Streamlining systems to respond to COVID-19

Paul Aliu and his team quickly address requests for Novartis medicines during the pandemic.

By Maryse Jandrasits | Jun 18, 2020

When the coronavirus pandemic broke out, Paul Aliu knew that he would have to act fast. His team at Novartis soon received a deluge of requests from physicians around the world. Doctors asked to access the company's medicines more than 1 000 times during the first two months of the crisis to help patients with COVID-19 disease.

Paul Aliu, Global Head of Medical Governance for Novartis Global Drug Development

While vaccines for COVID-19 could be well over a year away, researchers are working to identify treatments for patients in the near term. This effort includes repurposing existing medicines for patients with COVID-19 disease. When physicians and investigators outside the company want to use or evaluate a Novartis compound or product for a new application, they contact Aliu's group via the company's medical teams.

Aliu's group has been very busy the last few months. Even for a team used to rapidly responding to requests for Novartis medicines – in 2019 the team handled more than 10 000 requests, approving 96.8% of them – the workload is unprecedented. Aliu, who is Global Head of Medical Governance for Novartis Global Drug Development, rapidly created a streamlined, COVID-19-specific process to respond.

In general, the team receives two types of requests that are relevant to the coronavirus pandemic. First, a physician can ask to use a product that's been approved for a different use or that is not yet approved or available in a country for a patient with a serious or life-threatening disease through a managed access program (MAP).[1] Second, a physician-scientist can request drug supply or funding from Novartis for a clinical study to test a new application of a product through an investigator-initiated trial (IIT).

The workload of Aliu's team has increased by 50% during the pandemic. Yet the group is working at warp speed.

The standard review timeline for a MAP request is approximately five business days. The team can now approve COVID-19 requests within three to four hours and ship drugs to epicenters of the pandemic within 12 to 24 hours. Review times for IITs have also been significantly reduced – from more than 30 days to 48 hours.

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>
> **Paul Aliu**

Following are excerpts from a conversation with Aliu.

You seem energized rather than overwhelmed. Why?

We are in the middle of a global health crisis, and the world needs to move quickly to find solutions for patients. It's this strong sense of purpose that drives me forward. I've also seen what successful science means for communities. For example, I was fortunate enough to be part of the team at Novartis that developed the first pediatric antimalarial dispersible tablet. I visited a village in Mali that had seen almost a zeroing of malaria deaths in children as a result. That was one of the moments in which I just thought to myself, "This is why we do what we do".

How are you able to process requests so quickly?

We asked ourselves, "Which components of the process can we eliminate or tweak to ensure we address patients' needs at the epicenters faster?" And we had medical reviewers in Europe, North America and Asia, which allowed for the processing of incoming requests 24 hours a day. Regardless of what time a request comes into our system, there is a medical reviewer who can make a decision very quickly to ensure that drugs get to patients as fast as possible. In addition, everybody has pitched in. People are working around the clock.

What role did technology play?

Technology has been critical in the acceleration of the process. Physicians can place a MAP request directly on our website. Everything – from the review to the approval – happens within this end-to-end system, including an automated notification to the physician regarding the status of the request. When the pandemic broke out, we reduced the number of questions that physicians, who already are stretched at the epicenters, need to answer when submitting a request. The system enables us to collect follow-up data on each patient and send automatic notifications to physicians at set intervals after the initial treatment dates. We also streamlined other aspects of the process that take place behind the scenes.

Are there lessons that we should take for the future?

The pandemic showed me that in a time of crisis we are able to rally together and respond. Even as a big organization, we can be agile, cut bureaucracy, be pragmatic and adopt smart risk-taking. We can't maintain the hectic pace forever, but we should try to maintain agility and continue to streamline our systems and processes.

Main image from Adobe stock: 3D rendering of COVID-19, the novel coronavirus causing the pandemic.

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1. To qualify for a managed access program, the patient must have exhausted all currently available treatment options and be unable to enroll into a clinical trial. Such provision must also be allowed by local laws.

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