

How Technology is Making an Impact in Improving Managed Access Programs

In the pharmaceutical industry, it's critical to deliver medicine quickly to patients that need it most, but lengthy approval times for new treatments is not often something terminally ill patients can wait for. Looking at the big picture, it can take an average of 10 years for a new treatment to go from initial discovery to becoming commercially available in the marketplace. Terminally ill patients do have more direct access to investigational drugs and initial trials thanks to the Right to Try Act. However, the issues around process and approval times for new drugs was further illuminated during the COVID-19 pandemic.

Managed Access Programs, like you find with companies such as Novartis, have helped make new treatments more accessible and available to critically or terminally ill patients, but there's still work to be done in addressing rising patient needs. In the 1970s, the FDA opened these programs for cardiovascular patients in the US. The advent of the HIV crisis in the 80s and 90s, with its high mortality rate and lack of treatment options, the use of managed access programs broadened significantly. For example, drugs like AZT offered a "parallel track" to allow patients who were not in the clinical trial to still have access to these treatments, saving many lives. Almost 4,000 patients were allowed to access the treatment prior to approval over the course of 6 months.

While the benefits of these programs are obvious and oftentimes lifesaving, there are many issues surrounding how patients access care. For one, differences in national pharmaceutical regulations can make it more difficult for patients to receive medicines. MAPs are generally determined on an individual basis, with requests for developing drugs made by individual physicians and approved based on criteria determined by the pharmaceutical company. These criteria include exhaustion of alternative therapy/treatment options, ineligibility for or inability to access ongoing clinical trials, sufficient data to ensure the potential benefit of treatment

outweighs the risk, and that such access be allowed by local laws and regulators.

The lack of an overarching protocol surrounding the use of the pharmaceuticals can result in inappropriate use by physicians, which often leads to the reporting of possible adverse effects which could delay or derail marketing and regulatory approval. The allocation of separate resources to MAPs can impact ongoing clinical trials and delay commercialisation.

Another challenge surrounds the ethics of access to managed access programs. Pharmaceutical companies, ostensibly have an obligation to complete clinical trials as quickly as possible in order to ensure that an investigational drug can be made available to a wide swath of patients. However, MAPs raise the question of equitable access. Patients with a larger pool of resources (i.e money, social media access, well connected doctors) can reach out to pharmaceutical companies more quickly than those without but who may meet eligibility requirements.

These challenges were highlighted and exacerbated at the advent of the COVID-19 pandemic, when care providers and pharmaceutical companies alike were scrambling to find appropriate treatments for the never-before-seen coronavirus. For example, by mid-March 2020, Novartis was

receiving proposals from different global researchers and institutions looking to conduct trials against COVID-19 with Novartis compounds. Managing this high volume of urgent requests required developing a tailored response mechanism that streamlined the approval and distribution process of products through the MAPs system.

We worked with Novartis to launch GEMS, an end-to-end SaaS system for managing MAP requests. This COVID-19 specific workflow, once in place, led to significant reductions in turn-around times for processing and approving requests. It reduced review and approval times from five days to five hours and waived legal conditions to reduce delays that prior to the pandemic could last anywhere from 2 to 10 days. This in turn expedited the drug shipping process which was often occurring within 24 hours from the original receipt of the request. As a result of this implementation, the company was able to process over 1000 requests from individual patients and governments alike, allowing an estimated 2500 patients to access Novartis compounds within a 7-8 week period.

The benefit of leveraging SaaS technology for this purpose is that it allows companies to build and configure specific workflows for numerous variables in the managed access process. This flexibility allows pharmaceutical companies to create a single platform that





accelerates the process, granting access to drugs and treatments more quickly than before. Clinicians, patients, or anyone else requesting drugs or treatments can easily apply for MAPs through a single application page. Serving as a central hub and single point of access for all requests, this streamlines the process for both the requestor and grantor. At CyberGrants, we've built out this process for a bevy of pharmaceutical customers, including Novartis, who cite the flexibility of the platform and reporting capabilities as crucial differentiators when it comes to leveraging technology to support managed access.

The ability to speed up pharmaceutical approval processes while maintaining integrity and accountability in the process is critical for public health, a matter clearly

illuminated by the pandemic. The need for effective and efficient processes to address pain points common in other areas of pharmaceutical development and treatment will grow in urgency as countries return to "normal" in the next few years. Similar technologies can be implemented for other programs such as independent medical education, Investigator Initiated Research studies (IIRs)/trials, fellowships, and sponsorships.

For example, in the case of clinical trials, clinician participants often express dissatisfaction with a lack of ownership or active participation in the process, whether it be designing the study or analysing the data. To rectify this, clinicians often use IIRs to exert a modicum of control over the research. However, initiating, sustaining, and

financing an IIR requires a wide breadth of knowledge including regulatory oversight and medical writing, expertise in data analysis/management, and more.

A successful pharmaceutical study, be it one initiated by the manufacturer themselves, or independently undertaken by a clinical body requires collaboration and buy in from a variety of participants within and outside any single organisation. The technology used to create GEMS can be used to create a hub that centralises the processes for these research studies, providing a holistic view of the status and progress of these studies and their timetables, allowing for transparency and ease of communication among all participants, mitigating many of the common challenges in this field.

The goal of technology is to expedite and redesign familiar endeavors to make them easier to use for as many people as possible. As a result of technology, transparency, speed and collaboration are more critical than ever to innovation and growth within industries – especially the high stakes world of pharmaceuticals. Pharma companies should embrace flexibility as often as possible, not only when dire circumstances require it, to ensure that they're providing the best care and in turn best outcomes for their customers who need it the most.



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