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COVID-19 IMPACT: A WAKE-UP CALL FOR THE LIFE SCIENCES INDUSTRY

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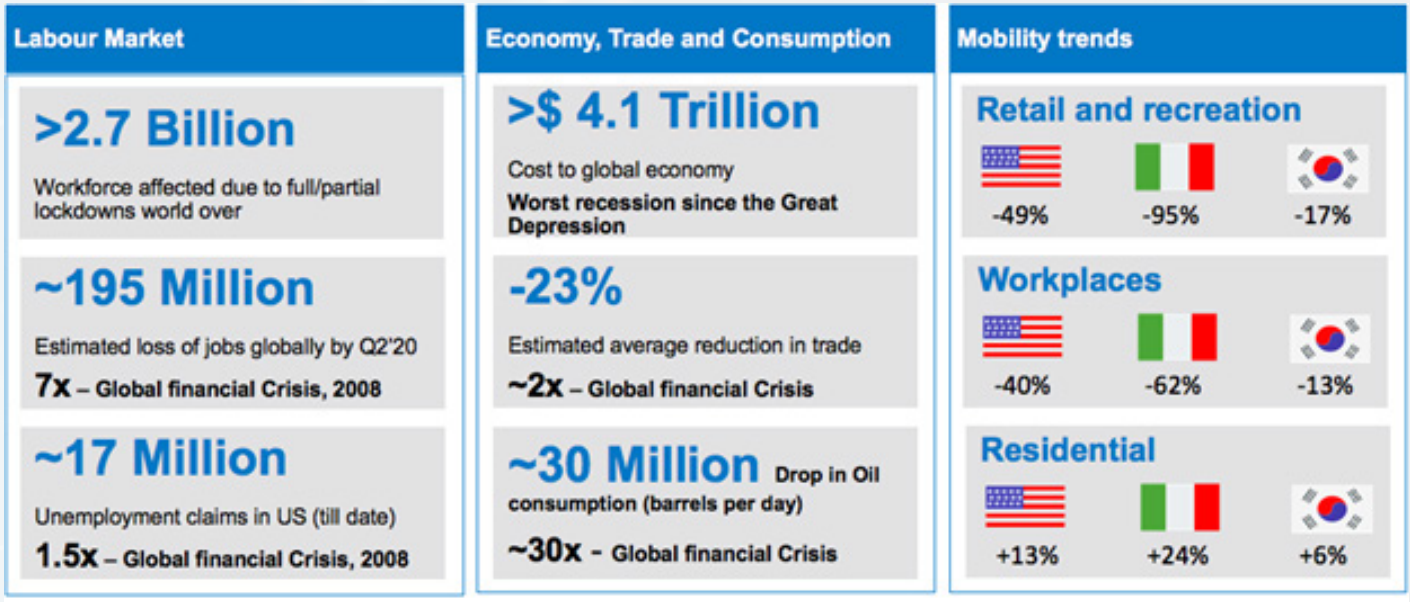
As we write this, the global total number of COVID-19 cases has surpassed 4.7 million with over 315,740 deaths. Though the pandemic has severely affected almost every industry, life sciences happens to be at the epicenter of the crisis. Pharmaceutical companies are grappling with unforeseen challenges that require immediate attention in order to control the outbreak and its calamitous impact.

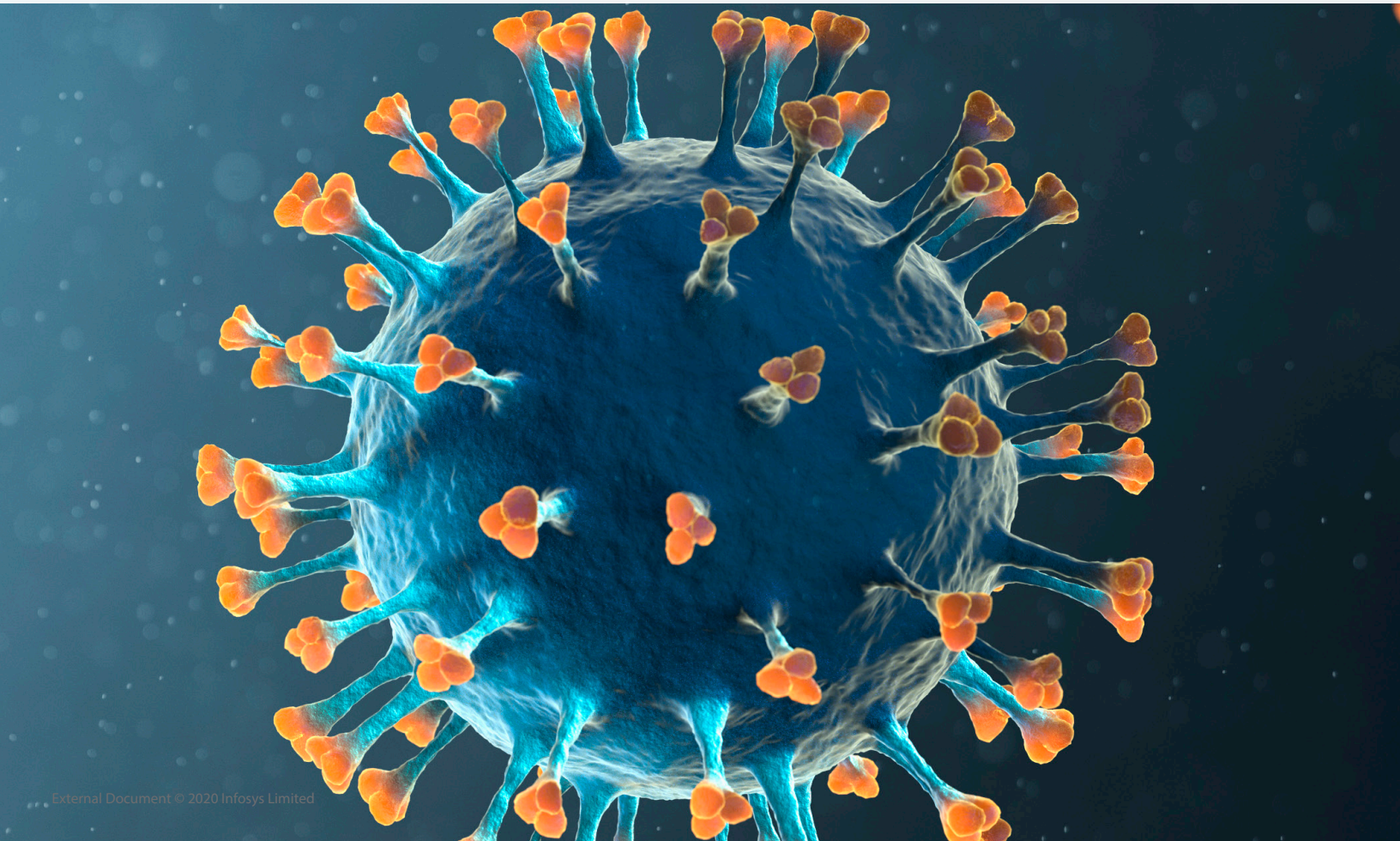
4,744,216	315,740	1,747,403	2,681,073
Coronavirus Cases	Deaths	Recovered	Infected Now

Source: Johns Hopkins (As of May 19, 2020, 06:00 GMT)



Revised data: **$8.8 Trillion** - Cost to global economy, **13% to 32%** Estimated average reduction in trade

Source: BBC, WTO



Disruption in Life Sciences

69.9% Clinical trials disrupted	**Remdesivir, Hydroxychloroquine, Sarilumab** Drugs being reused	**BMS-ozanimod; Novartis- ofatumumab; Roche-risdiplam; Galapagos-filgotinib aliqua** Delayed launches	**103** Emergency Use Authorization Issued by FDA	**100%** Increase in price of Paracetamol in India

Source: GlobalData, FDA

Medical device companies are under enormous pressure to develop and deliver personal protective equipment (PPE), diagnostic test kits, drugs and medical devices to provide supportive care to frontline workers and infected patients. For biopharmas, finding an effective vaccine to contain the impact of COVID-19 is the biggest concern. Governments and regulatory bodies are working in tandem to reform current stringent guidelines to accelerate clinical trials, maintain continuity of supply, and ensure fast-track approval of drugs and devices.

Navigating the Challenges

As the pharma industry sprints to find a cure for COVID-19, executive attention shifts from normal business to crisis management. A McKinsey survey revealed that Chief Medical Officers (CMOs) and medical leaders are spending 80% of their time managing the crisis and protecting employees and patients from the spread.[1] Circumstances demand pharma leaders to make rapid decisions and revise trial policies to stabilize the situation and ensure uninterrupted execution of clinical trials.

The pharma industry needs to focus on developing concurrent agile processes to enable global collaboration, dynamic manufacturing capabilities, fast movement of global information, and an integrated approach to therapy areas beyond oncology. But that is not all. COVID-19 poses new challenges and opportunities for the entire ecosystem that—if tackled and addressed on an urgent basis—can chart ways for a better tomorrow.

1. **Drug development:** Since April 2020, almost 70% of clinical trials have been affected due to suspension of enrolment, 17.3% have seen a delay due to slow enrolment and 12.8% have experienced delayed initiation.[2] These delayed trials include non-COVID research and trials as well. The worldwide lockdown, site closures, and travel ban have also left an adverse impact on both Research and Development (R&D) and clinical development operations.

   However, the limitation of movement has elicited an open exchange of ideas across borders leading to instant research data sharing and a concerted effort to manage the outbreak. Drug repurposing, which is an effective method in the rapid development of essential drugs, has also seen a spike. In March 2020, the US government allocated $8.3 billion to support and accelerate clinical trials.[3]

2. **Regulatory and safety guidelines:** With COVID-19 expected to last several more months, there is likely to be a shortage of several life-saving drugs. Though governments and regulatory bodies are mulling over lifting import and export restrictions on essentials drugs, the lengthy process of drug approval remains a challenge for pharma companies.

   On the brighter side, real-world data (RWD) and real-world evidence (RWE) can play a significant role in the regulatory decision-making process. The rise in COVID-19 cases has also seen governments expediting the process of approvals to scale up the development of vaccines and therapeutics.

3. **Commercial activities:** In the wake of the pandemic, manufacturers of branded drugs have been witnessing a shift in demand for antivirals and drugs for other chronic conditions as those treatments have been suspended to prevent people with pre-existing conditions from being exposed to Novel Coronavirus. The delayed drug launches are further aggravating demand. While pharma companies have to quickly address the unmet needs of the market, limited opportunities to conduct face to face stakeholder meetings are causing further delays in decision-making.

   In light of this, pharma stakeholders are adopting digital channels to collaborate and act quickly. It is helping to keep operational activities afloat amidst the global lockdown. Though the outbreak initially dampened investment prospects for the pharmaceutical industry, it is now generating new opportunities for companies to innovate and bolster growth in the long run.

4. **Global supply chain:** Prolonged lockdowns have also severely disrupted global supply chains, especially for raw materials. Several pharma companies have started airlifting raw material considering the need for Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSM). Other companies are on the verge of exhausting their existing inventories. Apart from the disruption in raw material supplies, the shortage of labor and logistics and the soaring cost of manufacturing are driving up the drug pricing.

   To combat the situation, pharma companies are looking at short-term supply interruptions with alternate supply arrangements. Many companies are placing irregular orders with vendors to avoid supply shortages while others are forging new alliances with non-traditional supply sources.

5. **Market access:** There has also been growing pressure on governments to channel public pharma expenditure towards generic medicines. In May 2020, a generic drug maker in the US received $354 million from the federal government to develop prescription drugs as well as their chemical raw materials.[4] Some of these medicines are being used to treat COVID-19 patients. The pandemic has also raised questions over the long-drawn patent battle.

   To facilitate limitations on patents and grant compulsory licenses, patent protection laws need to be amended. The pharma industry is already witnessing an altruistic drive to free testing from the grip of patent holders. For the first time, Israel has allowed the use of a generic version of a patent-protected drug, Kaletra, exclusively for COVID-19.[5]

Key Highlights for a Post-Covid Era

- Innovation will be driven by RWE, Artificial Intelligence (AI), Machine Learning (ML) and automation with reuse of existing drugs and new platforms/virtual trials
- Global collaboration and sharing of information with improvisation on policies for compassionate and off-label use would be the key
- An integrated approach to other therapy areas beyond oncology would gain momentum with the rise of digital channels
- Multi-purpose facilities with dynamic manufacturing capabilities aligned with non-traditional partners would be required to meet emerging needs
- Technology-driven dynamic processes and approvals to be designed to improve patient outcomes and efficiency

Harnessing The Power of Digital Technologies

With social distancing still in force, digital channels continue to see a surge in adoption across industries. There is increasing recognition that RWD, RWE, AIML and Robotic Process Automation (RPA) could play a key role in giving life sciences the impetus it needs. Below, we analyze the five key drivers of digital transformation and how they are going to reshape the future of the global pharma industry:

RWD and analytics: As the life sciences industry becomes increasingly data-driven, RWD and advanced analytics could play a role in the expansion of existing drugs beyond antivirals or in predicting surges in clinical demand. RWD could also challenge the existing Randomized Controlled Trial (RCT) methodology to accelerate clinical development. It can also pave the way for working with minimal information across the value chain, streamline evidence generation, and create newer ways for disease management. Integrated open-source RWD can also fuel operational excellence in the long run.

AIML and automated solutions: AIML can be leveraged across the disease continuum for understanding therapy transition, developing predictive models, early disease detection, disease profiling, and more. ML models can be used to evaluate the impact of any major epidemic or pandemic on customer demand and supply chain. Robotics can be deployed across the value chain for monitoring and automating the supply chain. Healthcare companies are leveraging AI and the Internet of Things (IoT) to boost patient engagement, deploying AIML-based models to create personalized interventions for patients and caregivers.

Digital engagement labs: The pandemic is breaking barriers that were earlier responsible for the slow adoption of telehealth. As telehealth is getting the much-needed push, creating digital engagement hubs can help enhance and scale remote monitoring capabilities. By integrating existing wearables technologies across industries, healthcare providers can also leverage these hubs for personalized patient interventions.

Patient registries would serve as powerful platforms for driving outcomes. For instance, contract tracing using bluetooth and blockchain can help in finding patients for plasma therapy for COVID-19 or forecasting herd immunity. The scope can be further broadened to stratify patient populations, develop integrated stakeholder engagement platforms for enhanced collaboration, registrations, reimbursement, provider availability, and so on.

Virtual trials: In the quest for patient-centricity, virtual trials are known to bring with it many advantages. Now, the necessity of social distancing is making it an even more viable solution. Digital technology and RWD can help identify relevant patient pools for randomized clinical studies, and also facilitate remote patient enrolment beyond geographies. Digital data capture minimizes the paperwork involved, freeing up the time of the research team from mundane tasks.

Enterprise IT and automation: Technologies like RPA can be used to develop smart hospitals by minimizing human intervention, thereby reducing the chances of delays and mistakes. There is also a shift in focus on improving collaboration and productivity across the enterprise by developing new digital ecosystems and becoming flexible about innovation. To create a future-ready safe and remote work environment, enterprises would need cloud to migrate key scientific modeling and bioinformatics apps. But to run enormous amounts of epidemiology or bioinformatics on cloud, the expertise of government and private players would be required.

The Future of Life Sciences

Going forward, intelligent collaboration is going to be a key imperative for the pharma industry. To emerge out of the global crisis, life sciences companies would have to redefine their position and emerge as a valued part of the modern healthcare system. Here are our recommendations:

Stabilize (Over the next three months)

Business continuity and mitigating risks for trials will remain the topmost priorities for the life sciences industry, followed by the need to amend policies to speed up trials and off-label use. Once regulatory challenges are solved, drug manufacturers will have to step up to respond to critical drug shortages thus restoring the supply-demand equilibrium. The need to eliminate barriers such as copays and prior authorizations to manage chronic and acute patients, and enable telemedicine would also gain focus.

When virtual operations become the new norm, industry stakeholders will focus more on digital channels to create virtual care models and remote detailing options. The remote working environment will require business leaders to protect and ensure the emotional wellness of employees through virtual training. Policies for compassionate use of experimental drugs would be expanded to save lives.

Technologies like RWD, AIML would be leveraged for off-label and compassionate use of drugs as well as interventions across the disease continuum. Existing patient registries and remote patient monitoring systems would also help in enabling such interventions. Companies will start using RPA and Intelligent Process Automation (IPA) to start automating some of their smaller processes to free up resources and gain efficiencies. Virtual trials would also see a surge.

Reconfigure (Over the period of 4-12 months)

It will be critical to invest in sustainable infrastructure for faster drug development, seamless digital health services, increased adoption of virtual trials, and remote monitoring. ePROs, e-diaries, non-invasive, vital sign-measuring devices would find usage in monitoring patients remotely to hasten the drug development path. Collaboration with patient support groups will be key in facilitating the diagnosis and treatment of wary patients. Robotics, IoT and automation will play a key role in diversifying the supply chain while analytics would be used to identify high-risk individuals.

Healthcare providers would be more focused on creating patient support programs to provide in-home care and telemedicine services. To develop force multipliers for providers in such a dynamic environment, new tools and information assets would be needed. The insurance sector will see an entirely new ecosystem capable of meeting the changing market demands. To combat such pandemics in the future, governments and policymakers would be required to revise the approved drug laws and policies.

As for the digital technologies, companies will use them to devise new ways to generate datasets for future use, create dynamic impact assessment and supply chain planning model, and scale remote patient monitoring and IoT-enabled capabilities. RPA and IPA would see further usage in automating a broader range of processes to gain efficiencies and drive value.

Transform (In the long term of 12+ months)

When the crisis subsides, the pharma industry will face the pressing need to strategize and rebuild research portfolios to address unmet needs for vaccines and antivirals. The need for expanding data-driven digital approaches for regulatory filings would be higher. Federal bodies would be under pressure to review patent protection laws and control the pricing of life-saving drugs. Digital tools would replace existing systems for cost management and patient care management.

Tele-healthcare will continue to reign the health sector, a robust feedback mechanism to develop and refine patient engagement models would become the need of the hour. Monitoring and motivating employees would also become a key concern for the leaders for which new KPIs would be developed. As collaboration would take the centerstage across the healthcare and life sciences industry, the need for a framework to monitor and refine the regulatory policies would become imperative.

The potential of RWD to fuel operational excellence would be recognized by the executives while AIML would gain importance in enhancing patient engagement. The need for reimagining the workplace would drive companies to deploy cloud whereas stakeholder engagement would be driven by integrated healthcare provider engagement platforms. Finally, technology platforms would become the mode of capturing ePROs, eConsent and eCOA, and managing retention and adherence.

The COVID-19 pandemic is not just another fleeting crisis. It is one such disruptive force that will leave a trail of long-term implications on how healthcare and life sciences industry work, how care is given, how drugs are developed and distributed, and how the ecosystem operates. When the panic of the pandemic will start to fade out, the need for trust, transparency, agility, and responsiveness will be paramount across the value chain. For the life sciences industry, this is the time to take measures to rebound from the crisis and recover its way towards a future that is still writing itself.

Authors

Ed Francis - Global Managing Director for Health and Life Sciences

Vishal Singal- AP in Health and Life Sciences, Commercial Analytics and Digital/AI Lead

Shipra Rastogi - Senior Principal Health and Life Sciences

References

[1]COVID-19 implications for life sciences R&D: Recovery and the next normal, McKinsey

[2]COVID-19 continues to disrupt clinical trials, with 69.9% of disruptions due to the suspension of enrolment, GlobalData

[3]Trump signs $8.3 billion emergency coronavirus spending package, CNBC

[4]Generic Drugmaker Gets Contract to Make COVID-19 Medicines in U.S., Wall Street Journal

[5]Israel approves import of generic of AbbVie's HIV drug for Covid-19

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