TRINITY

WHITE PAPER

Smarter Commercialization Investment for First Launch Biopharma

Lessons Learned from Companies Who Got it Right

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Introduction

With more momentum than ever to bring innovative medicines to market, there is increased pressure on emerging companies to get the launch right. The industry has seen record-breaking funding for therapies in recent years, and many have been commercialized by emerging biopharma companies launching for the first time. For many of these emerging biopharma companies, optimizing commercial launch spend is a critical consideration pre- and post-launch, and with limited funds it can be easy to misjudge the timing of key investments or underfund crucial capabilities.

To help guide commercialization decisions, in this paper Trinity Life Sciences explores pre-launch and first year commercial spend, specifically, U.S. Selling, General and Administrative (SG&A) costs; expected revenue; and actual sales. Leveraging our experience and industry network of experts, we uncover what works, and what doesn't, so emerging companies can leverage these insights to prepare for their critical launches. What works for one type of product or market doesn't necessarily work for another, and our analysis highlights the effectiveness of various launch investments across three market cohorts: Specialty, Rare Disease (non-Oncology), and Rare Oncology.

The study reveals several themes (by type of market) that should be considered as part of an emerging company's launch spend strategy to achieve commercialization success. Most importantly, more spend isn't always better; what matters is where and when you invest.

Methodology

Data Sets: This white paper is based on two main data sets:

I. **A custom-built Launch Spend & Sales Database** that utilizes company financials and consensus forecasts from time of launch to understand how spend impacts launch sales by cohort.

II. **Benchmarking data from TGaS Advisors (a division of Trinity)** via their proprietary membership network. This data provides detail on when the spend occurred and on what priorities. A unique component of the membership network is the access to biopharma Chief Commercial Officers as well as information about commercial spend which has been directly sourced from industry and is maintained at a cohort level, for instance, emerging rare oncology companies, and then used for benchmarking purposes.

TGaS® Advisors A DIVISION OF TRINITY

Definition of Success

Success can be hard to define, but clear when achieved. As noted in our recent white paper on the Next-Generation Launch Model, regulatory approval alone can no longer be equated with success. In general, launch performance (e.g., sales) should be measured against longer-term profitability, rather than predicated on hitting first-year revenue expectations at any cost. However, as the best objective metric for first launch companies, Trinity has defined initial success as **meeting or exceeding first year sales forecasts.**

Cohort Definitions

The first launch companies included are based on data from 2017 to 2021 and have been divided into three market cohorts: Specialty, Rare Disease, and Rare Oncology. These three cohorts of launches were selected because they represent the current focus areas of most emerging biopharmaceutical companies.

Specialty Drugs address niche needs of patients with more common conditions, often involving quality of life rather than mortality. Rare Disease (non-oncology) covers diseases with a very low prevalence in the general population (less than 200,000 people in the United States). Lastly, as is typical for first launch emerging biopharma companies, Oncology markets for this cohort are niche or rarer cancers that we have referred to as Rare Oncology throughout this paper.

Cohort Analyses

Trinity analyzed each of the three cohorts across:

- U.S. SG&A spend from 10Qs and 10Ks
- Forecasted U.S. sales pulled from Evaluate Pharma and Trinity's Drug Index database
- Actual U.S. sales pulled from Evaluate Pharma publicly available financial reports, and Trinity's Drug Index

Using these metrics, Trinity compared companies within and across cohorts to assess the amount of pre-launch SG&A spend versus forecasted and actual first year sales. The difference was then calculated between actual sales and forecasted sales to determine over and underperformers, as well as the rationale. All findings are presented at the cohort level. The Specialty cohort contains 13 companies, the Rare Disease cohort contains 7 companies, and the Rare Oncology cohort contains 7 companies

Summary of Data & Overall Trends

SG&A in L-1 and L+1 by Cohort

Across all three cohorts, pre-launch (L-1) spending ranged greatly, from 16 to 272 million USD, with a mean spend of ~79 million USD. Rare Disease companies spent the most, with a mean ~118 million USD spend in L-1 compared to only ~62 million USD for Specialty companies.

Spending in the first-year post-launch (L+1) also spanned a very wide range, from 28 to 227 million USD. Rare Disease companies still had the highest mean spend of the cohorts at ~187 million USD, as all cohorts increased mean spend by about 69% in the year after launch.

Data Call-Out

USD, Millions	SG&A Year Pre-Launch (L-1)			SG&A Year Post-Launch (L+1)			Change from L-1 to L+1	
Cohort	**Range**	**Mean**	**Median**	**Range**	**Mean**	**Median**	**Mean**	**Median**
Rare Disease	16-272	**117.9**	86.5	36-427	**186.5**	154.6	+58%	+79%
Rare Oncology	41-96	76.7	79.7	90-158	129.5	137.0	+69%	+72%
Specialty	21-201	**62.2**	63.1	28-227	113.2	82.2	+82%	+30%
TOTAL	16-272	79.4	71.4	28-227	134.5	126.3	**+69%**	+77%

First Year (L+1) Forecasts vs First Year (L+1) Sales by Cohort

Forecasted first year sales ranged between 12 to 179 million USD, with similar mean forecasts across cohorts, averaging out at ~58 million USD forecasted first-year sales. The Rare Oncology cohort had the highest mean first-year sales, (~94 million USD), achieving 160% of forecasted sales on average. Rare Disease companies also did well, achieving 116% of forecasted first year sales on average, while Specialty companies fell below forecast on average, achieving 49% of forecasted sales.

Success ranged greatly, with some companies achieving a mere 7% of their forecasted first-year sales, while others came out a whopping 375% over their target.

USD, Millions	First Year (L+1) Forecast			First Year (L+1) Actual Sales			First Year (L+1) Actual Sales as % of Forecast		
Cohort	**Range**	**Mean**	**Median**	**Range**	**Mean**	**Median**	**Range**	**Mean**	**Median**
Rare Disease	18-117	66.7	66.0	22-103	77.4	80.8	126-198%	116%	122%
Rare Oncology	15-123	58.4	51.0	11-356	**93.6**	55.5	46-375%	**160%**	109%
Specialty	12-179	53.7	42.0	1-100	26.6	20.2	7-222%	**49%**	42%
TOTAL	**12-179**	58.0	44.1	1-356	56.4	32.3	**7-375%**	97%	73%

Pre-Launch (L-1) SG&A vs First Year (L+1) Sales by Cohort

Looking at how pre-launch SG&A spend compares to first year sales, unsurprisingly we can see that most companies don't recoup their L-1 SG&A spend in just their first year of sales, with only 71% of L-1 SG&A recouped in the first year of sales on average. However, we do again see favorable performance in the Rare Oncology cohort, which achieved 122% of their L-1 SG&A spend in their first-year sales on average (though the median was just 70%).

USD, Millions	SG&A Year Pre-Launch (L-1)			First Year (L+1) Sales			First Year (L+1) Sales as % of SG&A	
Cohort	**Range**	**Mean**	**Median**	**Range**	**Mean**	**Median**	**Mean**	**Median**
Rare Disease	16-272	117.9	86.5	22-103	77.4	80.8	66%	93%
Rare Oncology	41-96	76.7	79.7	11-356	93.6	55.5	**122%**	**70%**
Specialty	21-201	62.2	63.1	1-100	26.6	20.2	43%	32%
TOTAL	16-272	79.4	71.4	1-356	56.4	32.3	**71%**	45%

Pre-Launch (L-1) and First Year (L+1) SG&A of Overperformers and Underperformers by Cohort

Overperformers met or exceeded first year forecasts; underperformers were below forecasts. From the analyzed cohorts, 57% of the companies in the Rare Disease cohort, as well as 57% of the companies in the Rare Oncology cohort were overperformers; only 38% of the Specialty companies were overperformers. As we have seen before in project work and white papers, non-rare and non-oncology launches struggle more to achieve expectations.

In the year before launch (L-1) SG&A spend for 'overperformers' ranged from 16 to 145 million USD, with a median of ~87 million USD. For the 'underperformers', pre-launch (L-1) SG&A spend ranged from 20 to 272 million USD, with a median of ~66 million USD.

In the one-year post-launch period (L+1), SG&A spending for the overperformers ranged from 37 to 224 million, with a median of 139 million; for underperformers from 28 to 428 million with a median of 82 million, all USD. As you can see, sometimes the overperformers spent LESS, which begs the question, are there lessons other companies can learn from how they spent their money?

USD, Millions	SG&A Year Pre-Launch (L-1)		SG&A Year Post-Launch (L+1)	
Cohort	**Under Performers Range (Mean)**	**Over Performers Range (Mean)**	**Under Performers Range (Mean)**	**Over Performers Range (Mean)**
Rare Disease	65-272 (202.3)	16-87.8 (64.5)	199-428 (348.3)	37-195 (94.9)
Rare Oncology	69-84 (79.7)	41-96 (84.0)	88-125 (118.4)	137-158 (139.5)
Specialty	20-69 (34.6)	43-145 (91.5)	28-200 (57.1)	127-224 (197.9)
OVERALL	20-272 (65.8)	16-145 (86.9)	28-428 (82.2)	37-224 (138.9)

Key Findings for Rare Disease Emerging Biopharma

Rare Disease companies spent the most in L-1, and had the most successful launches, as defined by our metric of meeting or exceeding first year forecasts. Most interestingly, when examining companies that overperformed (e.g., met or exceeded first year forecasts), we noticed that Rare Disease companies actually spent less than the underperformers. In this cohort, the median SG&A spend for overperformers in the year before launch was 65 million USD vs. a median 202 million USD for underperformers. Trends were similar for the year after launch, where the overperformers again spent less than the underperformers, though both groups increased spend.

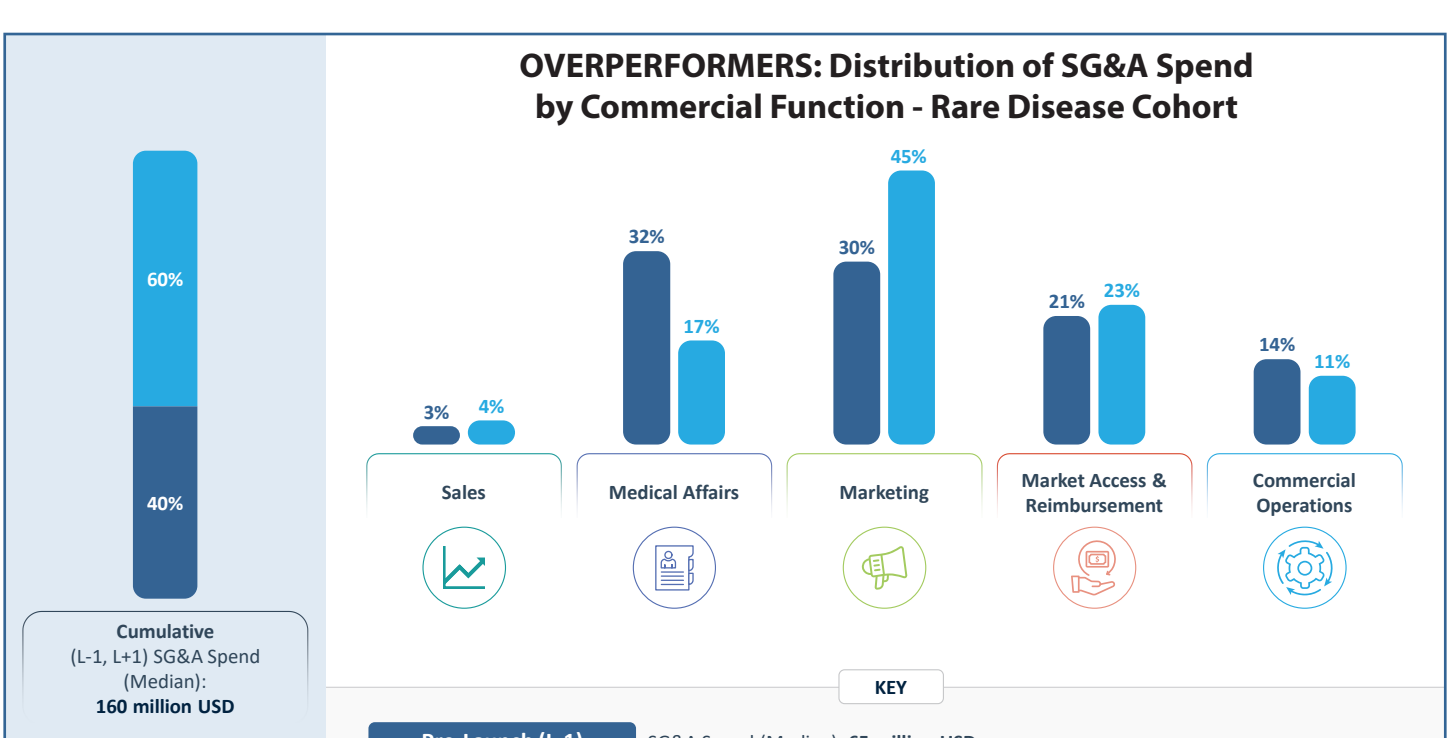
It's hard to uncover exactly where overperformers spend more effectively vs. underperformers, but we do know that for these markets you can't skimp on a few critical areas:

- **Market shaping via evidence and early medical engagement**
- **Robust patient services**
- **Early payer engagement**

The challenging part is to identify where else you can go lean or potentially outsource as the decisions here can significantly vary depending on your strategy.

When preparing to launch in a Rare Disease, there is a great deal of education and planning required to ensure that the medical community is clear on the unmet need in the space, and that a network is established to connect patients and physicians. A deep focus on market shaping, through robust evidence generation and publications, is key to help ensure the disease is well understood and the unmet need appreciated. Indeed, companies should keep in mind that this often begins well before the L-1 timeframe and budget appropriately.

Overperforming Rare Disease companies allocate 32% of their SG&A spend to Medical in L-1, the highest of all cohorts, and higher than the amount allocated to marketing. This changed during launch years, where medical spend decreased down to 17% of total SG&A spend and marketing spend increased to 45%. Additionally, in L+1, the Market Access & Reimbursement team's budget increased to approximately 23% of the SG&A spend.



Additionally, we see that overperforming Rare Disease companies tend to hire their medical team early and deploy MSLs as soon as there is significant clinical information (T-24).

Across the Rare Disease cohort, a critical enabler we observed is building robust patient services to create a seamless patient experience, supported by technology and services through a Patient Hub (a third party that handles the logistics of getting the product from a specialty pharmacy (SP) to a patient). However, not all companies did this equally well. For instance, some of the underperformers built extravagant apps and patient portals, partnering with multiple third parties handling the distribution and SP logistics. In contrast, the overperformers focused on streamlining patient services through a single website, with fewer and higher quality distribution and SP partners. When all details of the partnership were clearly outlined pre-launch, including a period of frequent touchpoints in the days and weeks following launch, the patient experience was more likely to be seamless.

Lastly, payer field team should also be in place a year prior to launch, to ensure that they are establishing the product's value to support market access. Rare Disease companies did this well, as "Establishing Value to Obtain Access" was more highly rated as a critical launch metric than specialty and oncology.

Key Findings for Rare Oncology Emerging Biopharma

Turning to look at the Rare Oncology cohort, the theme here is 'slow and steady'. The overperformers here invested in the right infrastructure and experience before launch, and then heavily invested in specialized field roles the year after launch to ensure continued success.

The overperforming rare oncology companies had three things in common:

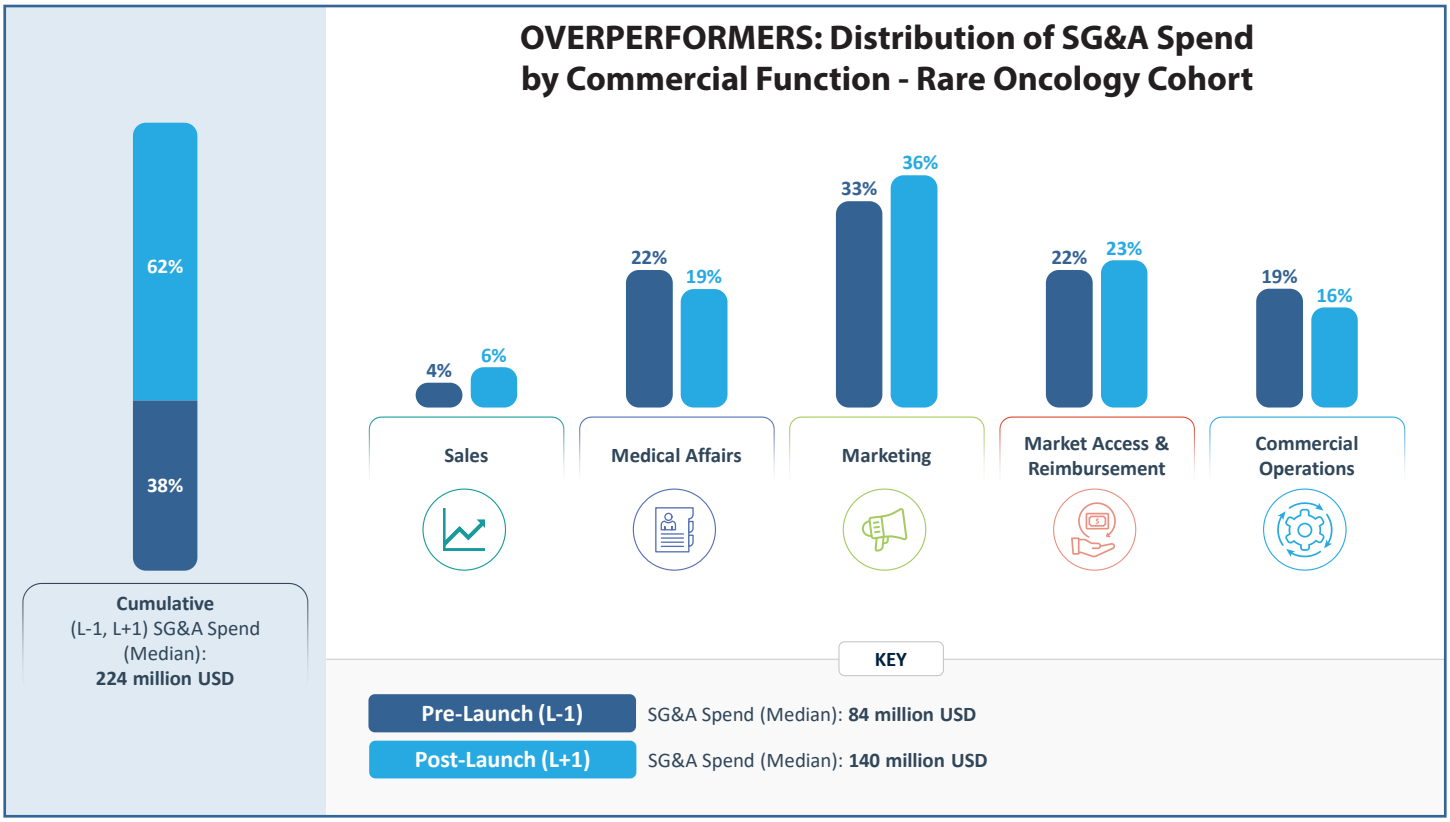
- **Dedicated project management to connect the dots and provide cross-functional coordination for key workstreams, such as diagnostics and customer experience**
- **Fit-for-purpose field teams with the right experience and clearly defined, customer-centric roles**
- **Targeted early spend on KOL engagement and brand strategy**

In this cohort, overperformers spent slightly more pre-launch (84 million USD SG&A spend) vs. the cohort median of 80 million USD. These companies invested more in internal resources such as dedicated launch project management, whether by internal employees or vendors. This ensured tight coordination across the company and linked complex diagnostic testing to the patient journey and experience.

Further, overperforming rare oncology launch teams typically minimized the number of customer-facing roles to reduce operational complexity. Underperformers tended to underinvest in corporate infrastructure, leading to fragmented coordination across commercial teams. One exception is having some field representatives fully dedicated to the companion diagnostic (CDx), where relevant, and educating labs and HCP offices on how to order and stock the testing kit. This increased uptake and effectiveness of both the diagnostic and the therapy.

In Rare Oncology, experience matters – it is about the right people vs. how many you have. Winning companies hired sales reps with an average of ~ten years of oncology sales experience, and on average ~five years' experience in the specific tumor type.

Overperformers in this cohort spent less on Medical Affairs and Market Access compared to other cohorts. Spending for each made up just ~22% of SG&A spend at both L-1 and L+1, while Marketing spend made up ~33% (L-1) and ~36% (L+1) in both periods. This trend demonstrates how **rare oncology products require less robust market shaping by Medical Affairs or Market Access teams**, due to the attention oncology research and therapies receive in comparison to rare and specialty therapeutic areas (e.g., at major congresses).



That doesn't mean you don't need to be in the field early; we saw that overperforming Rare Oncology companies had MSLs in place the earliest (T-36 vs. T-24 as seen with the rare disease cohort) and score the highest in self-reported satisfaction with their Disease Education and KOL engagement (almost 20% above average).

Lastly, companies with expected strong sales tend to hire the U.S. brand leader first, and then establish the U.S. launch team, before finalizing the brand vison and positioning. This gives the full team enough time to influence and shape those key elements. Conversely, underperformers executed those same milestones simultaneously.

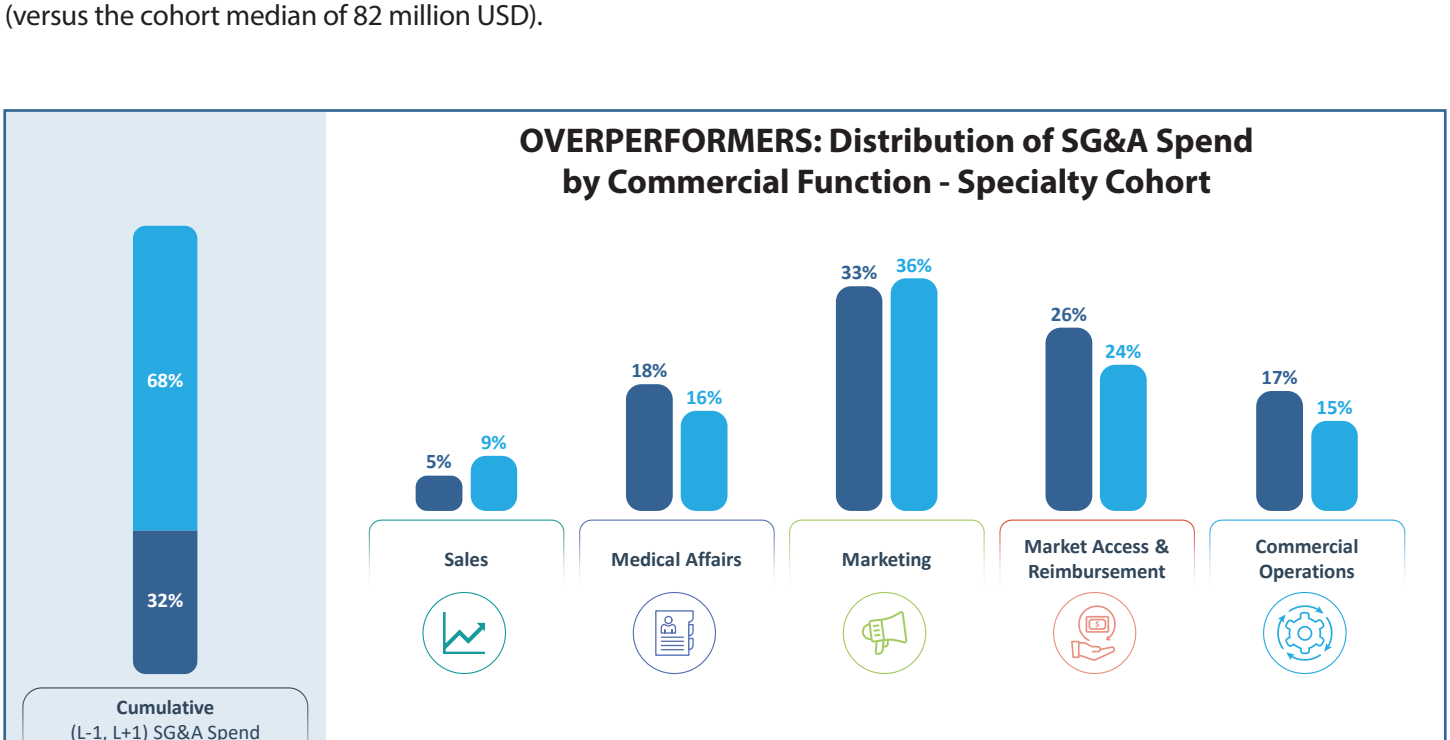
Key Findings for Specialty Emerging Biopharma

The Specialty cohort was the most conservative cohort, with the lowest median pre-launch SG&A spend at 63 million USD and lowest forecasted median sales at 20 million USD. The cohort also saw the lowest actual sales as a percent of expected forecast. For the overperforming companies within this cohort, key drivers of success were:

- **Focus on access**
- **Greater sales spending**
- **Development of robust patient hub services**

Patient services are often a strong differentiator when barriers to accessing treatment or staying on treatment are significant pain points in the patient journey, or when clinical differentiation is minimal.

Despite lower spending overall, we can see that the overperformers of this cohort spent more than their peers, with a median SG&A spend of 92 million USD in L-1 (versus the cohort median of 63 million USD) and 198 million USD in L+1 (versus the cohort median of 82 million USD).



The overperforming companies in this cohort tended to have significant market access expertise, which was deployed early. Market access expertise amongst the leadership was also beneficial, especially buy-and-bill experience for injectable/infused products. Established payer and Group Purchasing Organization (GPO) relationships help to build on and complement this experience.

Continuing to look at overperformers, we saw Sales made up 9% of SG&A spend on average in L+1 for the Specialty cohort, greater than the 4% spent by the Rare cohort and 6% spent by Rare Oncology. This aligns with the fact that experienced field personnel are a key characteristic of successful Specialty drug launches.

Lastly, the implementation of robust patient hub services is a key component of specialty drug launches (although for notably different reasons than the Rare Disease cohort). Winning companies have implemented easy-to-use digital interfaces and overall best in class patient and provider services, including field reimbursement, by supporting patients with custom hub services and organizational outreach, these companies help focus on getting patients on therapy sooner, by shortening the time between intent to prescribe and actual treatment.

Despite allocating ~18% of SG&A spend to Medical Affairs in L-1 (in line with the Rare Oncology cohort), overperforming Specialty companies had MSLs in place latest (seven months prior to launch) and scored the lowest in Disease Education and KOL engagement (almost 20% below average). These overperforming companies seem to have chosen to focus more on Sales than Medical Education, in the context of lower unmet need / scientific differentiation.

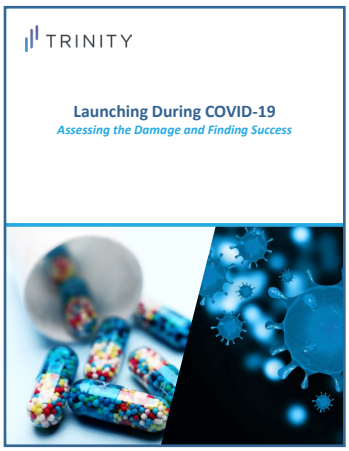
Continue reading for the white paper's conclusion and author biographies

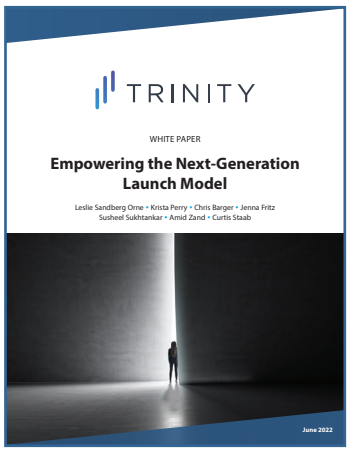
Conclusion

Getting it Right: Considerations for Commercial Launch Success

A final key consideration is – how has the pandemic impacted commercial launch success? If the pandemic has taught us anything, it's that today's landscape requires constant innovation, and "getting it right" requires applying learnings from the past while balancing risks and unknowns.

For more on this, see our other white papers:





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In conclusion, an emerging biopharma preparing for commercialization must identify where to prioritize their investment. Trinity can confidently say – spending more isn't always a golden ticket to success. It's **spending in the right places, at the right times**, that makes the difference between overperformers and underperformers. Now more than ever, emerging companies must know where they fit, what to prioritize, and how to invest, to optimize their value.

Authors

Jason Karas, MBA | Principal, Strategic Advisory

Jason joined Trinity in September 2019. He has significant expertise in helping develop and execute growth strategies for biopharmaceutical companies, from portfolio management (e.g. business development strategies, therapy area expansion, R&D prioritization, and investment decisions) to clinical development strategy support (e.g. using real-world data to identify right patient segments, pipeline and competitive analysis) to commercialization (e.g. opportunity assessment and launch strategy). Jason brings over decade of corporate and product valuation experience in the life sciences spanning his time at Accenture M&A Strategy group, IQVIA's Portfolio Strategy & Transactions team, now at Trinity, leading several global valuations across a range of technologies and therapeutic areas.

Jason graduated from University of California, Los Angeles. with a degree in biology and international economics, followed by an M.Sc. in Decision Sciences from The London School of Economics and Political Science, and an MBA in Entrepreneurial Studies from London Business School.

Ashley James | Principal, Launch Excellence

Ashley joined Trinity in 2020 and is a Principal in the Launch CoE, with nearly a decade of commercial strategy consulting experience. Much of Ashley's work has focused on commercial planning for emerging and rare disease biopharmaceutical companies across the major therapeutic areas, on products from their early development, through launch, and into their lifecycle. Her favorite projects help companies plan and scale for their first launch through a mix of qualitative and quantitative research methods, collaborating across the firm.

Prior to joining Trinity, Ashley began her consulting career at IQVIA and Publicis Health, mastering digital marketing strategies. Ashley holds a BS in Environmental Science from Temple University and outside of work enjoys rowing.

Sarah Cotter | Engagement Manager, Launch Excellence

Sarah has over six years of experience in the life sciences industry, including strategy consulting, agency-side, and digital health start-up experience. She joined Trinity in April 2020 and has since built expertise across all of our core Strategic Advisory and Launch Excellence offerings, including commercial strategy, dynamic market intelligence, brand and launch planning, and launch management support. Sarah has supported both pharma and emerging biotech companies with their launches, including supporting multiple gene therapy launches to date. Sarah joined Trinity from IQVIA's global strategy consulting group.

Sarah graduated from Queen's University in Kingston, Canada with a BSc in Biology and holds an MSc in Management from the Technical University of Munich, and has gained professional experience across Canada, Germany, and the U.S.

About Trinity

Trinity is a trusted strategic commercialization partner, providing evidence-based solutions for the life sciences. With 25 years of experience, Trinity is revolutionizing the commercial model by providing exceptional levels of service, powerful tools and data-driven insights. Trinity's range of products and solutions includes industry-leading benchmarking solutions, powered by TGaS Advisors. To learn more about how Trinity is elevating life sciences and driving evidence to action, visit trinitylifesciences.com.

For more information, please contact us at info@trinitylifesciences.com.