WHITE PAPER

REGULATORY APPROVALS IN TIMES OF COVID

Infosys®
Navigate your next

BACKGROUND

The COVID-19 pandemic has necessitated significant changes to regulatory processes across various industries and sectors. These changes have been aimed at ensuring public health and safety whilst also enabling the continued functioning of essential services.

One of the most significant changes has been the implementation of remote or virtual inspections and audits1. With travel restrictions and social distancing measures in place, many regulators have had to find new ways to conduct inspections and audits without physical visits to sites. This has involved the use of technology such as video conferencing, remote monitoring, and data sharing to enable inspections to be conducted remotely.

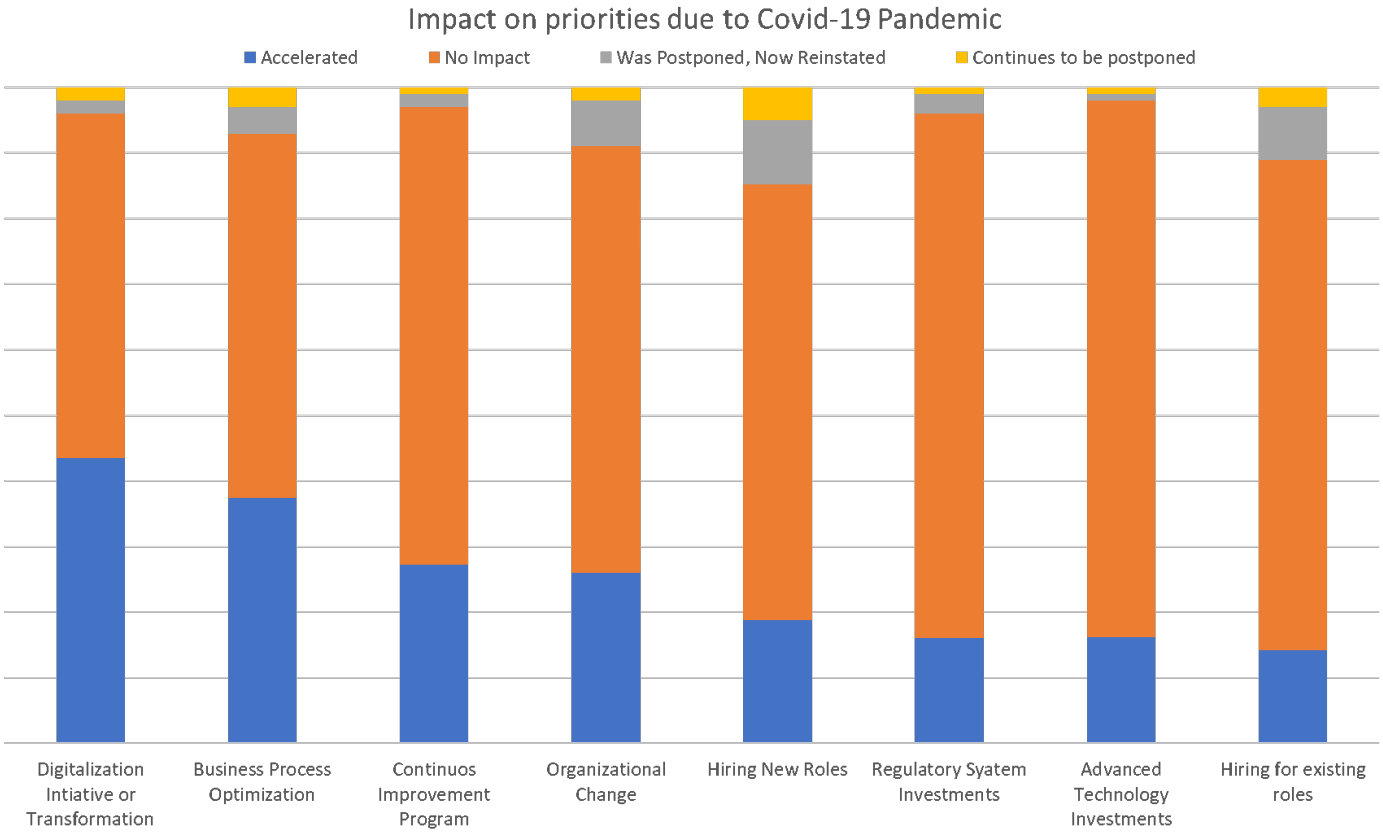
There has also been an increased focus on emergency use authorizations (EUAs) for medical products and devices. EUAs allow for the expedited approval of products that may be effective in treating or preventing COVID-19, without requiring the extensive testing and data that would normally be required for full approval. This has enabled the rapid deployment of vaccines, treatments, and diagnostic tests to combat the pandemic.

In addition, there have been changes to the regulatory requirements for clinical trials, with an emphasis on the use of virtual or remote methods for patient monitoring and data collection. This has enabled clinical trials to continue despite restrictions on physical interactions and travel.

Regulators with the ability to anticipate novelty and disturbance are better positioned to seize the prospects of technological advancement while minimizing the hazards. Governments like Canada, Singapore, Sweden, the United Arab Emirates, and the U.K. are allocating resources towards regulatory foresight to comprehend the outlook and be ready accordingly.

Overall, the regulatory process changes in times of COVID-19 have required regulators to be flexible, adaptable, and innovative in finding new ways to ensure public health and safety while also enabling the continued functioning of essential services.

The below stats2 depict the effects of the pandemic on regulatory activities, highlighting the shifts in requirements and risks. The data reveals that the top three regulatory activities that demanded increased attention in 2020 have became even more demanding in 2022. These activities include managing supply chain disruptions, dealing with customs and borders, and conducting virtual clinical trials. It is worth noticing that the increase in demand for these activities in 2022 was significantly higher compared to 2020. This could be attributed to the timing of the 2020 study2, which did not capture the full extent of the pandemic's impact. However, the study findings suggest that regulatory organizations faced a considerable amount of additional work due to the pandemic.



KEY CHANGES

Emergency Use Authorization Review Process:

The approval process for a typical vaccine involves several stages of clinical trials, which can take 10 to 15 years to complete. The trials must demonstrate that the vaccine is safe and effective, and the manufacturer must submit extensive data to regulatory agencies for review. Once the data is reviewed and approved, the vaccine can be licensed for use and distributed to the public.

In contrast, the emergency use authorization (EUA)1 process for COVID-19 vaccines has beenwas expedited due to the urgent need to address the global pandemic. The FDA utilizes Emergency Use Authorization (EUA) to enhance the nation's safeguard against chemical, biological, radiological, and nuclear (CBRN) hazards, including infectious diseases, by expediting the accessibility and utilization of medical countermeasures (MCMs) required during public health crises.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 564 allows the FDA to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency when the Secretary of Health and Human Services (HHS) declares an emergency use authorization is necessary. This authorization is only permitted for the diagnosis, treatment, or prevention of serious or life-threatening diseases or conditions caused by CBRN threats, and only when there are no sufficient, approved, and available alternatives. The decision to declare such use must be based on one of four determinations of threats or potential threats made by the Secretary of HHS, Homeland Security, or Defense.

The FDA has authorized the use of COVID-19 vaccines under an EUA, allowing their use during the ongoing emergency before the completion of the usual approval process. This is because the FDA has determined that the benefits of the vaccine outweigh the risks of not having a vaccine available, and there are no approved alternatives for the prevention or treatment of COVID-19.

Going Digital

The COVID-19 pandemic has accelerated the adoption of digitalization in the regulatory space, particularly in industries like pharmaceuticals. Remote inspections and electronic document review reviews have become more prevalent, allowing regulatory bodies to continue their work despite travel restrictions and social distancing measures.

Furthermore, the use of digital technologies has enabled more efficient and streamlined regulatory processes. For instance, data analytics tools can help regulators to identify potential safety concerns and compliance issues more quickly and accurately, while artificial intelligence can be used to automate repetitive tasks.

Implementing a cloud-based system for regulatory submissions (Veeva, Amplexor, Ennov RIM) facilitates a flexible and seamless exchange of information between regulatory agencies and industry, resulting in faster responses to public health crises like COVID-19. For instance, the regulatory agency like FDA now review reviews COVID-19 research protocols in just seven days instead of the previous thirty days required for clinical trial approval. If the data were stored in a cloud-based system, complete with readily available analytical tools, the review process could be accelerated even further.

Amidst the pandemic, the utilization of mobile devices and digital technologies, ranging from simple telecommunication and video conferencing software to advanced collaboration and analytical tools, has been enhanced and expedited. This has resulted in favorable outcomes for patients and a rise in the endorsement of these tools in the clinical research environment, which includes decentralized and remote clinical trials.

Clinical trial participants can now easily participate in trials from the comfort of their homes by using telemedicine and receiving study medications delivered directly to their doorsteps, among other adjustments. These methods enable the collection of data in real-time that is more representative of real-world situations and from a more extensive range of participants, with fewer restrictions. Consequently, this data can provide more pertinent evidence to support product safety and effectiveness, more closely aligned with the realities of patients' lives.

Overall, the pandemic has underscored the importance of digitalization in the regulatory space, and it is likely to continue to play a significant role in shaping the future of drug development and approval processes.

The Impact of pandemic Pandemic on Working Relationships with Health Authorities & other Other Stakeholders

The COVID-19 pandemic has led to a surge in collaboration among health authorities and industry players, both within and across borders. Governments worldwide have established partnerships and global consortia to foster cooperation among industry stakeholders and academia, expediting research and development of medical solutions to combat COVID-19. Apart from bilateral partnerships at government and industry levels, there are multilateral initiatives aimed at consolidating scientific knowledge and pooling resources to develop effective pandemic solutions.

Shared Initiatives	Description
Approach for COVID-19 Tools Expediter	Collaborates with diverse stakeholders, including governments, businesses, civil society, and international actors, to aid in the creation and fair allocation of medical treatments that can reduce fatalities and mitigate the impact of severe cases of COVID-19.
COVID-19 Treatment Expediter	Created by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, this platform has the goal of facilitating and assessing the development of novel and repurposed medicines and vaccines for the treatment of COVID-19 patients, and guaranteeing fair distribution and affordability, especially in areas with limited resources.
International Coalition of Medicines Regulatory Authorities (ICMRA)	Functions as a platform that promotes strategic coordination and global collaboration among regulatory bodies. In response to the COVID-19 pandemic, the members of ICMRA have focused on expediting and simplifying the research, production, and availability of COVID-19 vaccines and treatments, as well as ensuring a productive and efficient approach to regulatory procedures and determinations.

Exemplars of shared initiatives leveraged to combat the COVID-19 outbreak

Enhanced Supply Chain Management

The pandemic has highlighted the importance of supply chain management in ensuring the availability of critical medical products. Regulatory agencies have implemented new processes to monitor and manage the supply chain, including tracking and reporting on shortages and disruptions.

Regulatory agencies and life sciences companies are now placing a greater emphasis on transparency in the supply chain. This includes monitoring and reporting on supply chain disruptions and shortages (shortages (Insulin in 2019, Remdesivir in Apr 2020, Tamiflu in 2020), as well as sharing information with other stakeholders to ensure continuity of supply.

The pandemic has underscored the need for risk management in the supply chain, particularly in identifying and mitigating potential vulnerabilities. This includes conducting risk assessments, developing contingency plans, and implementing mitigation strategies.

KEY CHALLENGES

Regulatory authorities face several challenges in preventing and addressing data theft in the post-pandemic world such as increased cyber threats with more people working from home and using personal devices, there is an increased risk of cyberattacks. Hackers have been quick to take advantage of the situation, and regulatory authorities need to be vigilant in identifying and preventing cyber threats. However, with limited resources to invest in cybersecurity measures, Health Authorities may find it difficult especially if they are operating under tight budgets due to the economic impact of the pandemic. Additionally, with Jurisdictional jurisdictional issues, more cross-border transactions and remote work arrangements, regulatory authorities may face challenges in enforcing data protection laws and regulations across different jurisdictions.

It is necessary for health organizations and industry stakeholders to team up with digital and security solution providers to improve the resilience of systems and bolster security protocols. By doing so, confidence can be boosted when engaging in these novel working methods.

CONCLUSION

The pandemic has triggered a global shift in trends, giving rise to new norms that extend beyond regulatory bodies. The crisis initiated a chain of events that necessitated a departure from traditional practices, allowing organizations to demonstrate their capabilities and explore alternative methods. The "new" approach may not necessarily be superior to the "old" one; however, the pandemic presents an opportunity to experiment with different approaches, learn from experience, and select the optimal path forward for the organization.

As the pandemic approaches its 3 years mark, regulatory organizations are successfully adapting to novel obstacles. They have effectively navigated the virtual landscape to engage with service and solution providers, transformed their relationships with health authorities, and embraced new technology and procedures to streamline regulatory operations. With the pandemic exposing what is achievable, the future appears promising.

Aditi Sen

Consultant- Regulatory Affairs (Life Sciences)

Aditi is a seasoned Business Consultant with 12+ years of robust background in Pharma & Vaccines Regulatory Markets (US, EU & ROW) along with an academic background in Life Sciences. Her expertise lies in in regulatory submissions and post approval activities, RIMS upgrade and implementation along with specialization in Data Modelling and Governance setup, Document Management System upgrade and release. She is certified with Veeva Platform Associate White Belt, SAFe 5.1 and EU MDR 2017/745 from BSI.

Priyanka Rathore

Sr. Consultant- Regulatory Affairs (Life Sciences)

Priyanka has over 13 years of strong Regulatory, RIMS System Implementation & Project management experience. Her expertise lies in the E-2-E RIMS system implementation, Project management , Agile methodologies, submission management, submission publishing, and process improvements. She has extensively worked with regulatory submissions of eCTD/paper formats such as ANDA, IND, NDA, Initial MAA.

Reference

1. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
2. Gens & Associates: 2022 COVID-19 Regulatory Impact Follow-up Survey Whitepaper – Gens Associates (gens-associates.com)
3. Regulatory Approval in the Covid Era: How the Pandemic Changed Drug Development - Pharmaceutical Technology (pharmaceutical-technology.com)
4. Regulatory Agilities in the Time of COVID-19: Overview, Trends, and Opportunities (clinicaltherapeutics.com)
5. How automation can improve pandemic response in health care | CGI.com
6. Stats: Regulatory Agilities in the Time of COVID-19: Overview, Trends, and Opportunities (clinicaltherapeutics.com)
7. New Approaches to Regulatory Innovation Emerging During the Crucible of COVID-19 - PMC (nih.gov)

For more information, contact askus@infosys.com

Infosys®
Navigate your next