Drug Delivery in Less Than 24 Hours: Accelerating Access During a Pandemic

Mobilizing to Confront a Crisis

As research and development work at Novartis addresses the COVID-19/coronavirus pandemic, managed access programs have become more critical than ever. For physicians and their patients who are in urgent need of treatment and have otherwise exhausted their options, access to pharmaceuticals through these programs — to compounds that *might* have clinical utility — have become literally a matter of life and death. Depending on the country, these programs are also known as compassionate use, expanded access or special access programs.

In response to the pandemic, Novartis has screened its entire compound library for possible therapeutics, including options for repurposing currently marketed products as potential treatments for COVID-19. They have also started three phase III programs for compounds that show promise for addressing the coronavirus. In addition, they are engaged in investigator-initiated trials, having received proposals from all over the world, and are currently supporting 40 third-party studies that use Novartis compounds.

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Responding to a Rapidly Escalating Number of Requests

The whole response effort began to take shape in mid-March, when Novartis started to see requests from epicenters of the outbreak. There were a high number of patients, many in intensive care units. They had rapidly progressing, severe COVID-19 cases and had exhausted their other options.

Many of the compounds requested happened to be already under evaluation in-house at Novartis, where the science showed that they may have some clinical utility against the coronavirus. Some were already approved for other clinical indications and were readily available, but not approved for COVID-19. Such repurposed drugs, in many countries, can only be administered through managed access programs under the regulations. In a matter of weeks, hundreds of requests from different countries were coming in to the Novartis managed access program.

To date Novartis has received over 1,000 individual patient requests, and over 70 requests from governments or other institutions for investigational compounds. Novartis estimates that over the first two months since the requests began to arrive, over 2,500 patients have been able to access Novartis drugs through its managed access program for COVID-19.

Accelerating and Simplifying Workflows to Respond to the Crisis

The Novartis managed access program processes more than 1,000 requests every month for conditions other than COVID-19. At the broadest level, when a request comes in, it needs to be reviewed and approved by the relevant medical contact for that compound, and go through a contracting process with the physician to ensure consent. The drug supply steps and collection of data and outcomes then follow.

The COVID-19 outbreak not only brought a huge spike in demand, but also required an expedited process. Novartis put into place small, dedicated teams who looked at existing processes for simplifications that could allow the organization to respond with the timeliness required. They sought out expertise within the organization and engaged the right stakeholders who could make very quick decisions.

Fortunately, Novartis already had the right technology in place: an end-to-end system for handling all managed access requests, accessed through a web portal with which physicians were already familiar. The system has the ability to support the basic workflows, with the flexibility to make micro-adjustments to the processes as recommended by the dedicated teams. The system also collects essential information about the patient's condition and clinical parameters, the reason for the compound request, and the lack of alternative treatment. While a managed access situation is not a clinical trial, the system also collects some safety and outcomes data.

All of the information had to be gathered in a flexible way to balance the amount of information requested, the burden placed on the requested physician, and the need to gather the information and make the decision quickly in time to meet the urgent need.

Critically Needed Medicines in Hours, Not Days

Through the efforts of the dedicated team and their ability to leverage the greater Novartis community, they were able to make significant reductions to turnaround times. They reduced review and approval from the standard five days to less than five hours. The team leveraged the Novartis network of medical associates in various geographies around the world to expedite the reviews. They worked closely with the contract and legal teams to waive the contract for COVID-19 and converted it to a general statement on conditions of supply. This reduced the contracting period which could otherwise cause a two- to ten-day delay, depending on the country. They also worked with the drug supply hubs, so they were ready to ship the drug instantly on approval.

By quickly creating a specific COVID-19 workflow within the system, Novartis expedited a rapid turnaround of requests with approval in three to four hours. Drugs are being shipped to countries, sites and centers within 12 to 24 hours.

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Key Insights and Lessons Learned

Paul Aliu, Global Head of Medical Governance, Chief Medical Office at Novartis, shares his key takeaways for how managed access programs can make a greater impact during this global pandemic.

- **Be Prepared.**
  Get your ducks in a row in regard to your workflows, system, processes, roles and responsibilities.
- **Assemble the Response Team.**
  Utilize a small team who can pull together the correct stakeholders and decision makers quickly.
- **Leverage Expertise.**
  Understand the breadth and level of expertise in the organization that can be pulled together in a time of crisis.
- **Employ Agile Technology.**
  Have the right technological tools that allow you to pivot at a moment's notice with a systematic approach, as opposed to doing everything manually.
- **Maintain Robust Processes.**
  Have a deep understanding of the workflows and processes in place, and recognize where you can be flexible to expedite timelines when necessary.
- **Take Smart Risks.**
  Use your small, dedicated teams and task forces to evaluate what you can simplify, balancing risk against the urgency of the situation.
- **Harness the Power of Purpose.**
  Take advantage of the high level of motivation of employees to get involved; everybody wants to be part of the solution.
- **Find a Solution Partner.**
  When the time comes to act, ensure the solution you have in place is tailor-made for the size of your organization and how your organization is structured internally.
- **Clarify Roles and Responsibilities.**
  Clearly define roles, responsibilities and expectations so everybody knows how to react in a crisis.
- **Share Information.**
  Provide a dedicated link for information specific to the crisis, in a centralized location for easy access.
- **Don't Reinvent the Wheel.**
  Leverage existing processes and tweak them to meet the needs of the moment.
- **Reach Out to Your Network.**
  Use regularly scheduled webinars and calls to touch base with dedicated champions.

Making Incredible Happen

Want to know more? Listen to the complete conversation between Paul Aliu, Global Head of Medical Governance, Chief Medical Office at Novartis, along with Zach Gendron, Senior Account Executive at CyberGrants and an expert on managed/expanded access program technology.

Leading life sciences companies that use the CyberGrants platform for their philanthropic grantmaking have found its agile workflow system to be ideal for administering medical affairs grants. Talk to CyberGrants medical affairs grantmaking specialists and receive an end-to-end review of system best practices.

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