Fritz | Engagement Manager

Jenna Fritz has over 10 years of experience in commercial strategy, market research and project management across a range of therapeutic areas. Since joining Trinity, Jenna has been focused on supporting emerging and first-launch companies with launch management, benchmarking, analog analysis and commercial launch playbook development. Jenna started her career in global health and development working at the Bill & Melinda Gates Foundation and PATH. She has an MPH and MBA from Johns Hopkins University.

Soren Gessner | Associate Consultant

Soren Gessner joined Trinity in 2024 and has been primarily focused on new product launches and PMO support. During that time, Soren has helped to design and implement Trinity's in-house launch management software, developed go to market strategies for new product launches, and assisted with primary market research to better understand various disease markets. Soren Gessner started their career in philanthropic venture captial, before moving onto life sciences consulting. He has a bachelor of arts in neuroscience.

Launch Excellence

Trinity's Launch Excellence engagements help companies effectively and efficiently prepare for successful commercialization tailored to their market and situation. No matter where you are on the path to launch, Trinity works with you to define, execute and optimize your commercialization readiness. We directly support >60 companies annually in their launch journeys – strategy, planning and management – across dozens of therapeutic areas, from first-launch emerging biotech to the largest global pharma leaders.

About Trinity

With almost 30 years of expertise, a best-in-the-business team and unrivaled access to data and analytics, Trinity Life Sciences is a modern partner to companies in the life sciences industry. Trinity combines strategy, insights and analytics to help life science executives with clinical and commercial decisionmaking. We serve over 300 pharmaceutical, biotech and medical device clients, helping them develop the right drugs and devices for today's market and optimize them once in market. We have a diverse staff of over 1200 people and 11 global offices across the U.S., Europe and Asia. Ultimately, we know that every decision our clients make impacts a life, and when we help our clients achieve their goals, the world benefits. To learn more about how Trinity is elevating the industry and driving evidence to action, visit trinitylifesciences.com

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