

# Achieving Launch Excellence in this New Decade

## Four Must-Haves for an Agile Launch Strategy

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# INTRODUCTION

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**2**018 and 2019 were banner years for approvals with over 50 drugs approved by the FDA and the EMA each year.<sup>1</sup> 2020 looks no different. As you prepare for your unique launch in an ever-changing landscape, we understand the challenges you may face: limited resources, lack of prioritization, misalignment, diversity of markets. Based on Trinity's experience supporting dozens of launches in 2019 alone and through a landmark research study with 30 Chief Commercial Officers (CCOs)\* who had recently launched a product, we share our recommendations on how to be agile through effective and efficient planning for an optimized launch.

Our four top recommendations:

- 1** Make clear connections between launch strategy and your mid- to long-term strategy – and get everyone aligned
- 2** Develop a global strategy early
- 3** Invest in critical activities that elucidate the value of your product and your dedication to its success
- 4** Develop a ruthless prioritization mentality

<sup>1</sup> In stark contrast to 2017 and 2016 with 46 and 22 FDA approvals respectively.

\* Trinity and TGaS Advisors study fielded November-December 2019, including online survey and in-depth interviews with 30 CCOs across a range of biopharmaceutical companies.

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# RECOMMENDATIONS



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## **MAKE CLEAR CONNECTIONS BETWEEN LAUNCH STRATEGY AND MID- TO LONG-TERM STRATEGY – AND GET EVERYONE ALIGNED**

Many launch plans are patched together from siloed work within departments without alignment on the cross-functional critical success factors. This is a theme we heard consistently from CCOs reflecting on lessons learned, and we see it often in Trinity's own launch planning work.

Laddering tactics/activities back to the overarching strategy is critical to prioritizing resources and budget (*see #4*), and to ensuring alignment on company strategy. Are we focused on ultra-orphan markets with no current therapies or larger markets with unmet need through differentiation? What does the indication sequencing look like for this product? How does this product fit within our portfolio? Answering these questions and communicating them throughout the organization will allow for a more focused launch planning process. Additionally, this foresight can help influence the clinical development plan to optimize commercial success – for example, targeting a specific sub-population or choosing the right comparator or endpoint(s).

"It was not just executing a launch, it was educating and informing [the team] along the way."

For emerging biotech companies, this first launch is likely the one chance to get it right. The first impression for stakeholders (HCPs, payers, regulatory, analysts) is critical.

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Historically, launches in the industry have floundered because they either lacked a unified approach to launch or did not put in place the appropriate resources at the appropriate time. A key learning many took away from the world's first truly novel cell immunotherapy, Provenge®, is that it is vital to intimately understand the market for your product and to appropriately set expectations of the customers. Dendreon both vastly overestimated the demand for its product and, at the same time, underestimated the challenges of commercialization by not taking steps to ready the customer for the hurdles to receiving this truly novel therapy. Once the damage was done, it proved near impossible for three successive management teams to right the ship, highlighting the intractability of a poorly planned launch. This could have been overcome by communication and prioritization of near- and long-term goals and specific planning discipline that would have uncovered the realities of a novel launch.



## **DEVELOP A GLOBAL STRATEGY EARLY**

Relative to the overall commercialization strategy above, begin discussing the global strategy at least two years prior to launch. From our interviews with CCOs, we concluded that many companies showed a serious lack of an integrated global approach to launch planning. Although the US is usually a key priority market, understanding the ex-US potential and developing a strategic global launch plan is critical for success. Even if you're planning to partner in other countries, the early efforts here will help gain recognition of the value of your product. Efforts should include prioritizing select countries (based on addressable market, access, legal requirements, and distribution), developing a strategy for achieving reimbursement in prioritized countries, sequencing prioritized countries (based on pricing/reimbursement and regulation pathways/requirements), go-to-market strategy for each prioritized country, and determining if, when, and where to partner.

“The criteria [to go into a certain market] should be where and how well identified are the patients overlaid with the access/pricing question. Are you able to obtain an attractive price and stand to have a valuable product in the market?”

Partnering in specific countries is not a binary decision; options for partnering exist on a spectrum. There are a series of partnering options, including selective outsourcing, working with a contracted commercial organization, and partnering with a company with an in-country presence. Each partnering option offers a different level of financial commitment, risk, profit potential, and marketing control. However, in most cases, early efforts to develop and take steps to achieve a global strategy will enable a stronger position in partnering negotiations.



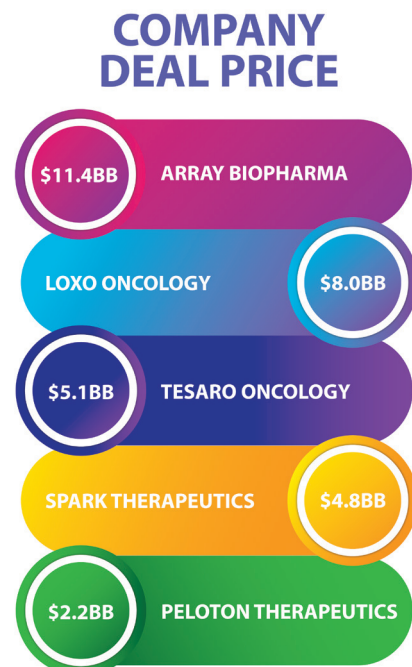
### **INVEST IN CRITICAL ACTIVITIES THAT ELUCIDATE THE VALUE OF YOUR PRODUCT AND YOUR DEDICATION TO ITS SUCCESS**

There are a handful of critical activities to focus on that help support the value of your product, including an evidence generation roadmap that will drive the story.

Nearly half (44%) of our respondents indicated a key activity – value proposition/value messages – was initiated too late in the launch planning process.

It's not just about the big studies or publications; it's about putting your money where your mouth is: hiring key heads of departments at the right time, spending money at conferences, spending to understand your markets and investing in regional leads (see #2). For emerging biotech, investing for a successful launch will increase your value whether you ultimately "go it alone" or partner/are acquired. Looking at just the first half of 2019, the top five deals<sup>2</sup> all involved companies that either recently built new companies ("went it alone"), launching their first or second asset, or were closely approaching launch.

Whether for Wall Street or a potential buyer, investing in activities that highlight the value of your product and your dedication to its success will ultimately benefit the organization internally and externally.



<sup>2</sup> Excluding the mega mergers of BMS/Celgene, AbbVie/Allergan, Takada/Shire, Danahar/GE BioPharma

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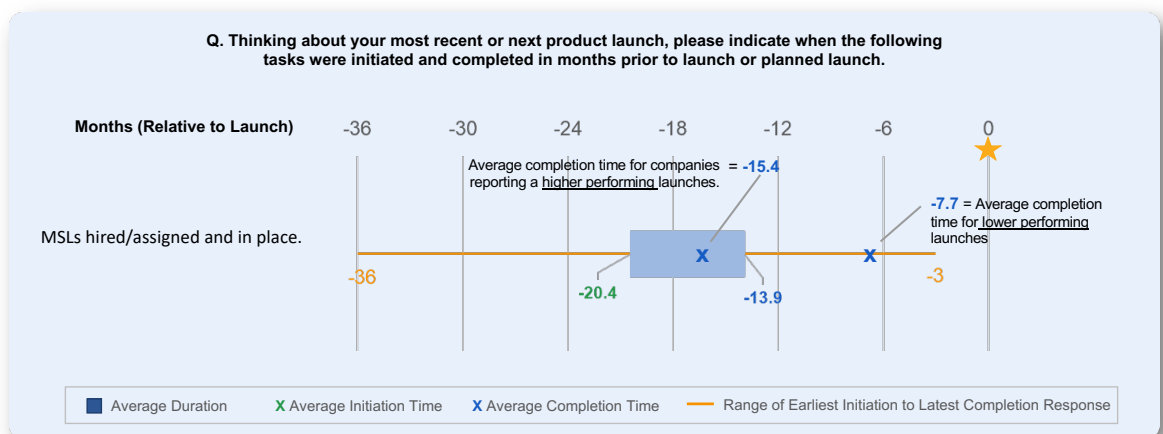
## DEVELOP A RUTHLESS PRIORITIZATION MENTALITY

The CCOs we spoke with noted that allocating budget, resources, and time appropriately was one of the most challenging aspects of their recent launch. As noted earlier, an aligned strategy and focus on critical activities that support the value story are critical areas to invest in early with both budget and people. However, more is not always better. Several companies noted that they had too much budget, which created its own problems. One CCO noted that because of their excess budget, “We did activities that we did not need to do and that were not value add. It also created friction within the company competing for dollars.”

From a recent Trinity and TGaS® Advisors survey with CCOs, getting people into the field, especially Medical Science Liaisons (MSLs), sooner was correlated with better product performance. Launches that did not meet expectations had MSLs in the field on average 7.7 months prior to launch, whereas launches that exceeded or were in line with expectations had MSLs out in the field on average 15.4 months prior to launch.

### The earlier the better with respect to hiring MSLs

On average, higher performing launches had their MSLs assigned and in place 15.4 months prior to launch. Lower performing launches did not have their MSLs out until 7.7 months prior to launch.



Note: For each task, average duration (months; when applicable) and average range (months; when applicable) are shown. Calculations are based on the difference between the average initiation time and average completion time for each task. Only respondents who entered numerical values were included in the calculation of duration.

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One key element in a constrained resource environment is understanding if, when, and where to outsource vs. doing it internally. From our CCO respondents' experience, it's most effective to find a few trusted partners/vendors to leverage that know the market and understand your strategy. Reducing the administrative and ramp up time for many partners/vendors will result in more efficiencies and alignment. Likewise, identifying a dedicated resource (internally or externally) to focus on launch planning and management is critical to tracking the prioritized activities and escalating gaps, issues, and risks to leadership.

“We would meet every week for high-level status and every month for a deep dive half day; you need crisp communication and clear accountability. You can't hide behind a desk or behind emails. Everyone must be accountable for their job.”

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**Launch planning can be overwhelming and stressful at times. Refining your team's focus on these four recommendations, together with creating a culture of communication and transparency, will foster an agile and effective launch environment.**

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# AUTHORS

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## Krista Perry

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Krista supports biopharma and biotech companies in their BD, launch, and commercialization strategy. She leads Trinity's launch excellence group and has supported the development and management of dozens of launches. Krista partners with companies focused on commercial assessments, BD/NPP strategy, pipeline/portfolio prioritization and strategy, and launch roadmap planning & execution, bringing deep experience in rare diseases. Clients leverage Krista's insights in navigating early-mid clinical stage product development opportunities and the commercial needs required to recognize their full potential, including: analog analyses, forecasting, market research, L&A opportunities, and cross-functional strategy & alignment.

Krista joined Trinity in 2006 and co-leads the San Francisco office. Krista studied psychology and pre-med while obtaining her BA from Dartmouth College.



## Herman Sanchez

Senior Partner  
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Herman has been working in the life sciences industry for over 20 years in various positions, including designing and running randomized trial research, optimizing of clinical administration of health services, and working as a strategic consultant to the life sciences industry. He joined Trinity over a decade ago and has worked closely with clients to support strategic decision-making across the product lifecycle. As a leader at Trinity, he has worked to build Trinity's European office and helps to run and build the company's centers of excellence in Market Access, Launch, and Health Economics and Outcomes Research (HEOR).

Herman earned an MBA from the Tuck School of Business at Dartmouth and an AB from Harvard University.



## Jackson Carroll

Principal  
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Jackson has 17 years of consulting experience and a strong business background. He has undertaken strategic analysis, assessment of new opportunities, launch support, forecasting, business planning and organizational redesign for leading pharmaceutical and healthcare companies in Europe. Jackson's consulting experience is in diverse therapeutic areas, including diabetes, oncology, and hemophilia and has worked for clients in the UK, US, Turkey, Thailand, and over 15 European countries.

Before joining Trinity, Jackson worked with McKinsey & Company, ZS Associates, Syneos Health Consulting, and Accenture, as well as working as a freelance strategy consultant for life sciences and pharmaceuticals firms in Europe. Jackson earned an MBA (with Distinction) from London Business School and a Bachelor in Information Technology from The University of Queensland in Australia.



## Curt Staab

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Curt leads the Emerging Life Sciences Network (elsN), a membership organization for emerging and pre-commercial life sciences companies. Curt has advised over 100 biopharma companies during his career with TGaS.

Previously, Curt led the TGaS Sales Advisory Practice, advising Sales Operations leaders across the industry on current and future trends and providing them with fact-based information and actionable insight in such areas as sales force structure, field technology, inside sales, career issues and incentive compensation.

An experienced professional with more than 28 years in pharma, Curt began his career at Merck where he held multiple positions in Sales, Sales Leadership, Marketing and Commercial Operations over an 18-year span.

Curt is a graduate of the University of Kansas and holds an MBA from Southern Methodist University.

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## About TRINITY

Trinity is a trusted strategic partner, providing evidence-based solutions for the life sciences. With over 20 years of experience, Trinity is committed to solving clients' most challenging problems through exceptional levels of service, powerful tools, and data-driven insights. Trinity's range of products and solutions includes industry-leading benchmarking solutions, powered by TGA Advisors. Trinity, together with its subsidiary TGA Advisors, has 5 offices throughout the US, including Boston, New York, Princeton, Philadelphia, and San Francisco, as well as Toronto, Canada, Gurgaon, India, and Munich, Germany. To learn more about how Trinity is elevating life sciences and driving from evidence to action, visit [trinitylifesciences.com](http://trinitylifesciences.com).

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## About TGA ADVISORS

TGA Advisors, a division of Trinity, is the leading benchmarking and advisory services firm for commercial organizations in the life sciences industry. With a roster of large, emerging and precommercial life sciences companies, TGA provides robust comparative intelligence and collaborative network membership services. The team includes more than 50 experienced professionals, most with senior-level experience in the life sciences and related industries. To learn more about TGA, visit [tgas.com](http://tgas.com).

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### LEAD: Launch Excellence Advisory Database

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