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COVID-19 – A Catalyst For Change In Patient Centricity

Insights From Bernie Zeiher, Astellas Pharma CMO

by Bernie Zeiher

Astellas' chief medical officer, Bernie Zeiher, shares perspectives on how COVID-19 has forced the health care industry to think differently about patients' diverse needs and how the best of these changes must become the norm in delivering patient-focused innovations.

COVID-19 has presented new, previously unimaginable challenges to all aspects of our global community, not least our health care systems. The pandemic has impacted almost every part of health care delivery – with new strategies to manage unprecedented patient numbers, elective surgery and equipment supply chains, and the increased use of e-health and virtual care.

For the pharma and biotech sectors, this has meant adapting many long-standing operational practices and responding with agility in a highly dynamic environment. We have also seen history made, with the rapid mobilization to develop safe and effective treatments and vaccines for COVID-19.

As we begin to look with hope to a return to some semblance of normality, it is critical we do not lose this sense of urgency and momentum driven by the pandemic. While many of the changes that have come with COVID-19 may only be necessary in the short term, there is still much to be gained from the lessons of working at 'pandemic pace.' And the re-evaluation of other practices will certainly accelerate a new and heightened patient-centric approach for the future.

COVID-19 Has Fundamentally Changed The Patient Experience

For patients everywhere, the pandemic significantly altered the way they access and receive care. New practices aimed at protecting our health care systems brought inevitable disruption but also drove a rapid transformation of health service delivery.

In the US, for example, the use of telemedicine was somewhat limited due to lack of reimbursement for virtual visits by Medicare and Medicaid. But COVID-19 made it a necessity, and reimbursement policies were quickly changed. Since then, virtual care has gained significant momentum, with both physicians and patients experiencing benefits as a result. While there can be technical issues, patients can enjoy the convenience of a virtual consultation without risking exposure to the virus or other illnesses and, vitally, health care providers are able to safely see more patients. This development has resulted in shorter waiting times for an initial consultation, improved flexibility, reduced costs, shorter consultations and less travel. According to a 2020 report from McKinsey & Company, across the US alone, nearly half of health care consumers are now using telehealth — up from one in 10 the previous year.

The use of 'direct to patient' channels to provide medicines has also increased dramatically, allowing patients to receive the therapies they need, as well as certain assistance and monitoring, without automatically being required to attend a clinic. In addition to reducing the risk of COVID-19 transmission while giving people the care they need, the use of telehealth and medicine home delivery services also has benefits for patients who are less mobile, and those in more remote areas. Another example is the demand for diagnostic equipment for at-home disease monitoring and management, which has grown not only as a result of the pandemic but also due to significant technological advancements.

Overall, COVID-19 forced the health care industry to think carefully about patients' diverse needs, and how care can be tailored in a safe, streamlined and more efficient way. And now patients are experiencing a new form of empowerment – as partners in their own care.

Maintaining Patient Safety During Clinical Trials – What We Learned

For the biopharmaceutical industry, the onset of the pandemic created tremendous challenges to clinical trial continuity. Investigative sites stopped allowing monitors for initiation or monitoring visits; site personnel were diverted to the conduct of COVID-19 trials or health care delivery and patients with non-emergent medical issues were not allowed in some health care facilities.

Like many other companies, *Astellas Pharma* temporarily stopped initiation of new trials and suspended enrollment of new patients for ongoing trials. Our focus shifted entirely to protecting the safety of the thousands of already-enrolled trial participants and ensuring data integrity was maintained across all of our studies. Fortunately, the FDA and other regulatory authorities issued guidance on the conduct of trials during the pandemic, which supported the approach we – and others – took during this unprecedented health care emergency.

The conduct of clinical trials is highly regulated and, as an industry, we have been relatively slow to change and embrace virtual technology, at least in the clinical trial setting where we are heavily reliant upon in-person activities. When the pandemic hit, as a first step, all of our study

protocols were assessed to determine which laboratory tests or procedures were critical to protect patient safety or ensure the ability to assess the primary endpoint of the study. Those that were not critical were reduced or eliminated to decrease the burden on patients and health care institutions. For tests that still needed to be performed, we explored whether in-home health care could be used to draw any necessary bloodwork or whether patients could travel to a local laboratory rather than health care institutions that may be overburdened with COVID-19 patients. Patient visits could be conducted via telephone or other virtual means, and study monitors began to conduct remote reviews of study-related documents. Where possible, investigational products were sent to patients' homes for self-administration and for injectable products we explored home administration.

Many of our trials are also multinational, which created added complexity as the waves of the pandemic hit at different times and the restrictions varied across health care centers. Even within the US, there was considerable variability. For example, in April 2020, New York City was at its peak; local hospitals were overwhelmed with COVID-19 cases, site personnel were unavailable and patients could not go to investigational sites. Meanwhile, other parts of the country had very low rates of infection and were operating more in a 'business as usual' manner. The regional variations necessitated that our protocols were redesigned in ways that enable them to continue during unforeseen circumstances.

Typically, when we consider major adjustments to our standard procedures, we test the new approach on a smaller scale as a pilot program. With COVID-19, there was no time for piloting a new approach. Measures like virtual patient visits and remote monitoring had to be implemented without fully knowing exactly how effective they might be. While not ideal, we have been remarkably surprised with the success of these measures. In the case of oncology studies, both patients and site personnel were highly motivated and their extraordinary efforts enabled the trials to continue with minimal patient dropout. We were even able to successfully complete a pivotal study of enfortumab vedotin – a treatment for adults with locally advanced or metastatic urothelial cancer – and *report its results* during the pandemic.

While it may not be unexpected in oncology, measures such as virtual visits, local laboratory testing, investigational product shipment to patients' homes and remote monitoring were also successful in our Phase III program of fezolinetant, a potential first-in-class treatment for menopause-related vasomotor symptoms. Given the non-life-threatening nature of the condition, we were concerned that many patients and sites would discontinue participation. The efforts and commitment of patients and study personnel have been truly remarkable and will help to ensure that these trials complete and provide data that characterizes the efficacy and safety profile of fezolinetant. It is these successes and learnings that must drive us to operate with this same level of agility and willingness to push the boundaries in a post-COVID world.

A Case For Lasting Change

Relentless pressure to change drives the evolution of many processes and systems. The pandemic, and the resulting urgency-driven environment, meant we had to incorporate many new practices and processes rapidly and simultaneously, rather than gradually. Changes discussed for years were implemented in weeks. We have seen incredible adaptability and partnership, with a singular focus on patient care.

As we witness the benefits, we should strive to maintain these new approaches as they are not only feasible, but they ensure trial continuity and reduce the burden on patients. This means continuing to incorporate measures like telemedicine, remote monitoring, direct-to-patient shipments, local labs and home nursing, as part of our core approach.

But we should also be looking further – beyond COVID-19, and beyond trials alone – to the entire therapy lifecycle, engaging with patients from the outset and incorporating their insights and feedback at every stage. When we prioritize what is best for the patient, we can be confident we are making the right decisions, and there is nothing stopping us from continuing to move with the same sense of urgency and patient-partnership in the post COVID-19 world.