

COVID-19 Briefing Series

Impact of COVID-19 on New Product Planning

As the world continues to struggle with the many implications from the COVID-19 pandemic, Trinity will be highlighting specific issues faced by our customers in the life sciences industry. In this briefing, we explore some of the immediate challenges presented to New Products Planning (also known as Early Commercial Planning or New Product Commercialization) groups.

Perspectives from 14 Industry New Product Planning Leaders

Highlights from Trinity's Recent Research Focused on Biopharma New Product Planning

New Product Planning (NPP) groups are working to forge ahead with business planning and execution despite the challenges presented by the COVID-19 pandemic. Trinity is bringing together the latest data on challenges and solutions NPP groups have been experiencing over the past month. This research activity is a joint project of Trinity's Strategic Advisory group and its benchmarking division, TGaS Advisors.

Background: 14 NPP leaders from the Trinity/TGaS benchmarking network participated in a survey to discuss how they are approaching the challenges and uncertainty caused by COVID-19. NPP groups in emerging life science companies and mid/large tier companies were surveyed. The survey aimed to identify the specific processes that COVID-19 has impacted across strategic planning, clinical development milestones, and R&D transitioning. The following pages highlight discussion related to each of these key themes.

- ▶ NPP teams have implemented virtual workarounds to execute most internal-facing activities; however, transitioning external engagement to virtual methods has proven more challenging and many external-facing activities have been delayed.
- ▶ Although NPP teams anticipate delays in market research as they shift to virtual methods, they may find HCP availability to be better than they expect, enabling them to continue critical research and strategic decision-making in the near term.
- ▶ Many biopharma companies have halted new enrollment in ongoing trials and paused initiation of new trials, causing uncertainty for NPP teams.
- ▶ Most survey respondents are uncertain about how COVID-19 will affect the volume of BD efforts; a few, however, believe that activity could increase in a climate of depressed valuations and increased need for cash.

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NPP teams have quickly adapted internal processes to remote working – leveraging web-based platforms for communication within their teams and cross-functionally – but indicate that these means of communication are yet as efficient as in-person meetings, and improvements may be needed to sustain effective remote work over a longer period.

“To date, we have primarily just changed how we communicate (remote vs. in person), but more significant changes to processes might be in order if the lockdowns persist for a long period of time. Our processes are not at all efficient for remote working.”

Several key NPP processes have been more significantly impacted – such as **diligence, where on-site visits are no longer feasible, portfolio reviews, where progress of pipeline product readouts have been delayed, and networking / in-person meetings (conferences, advisory boards, KOLs, congresses, meetings with external colleagues)**. A minority of NPP teams report having conducted advisory boards and KOL engagement via remote channels, with most expecting to do more of this if social distancing continues through the summer.



Have any of your NPP processes been affected due to COVID-19? (n=14)

Yes, 8 No, 2 Too early To Tell, 4

Please describe how your NPP processes have been affected

Diligences are slower/ delayed (especially for smaller biotech companies who need to open data rooms)
Slow down in primary market research, medical conferences and accompanying activities canceled, advisory boards postponed
Teams are evaluating delays to development and working virtually slows decision making
Less substrate/disease opportunities for analysis coming from our discovery team. Also impacts to timeline for our clinical programs and when we begin commercialization activities
Progress of some pipeline product readouts have been impacted. Portfolio Review has been delayed. Ability to participate in industry conferences / network with external colleagues
In person market research has been postponed and recruitment for virtual market research has also been impacted due to constraints on physician's time
Timeline shifts. Engagement plan is "on pause" and need to explore other approaches
All discussions are remote vs. in-person meetings (reduced efficiency), much more limited KOL interaction, and study startup processes (e.g., site visits) are delayed

Respondents highlight that NPP functions are downstream from many of the business units immediately impacted by COVID-19 (R&D and clinical development); however, NPP leaders feel that the long-term impact on their work is still being assessed.

Although NPP teams anticipate delays in market research as they shift to virtual methods, they may find HCP availability to be better than they expect, enabling them to continue critical research and strategic decision-making in the near term.

Social distancing requirements and the closing of non-essential businesses in many areas have brought in-person market research to a halt. NPP teams have adapted by shifting research to virtual methods – leveraging telephone and web-based interviews to conduct critical market research to support strategic decision-making.

“Almost everything we do in NPP can be done virtually. We have had to postpone some market research while we prepare for doing this kind of work virtually.”

NPP teams have extended timelines for fielding market research due to anticipation of new constraints on HCPs’ time. Although some NPP teams have stopped initiating new market research because of expectations around decreased HCP availability most anticipate these delays will be temporary.

Many hospital-based HCPs, especially in areas with significant COVID-19 caseloads, may have new time constraints as they are called to treat COVID-19 patients. However, a subset of HCPs may be increasingly available for market research that NPP teams may be less aware of. [A recent report from Trinity and Toluna](#) highlights that 49% of HCPs surveyed indicate an increased availability to participate in research studies, and 35% indicate their availability was the same as before COVID-19.

Bridging this disconnect between NPP teams’ perceptions of HCP availability during COVID-19 may help support the continuation of critical market research and strategic decision-making during this time.

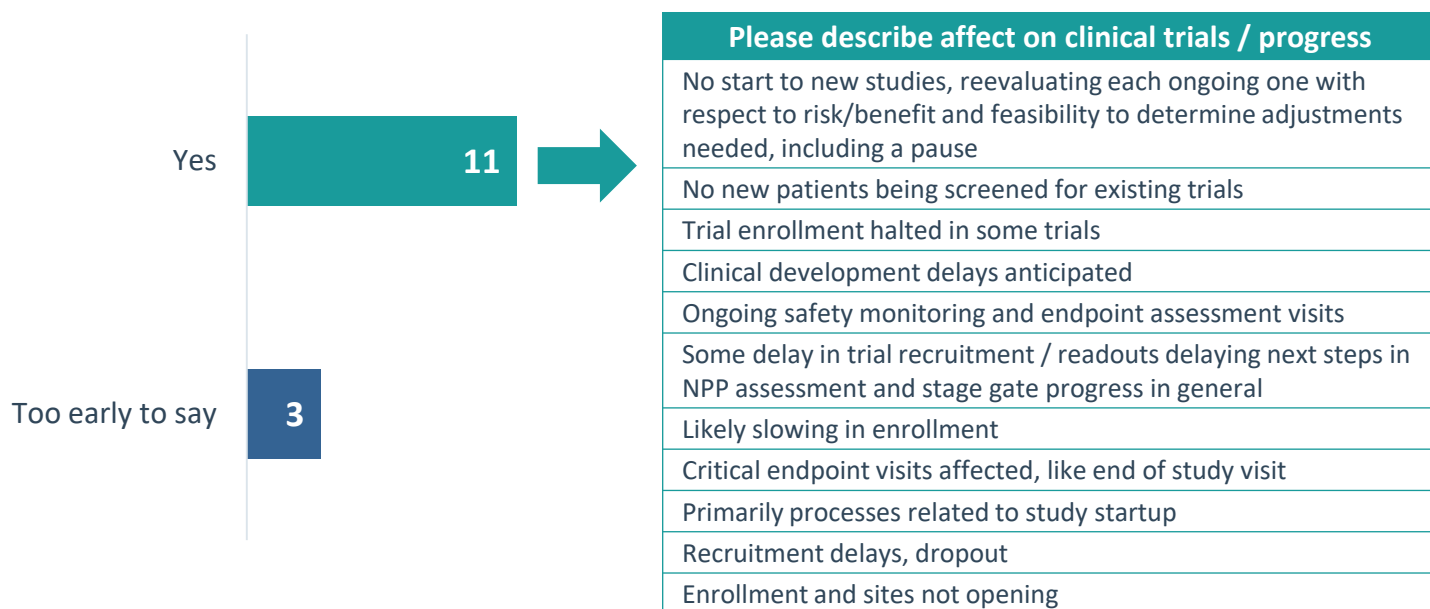
Importantly, some NPP groups are launching **new market research focusing on COVID-19**. One NPP group aims to assess how COVID-19’s impact on clinical trials is affecting the industry, and another is leveraging market research to gauge the relevance of their product’s MOA for COVID-19. Going forward, NPP teams will need to understand how COVID-19 will reshape delivery of healthcare and patient behavior, and how those changes will alter the commercial opportunity of pipeline products. COVID-19’s impact will likely continue to be felt throughout the industry for some time, and NPP teams will need to seek clarity on how to incorporate that impact into strategic decision-making.

Biopharma companies have halted new enrollment in ongoing trials and paused initiation of new trials, causing uncertainty for NPP teams.

Due to social distancing and limited non-essential hospital and medical office visits, clinical trial enrollment has declined. Several manufacturers have delayed initiation of new trials, and are re-evaluating feasibility of ongoing trials. Some manufacturers have determined that the risk of conducting trials during the COVID-19 outbreak outweighs the benefits of continuing them, and have opted to pause ongoing trials.



Have your company's clinical trials / progress been affected due to COVID-19? (n=14)



This has led to some uncertainty for NPP teams. Lack of clinical data has hindered NPP teams' ability to support development transitions (go/no-go's) and meet development milestones. The current status of clinical trial enrollment is therefore likely to cause broad delays to strategic decision-making throughout the pharmaceutical industry.

"Across stage gates, there is general development milestone uncertainty. Our ability to perform confirmatory research studies to support development transition has been impacted."

To help compensate for these delays, some NPP groups have pushed forward with commercial insights activities to shorten time needed for future decisions (such as guiding toward clear alignment on go/no-go criteria and future trial design). The hope is that these activities will shorten downtime between clinical phases once they re-initiate.

Most survey respondents are uncertain about how COVID-19 will affect the volume of BD efforts; a few, however, believe that activity could increase in a climate of depressed valuations and increased need for cash.

NPP teams are mixed in their expectations for the volume of business development (BD) efforts to change in the near term due to the COVID-19 outbreak.

Several feel it is too early to assess this aspect of their work, while others feel that BD efforts may be heightened during (or immediately following) this time. NPP teams are seeking ways to overcome delays in clinical development and may be looking to BD as a way to fill that gap. Moreover, depression of valuations and potential need for cash may create a climate of more deals in the wake of COVID-19, and NPP/BD groups want to be ready to move quickly.

“People still get cancer and it is a high unmet need area (that) will continue to be a priority for BD.”



Do you expect the volume of business development (BD) efforts to change in the near term due to COVID-19? (n=14)

Yes, increase = 4



No, decrease = 2



Have not determined = 3



Don't Know = 5



Which of the following best describes how your organization's BD efforts are being impacted by COVID-19? (n=2)

The internal process for assessing BD opportunities is being delayed / slowed down



Some NPP groups are more conservative in their expectations for BD efforts, anticipating these efforts to reflect a general slowdown of NPP activities due to the implications of COVID-19.

Conclusion and Summary:

The COVID-19 outbreak is likely to continue to have a substantial impact on processes critical to NPP teams over the coming year and Trinity will continue to monitor developments as the situation is evolving rapidly. Please contact Trinity at info@trinitylifesciences.com with any specific questions you may have.