

Considerations for Forecasting the Spread of COVID-19

*How can life sciences companies most accurately project
the spread of COVID-19 to plan for the future?*



Abstract

The COVID-19 pandemic has reshaped daily life worldwide through most of 2020, yet what we know about the virus itself, the best approaches to mitigate spread, the potential impact of emerging therapies, and when we might expect to see an effective vaccine changes every day. Forecasters we work with have been fielding COVID-19 related questions from their stakeholders on a regular basis to support a wide array of business questions. Amidst this constantly shifting information landscape, forecasters in life sciences need to forecast the impact of COVID-19 as accurately as possible, yet with the agility to adapt forecast scenarios in response to new data. A credible and adaptable forecast requires the development of a model that combines a rigorous approach to forecasting the spread of infectious disease and the best, most current information to inform the model.

As Trinity Life Sciences has worked with dozens of pharma, medical device, and diagnostics companies over the past months we have witnessed the struggle of forecasters and their stakeholders to stay on top of this information flow and translate it into meaningful insights to support decisions. We have also been part of many successful transformations of forecasting processes and model builds. Based on these best-practices and our experience forecasting pharmaceutical and medical device products for more than 20 years, we have formulated the framework we outline in this paper.

Overview

Who Needs to Track COVID-19?

COVID-19 has affected every aspect of life in the communities where it has spread, from the most basic and everyday actions – grocery shopping, going to work, spending time with family – to the specific challenges of healthcare systems grappling with treating affected patients. Nearly every life sciences company has been materially affected by the pandemic, whether that company is developing vaccines or therapies targeting COVID-19 itself, have forthcoming products whose clinical trials are affected by the challenges of COVID-19, or have existing products whose demand has been impacted by the spread of COVID-19. And like all employers, companies need visibility into the future of the pandemic to plan for the return to work of global employee bases. As a result, companies throughout the life sciences industry are looking for the best ways to model scenarios for the future of COVID-19 and incorporate those decisions into their forecasting and decision-making.

The outlook for development of COVID-19 therapeutics, vaccines, and diagnostics is complex with no contemporary precedent. Given the extent and devastation the disease has had on a global scale in a few short months, both the public and private sectors have already invested significant time and resources to better understand the virus, the disease it causes, and to develop therapeutics and vaccines that will lessen the global burden of disease.

More than 30,000 unique peer-reviewed, English language scientific papers on COVID-19 were published in the period from January 1, 2020 to June 19, 2020, and more than 250 treatments are in development, of which more than 150 are in clinical stage testing. More than 150 vaccines are in development, 16 of which have advanced to clinical development.

This represents an extraordinary worldwide effort toward mitigating the pandemic. It also represents a fluid market with rapidly changing information where developing plausible future scenarios to inform forecasting of COVID-19 cases and hospitalizations is fraught with significant challenges.

With so much at stake, and so much change, forecasting in this environment is both vital and difficult. The vast amount of relevant information being produced daily, combined with the need to create a multitude of scenarios to give stakeholders the necessary perspective required to make day-to-day decisions presents a novel challenge for forecasting teams.

Forecasters in life sciences companies developing vaccines and therapeutics targeting COVID-19 need to consider a series of assumptions that are critical to projecting the future of the COVID-19 pandemic. These are:



Virus Characteristics

Properties intrinsic to SARS-CoV-2 virus, the virus that causes COVID-19



Pandemic Characteristics

The extent of disease spread and recurrent waves, and the impact of policy decisions on disease spread



Vaccine Characteristics

Properties of vaccines used against SARS-CoV-2, as well as the ramp-up and deployment of vaccines



Therapeutic Characteristics

Properties of emerging treatments for COVID-19, including their efficacy, as well as the setting in which they are used



Economic Characteristics

Factors that will impact the likelihood of widespread access to relevant treatments and vaccines



Virus Characteristics

As new data are published daily, our understanding of the core properties of the SARS-CoV-2 virus continues to expand. This information needs to inform models forecasting the trajectory of the pandemic, especially as it will have a significant impact on the spread of the virus from person to person and on how both the short- and long-term trajectory of the pandemic will evolve. Several characteristics of SARS-CoV-2 appear to be intrinsic to the virus and agnostic of country, demography, and healthcare infrastructure. These include:

Infection/ Incubation Period	Immunity	Seasonality	Viral Evolution
The period during which an infected individual can transmit the virus to others	The extent and duration of natural protection from re-infection after disease recovery	The extent, if any, that transmissibility increases during the cooler winter months, resulting in greater disease outbreaks during this time	The extent to which the genomic sequence of the virus changes over time, and whether those changes affect the efficacy of vaccines or therapeutics

Infection/ Incubation Period

Understanding the incubation period of SARS-CoV-2 is of critical importance to public health initiatives, and especially for determining the necessary period of time for potentially infected individuals to undergo quarantine. At present, the incubation period is estimated to range from 2-14 days. However, even recently published analyses rely heavily on data gathered early in the epidemic, and subsequent analyses may continue to refine our understanding of the incubation period, particularly in pre-symptomatic and asymptomatic individuals.

Immunity

A considerable degree of uncertainty surrounds immunity to SARS-CoV-2. Published literature indicates that most patients who recover from COVID-19 retain some degree of immunity¹, but it is not yet known how long immunity will last, and the duration of immunity specific to SARS-Cov-2 may not be known for some time. The duration of protection is critical to modeling the future coronavirus market, because if immunity is not permanent, recovered patients must be reintroduced into the pool of susceptible patients to estimate the size of future outbreaks. Two studies have suggested that levels of neutralizing antibodies wane after only a few months in some patients; however, both are relatively small and neither estimates the average duration of immunity post-infection.

One approach² to modeling the duration of immunity is to use related coronaviruses as analogues to forecast the future susceptible population for infection with SARS-CoV-2, as seen in the model developed by Kissler et al. to project transmission dynamics of the virus during the post-pandemic period. The duration of immunity against reinfection for related coronaviruses ranges from 40 weeks for HCoV-OC43/HKU1 to 2 years for SARS-CoV-1³; if SARS-CoV-2 has a similar duration of immunity, the virus will enter into regular circulation and subsequent outbreaks can be expected. However, a clearer picture of the periodicity of outbreaks will not emerge until the duration of immunity of SARS-CoV-2 itself is more clearly documented.

Seasonality

The potential for seasonality in the pattern of infection with SARS-CoV-2 also remains an open question. Other coronaviruses of zoonotic origin have circulated seasonally following the initial wave of infection, similar to the seasonal variation in influenza infection. To date, academic models estimating the seasonality of SARS-CoV-2 rely on analogues such as HCoV-OC43/HKU1⁴, which shows a modest winter increase but one of lower magnitude than seen with, for example, influenza in cooler regions of the world. However, this understanding of SARS-CoV-2 could shift as the body of knowledge about the relationship between temperature, humidity, and other seasonal factors continues to grow and provide more specific information about SARS-CoV-2 itself.

Viral Evolution

Finally, the viral evolution of SARS-Cov-2 is not yet well understood, but is certain to have an impact on development of vaccines and therapeutics. The influenza virus is likely the best-known example of a virus that mutates rapidly enough to necessitate adaptations to the vaccine on a regular basis and to require annual vaccination programs to continue to aim for widespread immunity in the general population. Again, the fact that SARS-CoV-2 has emerged so recently makes an accurate estimation of the mutation rate challenging and the emergence of new strains difficult to predict.

Research predating the emergence of SARS-CoV-2 estimated a mutation rate for coronaviruses of approximately one-tenth that of influenza virus⁵; however, research cannot rule out the eventual emergence of strains with mutations to molecules that are being explored as targets for vaccines and therapeutics, most notably the spike protein and the RNA-dependent RNA polymerase.



Pandemic Characteristics

While the virus has certain universal features, individual country and state responses to combating the spread of COVID-19 have been highly variable. Enforced or encouraged social mitigation measures, the number of currently infected individuals in a population, and hospitalization rates for COVID-19 patients, all have an enormous bearing on what the future market for COVID-19 therapies will look like.

Measures to mitigate the spread of disease can have a substantial impact on the course of the COVID-19 pandemic; however, a clear understanding of what measures have the greatest impact and the magnitude of impact of those measures is only now beginning to emerge. Notably, the impact of measures to curtail airborne transmission – especially the wearing of face coverings – was not emphasized by either the Centers for Disease Control and Prevention (CDC) or the World Health Organization (WHO) early in the pandemic. However, recent research suggests that the wearing of face masks combined with testing, quarantine, and contact tracing efforts presents perhaps the most powerful means to substantially slow the spread of COVID-19 prior to the development of an effective vaccine⁶.

National, state, and local governments have adopted these measures to varying degrees. Individual US states have taken widely varying approaches to curbing the epidemic. In May 2020, several states relaxed stay-at-home orders and allowed a wide array of businesses to reopen; by mid-June rising infection and hospitalization rates began to raise concerns that some businesses reopened too soon and with too few precautions. In July, several states announced new measures to curb the spread of COVID-19.



To understand both the near-term and long-term future of COVID-19 infections in the United States, then, forecasters will need to monitor trends in both new infections and the implementation of measures to curtail infection.

Developing a forecast that accurately takes pandemic characteristics into account can be accomplished by incorporating, monitoring, and adjusting three key variables:

Current Reproductive Rate of the Virus (R_t)

Cumulative Incidence Rate

Hospitalization Rates

Current Reproductive Rate (R_t)

The current reproductive rate (R_t) is the number of individuals an infected person can subsequently infect at a given point in time and is a function of the degree of person-to-person interaction. An $R_t > 1.0$ results in exponential growth in infections, while an $R_t < 1.0$ results in a decline in infections. R_t is a particularly important variable for tracking the coronavirus outbreak because it indicates the current rate of transmission in real time, allowing for an evaluation of public health interventions, comparison of different geographies, and expected new cases in a population. For R_t to be used effectively in forecasting the spread of COVID-19, it needs to be updated frequently; otherwise it will not accurately represent the real-time rate of transmission.

Cumulative Incidence Rate

Experts also rely on the 10-day cumulative incidence rate to gauge the trajectory of disease spread. 10-day cumulative incidence should track to directional changes in the R_t . The 10-day cumulative incidence rate is a core driver behind concerns expressed by public health experts following the recent easing of mitigation measures seen across US states.

Hospitalization rates

Hospitalization rates – the proportion of confirmed COVID-19 cases that are admitted to the hospital for inpatient monitoring and treatment – are a key variable in estimating the size and severity of the pandemic, and are critical to clearly defining the outpatient vs. inpatient market for COVID-19 therapies. Hospitalization rates can vary by state and country due to admission standards, cultural norms, and public vs. private healthcare system infrastructure, as well as the extent to which COVID-19 testing is occurring throughout the population.

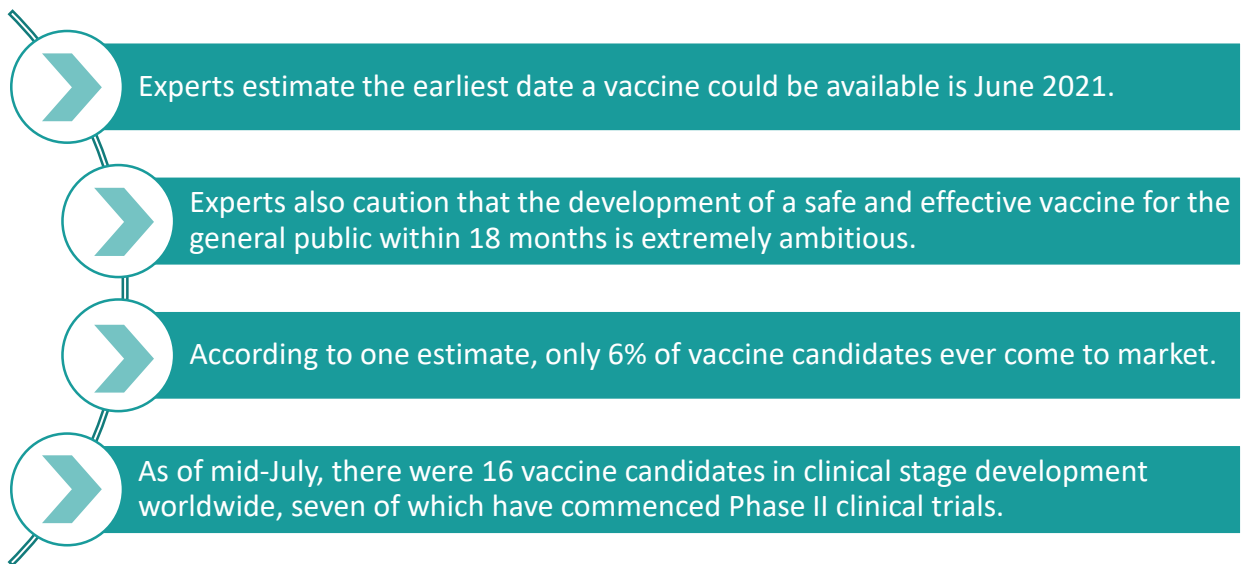
These characteristics shape the short-term outlook for the COVID-19 outbreak and can help forecast the outlook for the evolution of COVID-19 in the US as well as understand whether some countries will be disproportionately affected by future waves of this pandemic. Notably, pandemic characteristics will evolve as knowledge about the intrinsic properties of SARS-CoV-2 evolves; for example, a better understanding of the virus's seasonality will in turn lead to increased mitigation efforts in cooler regions of the world if transmission is indeed likelier in the fall and winter months. Those mitigation efforts will in turn alter R_t .



Vaccine Characteristics

The development of a vaccine could dramatically reshape the trajectory of the COVID-19 pandemic; however, while the focus in major news outlets has often been the question of when a vaccine will arrive, it is by no means the only critical piece of the vaccination puzzle. Vaccine efficacy, ramp-up, and deployment will also affect the future of COVID-19 cases throughout the world.

Despite hope for an earlier launch, experts estimate that the earliest date a candidate vaccine could be available is June 2021; however, these experts also caution that the development of a safe and effective vaccine for the general public within 18 months is extremely ambitious. Furthermore, the failure rate for vaccine candidates is relatively high – according to one estimate, only 6% of vaccine candidates ever come to market. As of mid-July, there were 16 vaccine candidates in clinical stage development worldwide, seven of which have commenced Phase II clinical trials⁷ (Milken Institute ref).



Vaccine Efficacy

Vaccine efficacy is the protection or immunity conferred by a given vaccine defined as the percent reduction in incidence in a vaccinated population compared with an unvaccinated population. The WHO developed a target product profile for a COVID-19 vaccine with a target vaccine efficacy of 70%, with consistent results among the elderly population⁸. Efficacy correlates with variables including age and underlying health; therefore, consideration of the age and co-morbidity of the target population is necessary to anticipate the impact a COVID-19 vaccine will have on overall infection rates.

Ramp-up

Once a viable vaccine is developed and approved for use, a period of time for “ramp-up” will occur in each region before the target population in any given country or region is vaccinated. Ramp-up depends on numerous factors including manufacturing scalability, shipping logistics, the country of origin of the successful vaccine manufacturer, national spending power, and others. During this time, some high-priority populations may be vaccinated before the vaccine is deployed on a widespread basis throughout the community. Healthcare workers and the elderly, for example, are likely to be early targets for a COVID-19 vaccine. To condense the time to vaccine distribution, several private-public partnerships have invested in developing infrastructure to manufacture and distribute several vaccine candidates at-risk, which would expedite the ramp-up to mass, global distribution when a vaccine is approved.

Adoption

The percentage of persons expected to be vaccinated is also a critical variable independent of ramp-up. Adoption of a vaccine in the broader community is highly influenced by social behavior and public health infrastructure; therefore, country-specific information is needed to inform estimates of vaccination rates. Historic vaccination rates may provide a starting point for forecasts, but forecasters will also need to monitor circumstances specific to COVID-19, especially any challenges or disruptions related to public health infrastructure caused by the pandemic itself.

Emergency Use Authorization

Finally, the question of whether regulators will apply processes authorizing emergency use of unapproved products to expedite access to vaccines, especially in vulnerable populations. In the United States, for example, under section 564 of the FD&C Act, the FDA Commissioner may issue an Emergency Use Authorization (EUA) to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency when there are no adequate, approved, and available alternatives. However, to date, although the FDA has issued over 100 EUAs, it has only done so for a vaccine once. In 2005 an EUA was granted to allow members of the military access to a vaccine against inhaled anthrax because of a perceived risk of an anthrax attack⁹.

There is, therefore, no precedent for issuing an EUA for a vaccine intended for widespread use in the general population.



Therapeutic Characteristics

Tracking the drug development landscape is vital for projecting the size and characteristics of the COVID-19 market. The pipeline has rapidly grown to encompass more than 150 candidate treatments in clinical development, spanning a broad array of technologies and molecular targets. The COVID-19 pipeline should be viewed as highly fluid; the rapid pace of new scientific research is likely to lead both to new drugs entering the pipeline and the discontinuation of some agents deemed less likely to prove effective.

At present, the COVID-19 pipeline includes agents that have been investigated or approved for other conditions; many of the compounds that have already advanced to clinical development are antiviral agents or immunomodulators that were identified long before the COVID-19 pandemic, but the pipeline also encompasses innovative compounds that have been rapidly developed specifically to target SARS-CoV-2. These include manufactured antibodies or cocktails of monoclonal antibodies developed by analyzing the blood plasma of patients who have recovered from COVID-19 and novel antivirals, as well as cell-based therapies and a variety of other approaches.

Results from trials of potential COVID-19 therapies are already emerging. On June 16, 2020, the University of Oxford issued a press release announcing results from the RECOVERY trial, a randomized trial testing a range of treatments for COVID-19 including low-dose dexamethasone. The results reported in the press release indicate dexamethasone reduced deaths by one third in ventilated patients and by one fifth in patients receiving oxygen only, with no benefit in patients who did not require respiratory support.

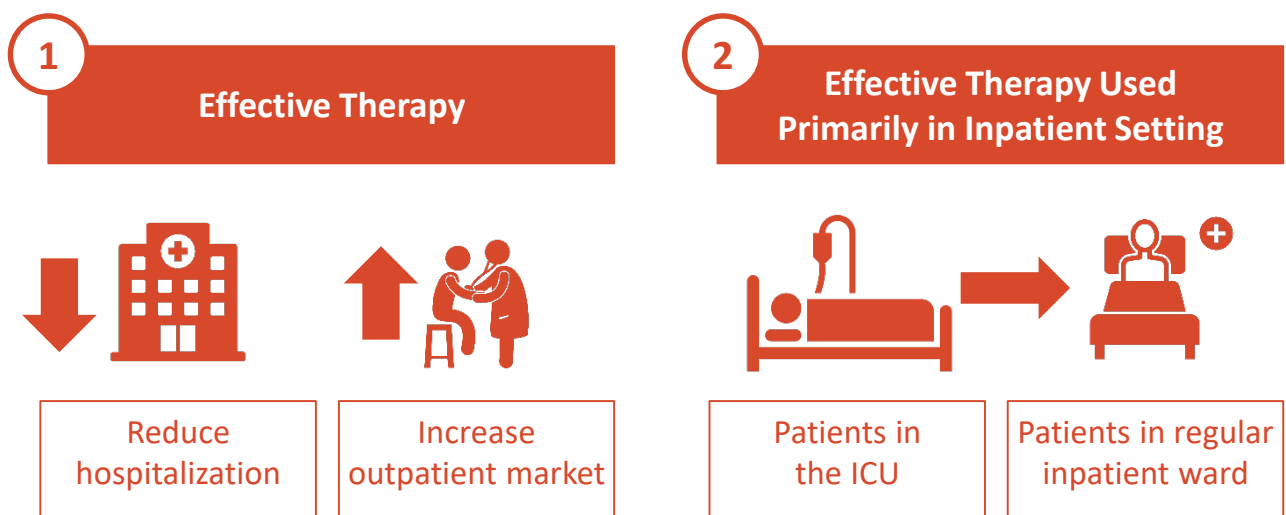
Based on these results, dexamethasone appears to be the first therapy shown to provide a survival benefit in hospitalized patients suffering from COVID-19¹⁰.

Forecasting the emergence of COVID-19 therapies should take into consideration the use of emergency regulatory pathways including the EUA in the US. On February 4 of this year, Health and Human Services Secretary Alex Azar determined that COVID-19 represented a public health emergency that justified the authorization of the emergency use of drugs and biologic products pursuant to section 564 of the FD&C Act.

To date, FDA has issued two EUAs for drugs to treat COVID-19: Gilead’s remdesivir to treat hospitalized patients with severe disease, and chloroquine phosphate and hydroxychloroquine sulfate to treat adults and adolescents who are hospitalized with COVID-19 and for whom a clinical trial is not available or participation is not feasible. However, on June 15, 2020, the FDA revoked the EUA for hydroxychloroquine and chloroquine based on data from a large, randomized clinical trial that showed no benefit for hospitalized patients for decreasing the likelihood of death or speeding recovery. The FDA has not yet acted in response to data showing a mortality benefit for dexamethasone; notably, the data have not yet been peer-reviewed. The UK, however, immediately authorized the use of dexamethasone for patients hospitalized with COVID-19 who require oxygen, including those on ventilators.

The pipeline can be examined and segmented not only by class of drug, MOA, and phase of development, but also by target patient population. Some agents may be more likely to be used in the inpatient vs. the outpatient setting, for example; within the inpatient setting, some may see greatest use in the ICU for patients suffering from acute respiratory distress syndrome. Understanding the potential use of a COVID-19 therapy is essential to understanding its likely impact. For example, an effective therapy could reduce the number of patients requiring hospitalization, thereby increasing the outpatient market size and decreasing the inpatient market, or an effective therapy used primarily in the inpatient setting could shift patients from requiring mechanical ventilation in the ICU and allow for patients to be treated in the regular inpatient ward with supplemental oxygen. To incorporate the impact of emerging therapies effectively, forecasters will need to pay close attention to the likely use cases of emerging agents.

Understanding the potential use of a COVID-19 therapy is essential to understanding its likely impact. For example:





Economic Characteristics

Finally, the economic impacts of COVID-19 will impact therapies in vastly different ways. Access, of course, is an important consideration; so are pricing and discounting, distribution, demand, and site of care. Pricing of vaccines and therapeutics in particular is likely to come under close scrutiny from the media and from elected officials and public interest groups; pharmaceutical companies will need to consider what pricing will be perceived as fair and reasonable – and avoid the perception of price gouging or profiteering.

On June 29, Gilead released pricing information for remdesivir. In the United States, a course of therapy will cost \$3,120 to hospitals for patients with private insurance¹¹. This price tag has been viewed generally fairly and positively: according to the Institute of Clinical and Economic Review (via the New York Times), this \$3,120 is roughly halfway between what Gilead needs to charge to recoup costs and what would make it a cost-effective therapy. However, Gilead will only be releasing the drug to the US through September, while the drug maker continues to manufacture more.

All of these can be impacted by secondary and tertiary economic impacts that may take a significant time to unfold and disproportionately impact some therapies more than others. Modeling for therapeutic impacts of COVID-19 will need to take all of these factors into consideration and be both sensitive and flexible enough to account for those economic impacts.

Conclusion

Given the sensitivity around each assumption in informing each country's COVID-19 outlook, forecasters need to develop models to be flexible enough to incorporate the findings from emerging scientific literature, adaptive to most recent case data, and pliable to emerging consensus from public health experts on plausible real-world scenarios. Forecasters must also develop the processes to bring in emerging data from an array of sources – including some new and unfamiliar sources that they have not previously encountered in forecasting work. Finally, they must communicate fast-changing results with stakeholders. We recognize that this is a tall task for forecasters but believe that forecasting in the midst of COVID-19 can be done well if companies move quickly to apply best practices and remain disciplined over time.

Trinity has developed a suite of products and offerings focused on helping organizations respond to challenges and opportunities presented by COVID-19. Trinity experts have been involved in COVID-19 related forecasting projects with dozens of companies in the past few months.

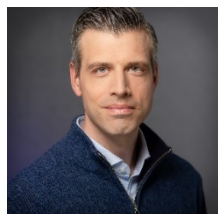
For forecasters, the **Trinity COVIDCast** offering includes robust dynamic models of the spread and impact of COVID-19 to support decision making. It can include weekly updates to keep models informed by the latest research and data. **Trinity COVIDPulse** is a survey-based offering that tracks key metrics among HCPs such as patient volumes, treatment restrictions and unmet needs. Both Trinity COVIDCast and Trinity COVIDPulse can be configured to support companies that are a) developing vaccines, therapies, or diagnostics related to COVID-10 or b) have products to promote or key decisions to make that are impacted by the spread of COVID-19.

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

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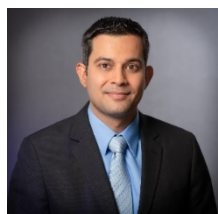


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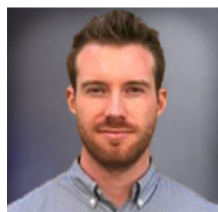


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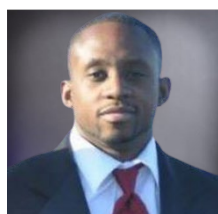
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