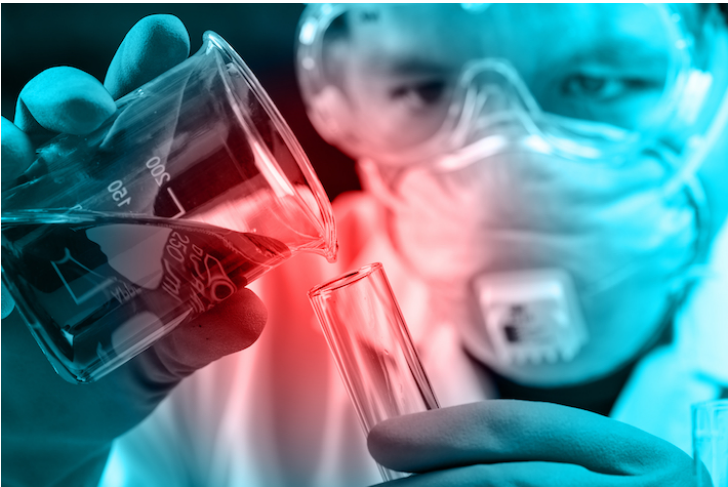


## Applying cushion for India against future supply shocks

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**The disruption of supplies from China in the initial months of the pandemic brought home an important realisation for the pharmaceutical industry**



As the world grapples with a never before seen viral pandemic, the pharmaceutical sector has been at the forefront of a mounting global response. Within a year of the outbreak, around seven vaccines have already received approvals in different parts of the world while another 10 are already undergoing phase 3 trials. At the same time, scientists are also working to find anti-viral drugs that can help treat or reduce mortality from COVID-19.

As pharma majors focus on efforts to get rid of coronavirus, the trials and studies for non-COVID-19 diseases has definitely suffered a setback. However, the pandemic has served to galvanise the global pharmaceutical industry like never before. In what are expected to be lasting effects, biopharma is likely to move towards adopting faster drug development cycles, greater collaborative efforts between industry players and academia as well as decentralised R&D efforts. Technological innovation is likely to push the sector towards greater digitisation and agility with remote patient engagement, use of AI and Big Data likely to lower the cost and time of making new drug formulations.

Clearly enough, the COVID-19 pandemic has hastened the evolutionary process of the pharmaceutical sector in India as well as across the globe. Here are a few effects that are likely to stay on even after the pandemic subsides:

### **Collaborations within the industry and with academia**

With the need to speed up vaccine development a top priority, major pharmaceutical companies joined forces this year in an unprecedented way. Under the umbrella of Bill & Melinda Gates Foundation, major pharma companies committed to share sections of their compound libraries to speed up the drug industry's response. R&D Heads of several biopharma companies were also reported to have met to coordinate a joint response. British pharmaceutical giant GlaxoSmithKline decided to join hands with Germany's CureVac to find and develop mRNA vaccines and monoclonal antibodies.

Similarly, the pandemic also underlined the need for fostering greater symbiotic relationships between private companies and public/academic clinical researchers. The breakthrough achieved on the vaccine front by AstraZeneca's joint effort with

Oxford University scientists makes a major case for better industry-academia collaborations.

Such collaborations are sometimes looked at with doubt by both sides because of commonly encountered difference in approach to research between private and public sectors. The former is often accused of deciding funding based on market dynamics. However, more productive collaborations can definitely be achieved. These collaborations – both within the industry and with academia - are likely to become more common in a post COVID world.

### **Greater agility in clinical trials**

Clinical trials for drug and vaccine development are a long drawn process. In normal circumstances, the process of a new drug or vaccine development may take up to 10 years adhering to clinical trial protocols. However, the urgency for a COVID-19 vaccine forced researchers to adopt multiple deviations in the process. While this has raised questions and doubts over efficacy and integrity of the trial process, it has also opened up ways to hasten the process. Some of these agile processes are bound to flow into the clinical trial processes even after the pandemic.

To overcome challenges such as the need for volunteers and researchers to always physically visit trial sites, virtualisation of clinical trials is emerging as a critical alternative. Remote patient engagement and shifting some elements of trials such as nurse visits outside of trial sites to patient's homes are being actively considered today. The emergence of a patient-centric approach to clinical trials has been found to improve retention rates of volunteers and helps bring more agility to the entire process. The COVID-19 vaccine development effort has drilled home the realisation that this change in trial procedures can be done to bring down the cost and time of the process. Over time, R&D experts are likely to incorporate such agility-inducing tools and elements increasingly into their portfolios even in a post COVID-19 world.

### **Use of Big Data and AI to reduce time-to-market for drug discovery**

Artificial Intelligence (AI) and Big Data undeniably hold the future of every industry. Pharmaceutical industry is no different. Pharma manufacturing has already embraced digitisation and automation on multiple levels to ensure quality of production and compliance are uncompromised. The use of AI algorithms and Big Data are the next elemental technologies that will help the sector significantly improve its processes and reduce cost and time of the entire R&D cycle.

### **Towards indigenisation of entire scale of production**

The disruption of supplies from China in the initial months of the pandemic brought home an important realisation for the pharmaceutical industry. The industry realised that excessive dependence on imports of (active pharmaceutical ingredients) APIs from China could paralyse the entire drug production in case of such supply shocks, and was not sustainable for the Indian industry. Taking cue, the government and the industry have launched efforts to re-develop indigenous manufacturing capacity of key ingredients and bulk drugs. With plans to localise manufacturing of 53 critical APIs and intermediates, the government has launched a Production Linked Incentive scheme for bulk drugs. The scheme has already received a warm response from the industry which now realises the importance of indigenising the entire scale of production.

This move towards greater self-reliance will not only cushion India against future supply shocks but will also allow greater diversification of supply centres for the world.

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