

# Approaching Launch in the Age of COVID-19

## The New Normal for Drug Launches: How to Shift and Stay Ahead of the Curve

While COVID-19 is grinding world economies to a potentially disastrous halt, the pharmaceutical and biotech industry continues to move forward. However, the pace is slower, and there are new challenges. Many launches will be delayed, and while those delays are costly, they will not continue indefinitely. How can companies ensure an agile launch despite the uncertainty and ensure launch success during and in a post-COVID-19 world?

Trinity Life Sciences is actively engaged with more than a dozen pharmaceutical and biotech organizations tracking towards product launch in the coming months and years. Leveraging our current client engagements and unrivaled benchmarking data, we have identified a few key considerations for planning, navigating, and executing launch in this "new normal."

Launch planning is made both more difficult and more vital given new uncertainties about timing and the capabilities required to drive success.

In an earlier <u>whitepaper</u> Trinity published in January 2020, Trinity identified four "must-haves" for an agile launch strategy:

Make clear connections between launch strategy and your mid- to long- term strategy – and get everyone aligned

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- 2 Develop a global strategy early
- Invest in critical activities that elucidate the value of your product and your dedication to its success
- 4 Develop a ruthless prioritization mentality



All four certainly apply in the age of COVID-19. Agile launch is more vital than ever. Starting immediately, launch excellence teams need to consider ways to imagine and track the changed world their product will be entering. And given the range of uncertainty about that future, creating capacity for flexibility is perhaps the most important task for any launch planning team. Since March 2020, Trinity has identified four additional needs that work together with the original four "must-haves" to set the stage for a successful launch. The "Four Needs" are:

### 1. The Need to Recognize and Adopt a Mindset of Change

Creating a launch excellence culture that welcomes change as part of the process, and not a barrier to it, will better prepare your team for the flexibility needed to recognize success. Pharma leaders have made it clear that COVID-19 is likely to drive permanent change to the way they engage with customers. Recognizing which changes you want to keep in the long-term versus those that were only necessary to navigate this short-term situation can lead to important and sustainable long-term capabilities.



For example, a recent Trinity survey (by benchmarking division TGaS Advisors) showed that 89% of companies have had an impact to their pre-launch activities due to COVID-19, with almost half of these companies reporting a high impact.

### 2. The Need for Customer Driven Flexibility

We expect that the coming months and years will prove to be a 'forced' experiment, accelerating the need for tools and strategies to allow for flexible engagement. This will ultimately highlight the value of a thoughtful commercialization plan that is heavy on adaptable engagement with HCPs, payers and patients on their terms and light, by necessity, on some traditional selling and marketing tactics. And it will also expose the importance of combining thoughtful field team engagement with supporting tactics for HCP, payer and patient engagement. Customers are likely to seek advice, training, and data from new places and may be open to (or even demand) new types of communication.

### 3. The Need for Organizational Flexibility: Planning, Communication, and Alignment

Uncertainty and change are driving pharma launch teams to prioritize flexibility in both launch strategy and tactics. This need for flexibility enhances the required planning, communication, and stakeholder alignment. For example, what if restrictions on field representatives last longer than anticipated? Or if field representatives are not able to see as many HCPs even after restrictions are lifted? Or if new virtual support capabilities are required to maximize effectiveness or HCP access? Can enough flexibility be built into the launch plan, with agreed upon milestones and gating, to trigger necessary changes to strategy and tactics? Launch teams will need to be ready to embrace change and have the processes in place to effectively adapt tactics accordingly.



#### 4. The Need for Data Driven Flexibility

Incorporating flexibility into the commercial launch planning model can only be done with data. Evidence of success or struggle should be available quickly to prompt decision-making. Planning for the appropriate flow of data and the ability to quickly interpret, compare, and generate insights from the data will be vital to every successful launch plan. The silver lining is that the 'forced' experiment of COVID-19 will produce new data on the effectiveness of alternatives to traditional launch activities. Ultimately, the best pharma organizations will serve their customers better when they create avenues for feedback and structures to act quickly on that data.

How can these four needs be met by pharma launch leaders? To achieve the level of flexibility required to succeed during COVID-19 and beyond, pharma organizations will need to create the culture and consider the people, processes, and tools that are the scaffolding for launch excellence.

### The show must go on...with a shift in mindset

These needs are not brand new – they have been taking root for many years – but COVID-19 is bringing them to the surface and accelerating the need to be flexible and agile.

Priorities are changing and communication is becoming more challenging, but drugs are still being developed (both new products and new indications) and moving towards launch (with many expected in the next year). Leaders must take a step back and think about whether they have a culture that considers change to be inherent and the necessary processes and tools in place to adapt to change, ensuring seamless launch readiness in any environment.



14 TGaS network members responding as of 4.10.20



#### **Communication is critical**

Although in-person interactions still hold strong value, our methods and avenues for communication are evolving and becoming more important than ever.

Successful communication is hard work and requires active participation from leaders and their entire teams. A successful product launch requires teams to be in lockstep in terms of both strategy and the tactics that follow. As we've seen historically, there is a tendency for the various teams/functions involved in product launch to become siloed that will only become further exacerbated in this more virtual world.

Alignment requires a system designed to promote communication and a culture where every team member is comfortable speaking up with updates, concerns, and ideas. Maintaining this in the current environment comes with new challenges. A couple simple tips below can help your team recognize the value of communication in its many forms.

According to a recent Trinity survey (by TGaS Advisors), "Maintaining an aligned organization" was reported as essential by 100% of respondents in high-performing launches.



# Just as launch is a process and not a point in time, communication follows

Rather than being a one-time engagement, launch planning demands continuous iteration to adapt to dynamic situations such as shifting FDA deadlines, uncertain distribution readiness dates, or surprising clinical trial results. Your communication strategy and tactics should too. Try different types of structured connections – 1:1, small groups, larger workshops – to see what works best for each situation. And be proactive about scheduling time to talk about the *process* as much as the *performance*.

While structured meetings are important to launch planning, unstructured communication is often eliminated, especially in this new virtual environment. Yet, that is a key avenue for connection. One idea is to schedule a 10-15 minute "stand-up meeting" (virtually for now) - with no agenda - to create space for unstructured communication and focus on relevant wins, challenges, and discussion topics.





# Foster time and space for people to challenge and question

In every launch engagement, there is a "comfort curve." Functional/sub-team leads see one of their activities flagged as "At Risk" or "Delayed" and immediately panic, feeling as though they need to justify or remove the flag. In reality, the launch process will be filled with questions, surprises, and even risks. There will be misalignment and missed deadlines. And with COVID-19 making everything even more unpredictable, these "flags" will likely pop up even more often. Don't panic! You are not alone on the path to launch readiness. Your question may elucidate a key area of misalignment and allow for early mitigation to avoid any downstream effects. Your idea may help someone else answer a question that they had been mulling over but had not yet asked. Remember that your team is there to help you and those pesky flags are only meant to prompt discussion and facilitate support and mitigation when most needed.

### Launch management is more important than ever

Don't underestimate the value of Project Management Office (PMO) in today's environment.

Ruthless prioritization mentality is still a must-have for launch, yet not at the expense of a focused PMO resource.

We knew PMO functions (either sourced internally or externally) were critical prior to COVID-19. With this new changing and dynamic environment, your PMO resource(s) are now more important as plans, communication, priorities, and resources shift.

Recently, we have watched our clients work tirelessly to reprioritize and maintain progress in the current environment, and we have seen first-hand that PMO processes remain a critical priority for many of our clients.

According to a recent Trinity survey (by TGaS Advisors), 67% of companies that had a PMO function (or similar) in place to oversee launch reported that their launch performed above expectations vs. only 17% for those that did not have a PMO function in place.

The virtual transition has not always been seamless, but companies that already had strong communication and management processes in place were able to make this transition more smoothly and maintain cross-functional alignment.



A detailed and cross-functional plan is critical to elucidate interdependencies and ensure alignment to the over-arching strategy. This plan serves as the single source of truth, even as priorities shift and resources change. But a plan is only as accurate as it is updated. Even though updating the launch plan may get moved to the bottom of your to-do list – why plan when you barely have the time to DO? – continuing to update the launch plan regularly will ultimately make the launch readiness process more efficient and effective.

In addition to the obvious benefits of having an updated plan, there is a positive "cycle of accountability" factor here that helps elevate the effectiveness as well. When there is critical mass (enough people/teams keeping their plans updated) and sufficient transparency, accountability is at its highest and people are more motivated to keep their plans up to date. At that point, the launch team and leadership can trust the plan, and it becomes a nexus that connects the teams, contributing to an environment that is conducive to constant collaboration and alignment. An effective launch is realized not only through tracking key tactics (aligned to strategy), but also through diligent tracking of the process itself.

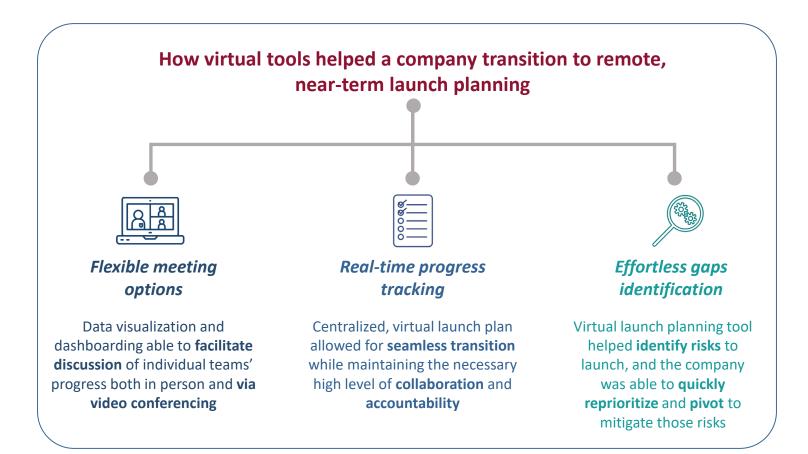
### Flexible tools elevate your communication and management

When existing communication, collaboration, and tracking processes become impossible, flexible and customizable tools and technologies can help fill the gap.

Technology and governance processes need to be engaged early and effectively to counter the current crisis and meet shifting need and demand. These tools must be flexible, user-friendly, efficient, and customizable and can ultimately provide the framework to ensure cross-functional communication and progress. These tools will become the backbone of this "new normal" and allow organizations to maintain (or even improve!) upon their current level of collaboration, transparency, and alignment. We have seen first-hand how the industry is turning to virtual and digital platforms to engage both with customers and internally to track and report on key performance indicators (KPIs). The case study on the following page provides an example of the flexible virtual tools facilitating launch success.



### Real-World Case Study of an Emerging Biotech Launching an Oncology Product in 2020



Successfully leveraging these platforms to drive efficiency, prioritization, communication, and execution will ensure that therapies reach the patients who need them as soon as possible, even in unpredictable times.



#### **Conclusion**

COVID-19 has reshaped the world as we know it. While it has threatened both lives and livelihoods, it has also highlighted the importance of the human element in everything we do. Maintaining communication, collaboration, and organization is more important than ever. As we recognize this new normal and accept the change we know is needed, there are avenues to help you succeed on your journey to launch. Prioritizing resources that align with your strategy is more important than ever. Having the right people, processes, and tools to recognize this shift and catalyze continued success is critical.

"Those who launch pharma products in the age of COVID-19 need not do so alone. A successful partner in launch readiness recognizes the need for change, but does not compromise the human element of launch success. At Trinity, we believe in facing challenges with data, flexibility, and collaboration. Your peers are facing similar challenges and evolving their processes and best practices to overcome these hurdles.

Our launch planning processes and tools incorporate these comparative experiences and learnings (in collaboration with our TGaS benchmarking division) to help our clients evolve their own processes and best practices to ensure launch success. Our flexible and adaptable Launch Accelerator tool ensures coordinated tracking and collaboration, no matter the environment. We are proactively preparing for a new launch normal – are you ready?"

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