OVERCOMING COVID-19

Adapting to a new trial landscape

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In a recent survey of clinical trial sites, one-third reported that they expect COVID-19 to have a "big or extremely big" impact on recruiting patients or keeping them enrolled in trials.[1] On March 23, 2020, Eli Lilly and Company became the first major pharmaceutical company to announce that most new study starts will be delayed and enrollment in most ongoing studies will be paused.[2] Bristol Myers Squibb has also recently outlined its policies on enrollment and new site activation during this time.[3]

While it is expected that all trials will be affected in some shape or form, the degree of disruption will likely depend on the type of study, patient population, location of treatment (hospital vs private clinic), and current status of the trial, among other factors. As part of our **"Overcoming COVID-19" series, we assess COVID-19's impact on clinical trials, planned and ongoing, and consider what marketers can be doing now to adapt to these changes.**

With the safety of all patients, researchers, and professionals a top priority, companies are now trying to understand how their current and future trials are affected. The FDA's published guidance lays out how institutions and trial sponsors can rapidly adjust the way current trial participants are monitored to achieve maximum patient safety.[3] Typically, trials have prespecified rules for treatment interruption in their protocols, but the requirement for thorough documentation of the effects of COVID-19 on the trial will help ensure that the resulting data are interpretable.

A summary of the FDA guidance on conduct of clinical trials during the COVID-19 pandemic

- Trial sponsors should evaluate whether phone calls, virtual visits, or alternate locations for assessments can be used in lieu of protocol-specified visits
- Changes to study protocols to protect the participants from COVID-19 do not need to be approved by the institutional review board (IRB) before implementation (changes must be reported to the IRB afterward)
- If a patient misses a visit or discontinues a trial due to COVID-19, this must be documented and summarized in the clinical study report (CSR)
- Prior to locking trial data for statistical analysis, the trial sponsor should address in the statistical analysis plan how COVID-19-related protocol deviations will be handled in the analyses
- This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS)

As marketers, it is worth considering how any delays or approvals to clinical trials will not only affect our own brands, but also any competitive products. On the following page, we review three different trial scenarios and how brands can adapt their plans. To discuss how we can help prepare for any potential impacts, contact your Evoke account lead or email us at business@evokegroup.com.

Adapting to a new trial landscape

Scenario 1: Products with completed clinical trials and imminent launches

Currently, data readouts and approvals have been minimally disrupted because patients in the trials were already treated before the pandemic started. For products launching during the pandemic or soon after, **the tone of communications is important**. While press releases and Day 1 websites may be launched as planned, social media posts about new products should be balanced with the company's response to COVID-19 and what kind of support they are providing to patients and HCPs.

Additionally, it is important to keep an eye on your competition as well as your own timelines. Some brands may unexpectedly shift ahead of their competition, resulting in a rapid reordering of priorities as the strategy changes. If a new product does not treat a life-threatening condition or is entering a crowded marketplace, companies may want to consider delaying launch. If a new product was to be part of a franchise, a shift to franchise marketing during this time can help keep the company's portfolio top-of-mind and generate enthusiasm about the company's work in this space for when the new product is released.

Scenario 2: A product with good early-phase data and an ongoing pivotal trial

This scenario is likely to be the most challenging, because a brand team and marketing agency will already be in place, but the data readout could be delayed due to the inability to collect follow-up data during the COVID-19 pandemic. This is a good time to make critical decisions about your market research plans. As HCPs may be less available right now, the plan of when and how to conduct market research should take that into consideration.

For brand marketers who are faced with this situation, consider what type of unbranded material can be developed during an unexpectedly long lead time to shape the market, particularly if your competition is also experiencing delays. This can be an opportunity to partner with your agency to brainstorm creative concepts and tactics that will break through and reach targets when the time is right.

Alternatively, you may want to pivot your messaging objectives in response to what your competitors are doing. It may be prudent to delay campaigns or data messaging created in response to new entrants that were expected to disrupt a market. Brands may want to shift messaging to focus on long-term outcomes and real-world data, to gain an advantage over the competition. Scenario planning can be an effective exercise to help anticipate how competitors are going to handle their delayed launch.

Additionally, since major congresses are going to be virtual for the foreseeable future, it is important to determine **the best ways to make a virtual splash at these events**.

Scenario 3: Products in early-phase trials

Finally, there may be drug candidates with promising preclinical or early clinical data that are put on hold. These decisions could affect the industry and brand marketing over the next several years. However, products with promise for areas of high unmet need, such as oncology and rare diseases, will likely continue as soon as possible after the COVID-19 pandemic has waned. In the meantime, marketers can increase corporate or franchise messaging. Keeping pipeline websites accurate and up to date will also help raise awareness of promising drug candidates while the clinical trials are on hold.

1. *http://www.appliedclinicaltrialsonline.com/measuring-impact-covid-19-outbreak-clinical-trials*
2. *https://investor.lilly.com/news-releases/news-release-details/lilly-provides-update-clinical-trial-activities-during-covid-19*
3. *https://www.bms.com/about-us/responsibility/coronavirus-updates/covid-19-update-letter-to-investigators.html*
4. *https://www.fda.gov/media/136238/download*