Response and Resilience

Lessons Learned from Global Life Sciences Ecosystems in the COVID-19 Pandemic

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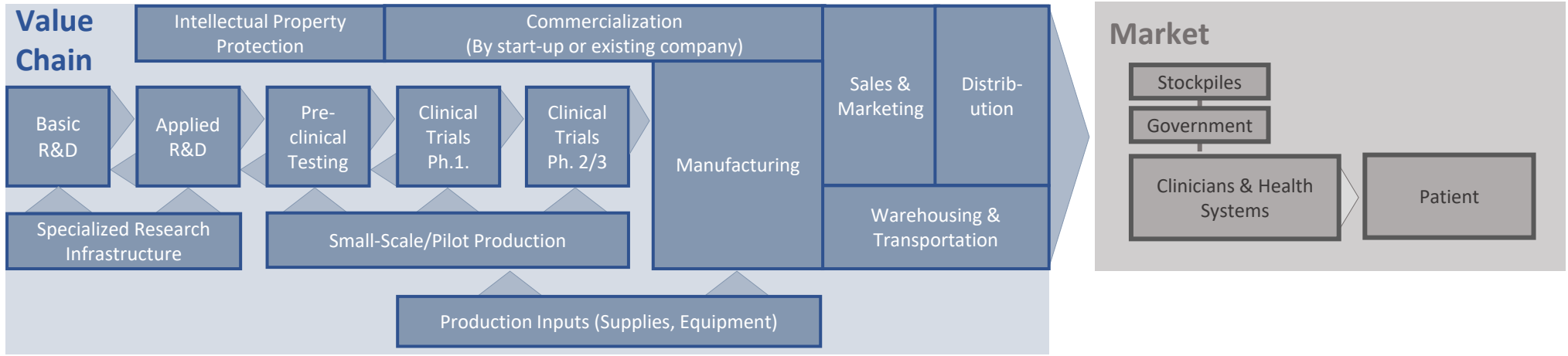
Project Goal

- The central goal of this study is to generate enhanced understanding of the favorable characteristics of global life sciences ecosystems that were able to energize their intellectual and infrastructural resources to respond to the COVID-19 challenge.
- It seeks to communicate the characteristics of best-practice ecosystems, so that the world and individual nations can be better prepared in the future.

About the Project

- The study identifies key lessons learned in national responses to COVID-19.
- Seeks to help policymakers across the globe focus on advancing favorable characteristics and emerging best practices that contribute to success.
- Examines the approaches of 13 nations that have active biomedical life sciences ecosystems.

Core Activities



Cross-cutting Supports

Talent

Skilled Workforce & Management

R&D Personnel	Trials Management	Production	Business Operations

External Professional & Contracted Services

Capital

Investment in R&D (Public & Private)	**Early-Stage Capital** (Governmental, Private Equity or Industrial)	**Production and Operations Capital** (Industrial, Private Equity, & Commercial Markets)

Policies & Regulation

Education	Workforce Development	Government Research Funding	Trials Regulation	Production Process Regulations	Quality Controls	Workforce Safety & Health Regulations	Public Health System Price Policies	Trade Policy	Market Access
Collaboration Supports	Intellectual Property Protections	Government Grants & Incentives	Government Co-investment	Taxation Policies	Liability Regulations	Environmental Regulations	Predictability & Stability	Market Rules & Regulation	Contingency Planning

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Lessons are attached to each ecosystem element

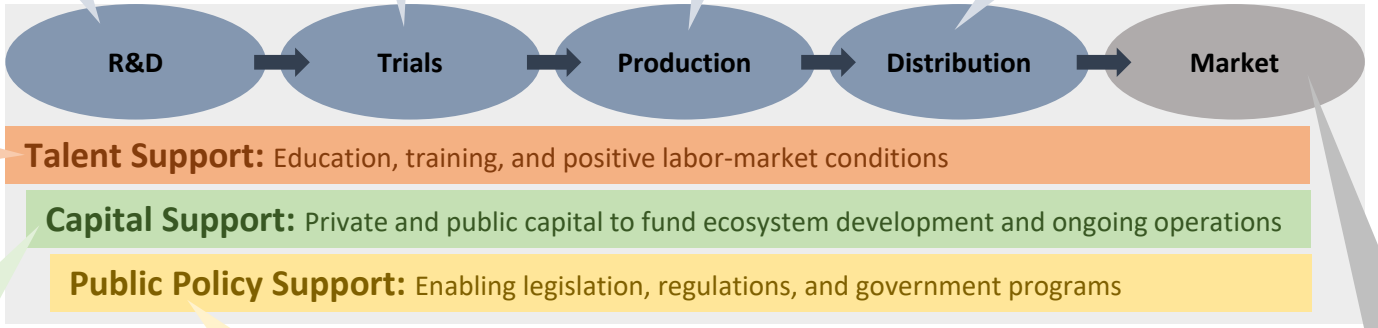
- *Innovations derive from a diversity of research settings in universities, government labs, nonprofit research institutions, and industry, no single typology dominates.*
- *Collaborations appear to have accelerated candidate vaccines and therapeutics.*
- *R&D-performing entities themselves will be negatively impacted in a pandemic.*
- *Prior investment in large-scale signature R&D and scientific infrastructure (e.g. supercomputers, synchrotrons, etc.) pays dividends.*
- *The economic cost of a pandemic dwarfs the investment in the R&D resources needed to address it.*

- *Adoption of virtual and contactless solutions sustains trials.*
- *Proactive and responsive regulatory guidance is highly important.*
- *Speed in trials for vaccine and therapeutic advancement is critical.*

- *Big and small players will be contributing solutions and collaborating.*
- *Supply-chain resiliency must be built.*
- *Advanced production methods need to be accelerated.*
- *Regulatory oversight of GMP production can be accomplished remotely.*

- *Multiple sources of critical supplies are beneficial.*
- *Well-planned supply chains and distribution agreements may be interrupted.*
- *Digital supply-chain monitoring is desirable and feasible.*

- *Scaling a life sciences workforce requires foresight and a long time horizon.*
- *Protection of workforce and contingency planning should be emphasized.*
- *Advancement of life sciences, digital, and advanced analytics convergence skills is required.*

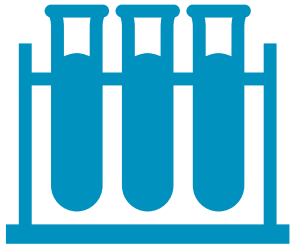


- *Research grants and development support set a key foundation for rapid innovation.*
- *Public co-investment can be a significant catalyst.*
- *Inter-industry partnerships and collaborations make a difference.*
- *Public markets may infuse capital.*
- *VC and angel investor activity primes the pump of innovation.*

- *It is important to sustain the existing fundamentals that are favorable to life sciences ecosystem operations.*
- *Centralized, preplanned, and professionally implemented rapid national response strategies are critically important.*
- *Emergency regulatory flexibility is required.*
- *Liability and other risk mitigation should be addressed.*
- *Commitment to building strategic stockpiles and government purchasing is required.*
- *Disinformation and misinformation must be proactively combatted.*
- *Government can facilitate the implementation of new biopharma production technologies.*

- *Virtualization or digitalization of healthcare has accelerated*
- *Universal, patient-centric access to care, diagnostics, therapeutics, and vaccines must be facilitated.*
- *There will be growth in product and service market niches rooted in pandemic preparedness and response.*
- *Long-term health implications for patients recovering from COVID-19 are, as yet, unknown.*

Summary of Lessons Learned for Life Sciences R&D



- Innovations derive from a diversity of research settings in universities, government labs, nonprofit research institutions, and industry, no single typology dominates.
- Collaborations appear to have accelerated candidate vaccines and therapeutics.
- R&D-performing entities themselves will be negatively impacted in a pandemic.
- Prior investment in large-scale signature R&D and scientific infrastructure (e.g., supercomputers, synchrotrons, etc.) pays dividends.
- The economic cost of a pandemic dwarfs the investment in the R&D resources needed to address it.

Summary of Lessons Learned for Clinical Trials

- Adoption of virtual and contactless solutions sustains trials.
- Proactive and responsive regulatory guidance is highly important.
- Speed in trials for vaccine and therapeutic advancement is critical.

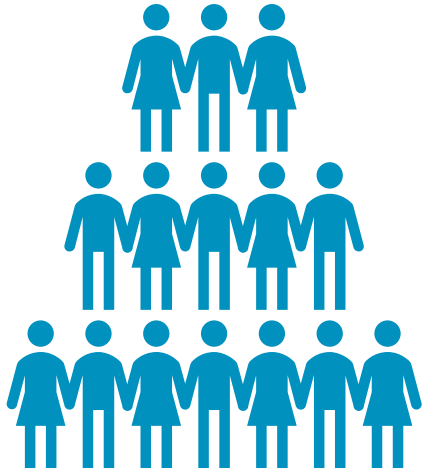
Summary of Lessons Learned for Production

- Big and small players will be contributing solutions and collaborating.
- Supply-chain resiliency must be built.
- Advanced production methods need to be accelerated.
- Regulatory oversight of GMP production can be accomplished remotely.

Summary of Lessons Learned for Distribution

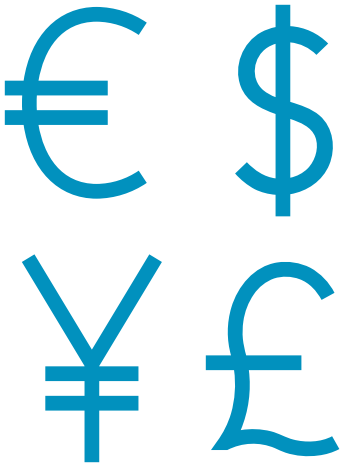
- Multiple sources of critical supplies are beneficial.
- Well-planned supply chains and distribution agreements may be interrupted.
- Digital supply-chain monitoring is desirable and feasible.

Summary of Lessons Learned for Talent



- Scaling a life sciences workforce requires foresight and a long time horizon.
- Protection of workforce and contingency planning should be emphasized.
- Advancement of life sciences, digital, and advanced analytics convergence skills is required.

Summary of Lessons Learned for Capital



- Research grants and development support set a key foundation for rapid innovation.
- Public co-investment can be a significant catalyst.
- Inter-industry partnerships and collaborations make a difference.
- Public markets may infuse capital.
- Venture capital (VC) and angel investor activity prime the pump of innovation.

Summary of Lessons Learned for Policies and Regulation

- It is important to sustain the existing ecosystems characteristics that are favorable to life sciences ecosystem operations.
- Centralized, preplanned, and professionally implemented rapid national response strategies are critically important.
- Emergency regulatory flexibility is required.
- Liability and other risk mitigation should be addressed.
- Commitment to building strategic stockpiles and government purchasing is required.
- Disinformation and misinformation must be proactively combatted.
- Government can facilitate the implementation of new biopharma production technologies.

Summary of Lessons Learned for Customers and Markets

- Virtualization or digitalization of healthcare has accelerated.
- Universal, patient-centric access to care, diagnostics, therapeutics, and vaccines must be facilitated.
- There will be growth in product and service market niches rooted in pandemic preparedness and response.
- Long-term health implications for patients recovering from COVID-19 are, as yet, unknown.

The lessons learned lead to five core conclusions with associated recommendations

1. Prior investments and advancements toward a robust life sciences ecosystem matter greatly in responding to a pandemic.

- The fact that, in the face of the COVID-19 pandemic, so many vaccine candidates and drugs have been brought forward into testing, trials, and emergency use is a heartening achievement.
- It is a testimony to the foresight of those who have developed, work in, and support the complex life sciences R&D and industry ecosystems around the world.
- The complexity of the ecosystems that must be in-place to advance R&D, product development, and production and distribution of biopharmaceuticals, vaccines, and diagnostics is such that they cannot be stood up from scratch in a real-time situation. They must already be in place, fully operational, well proven, and well funded in advance of an emergent need.

- Recommendation—Policymakers must prioritize and sustain investments in life sciences research infrastructure, workforce development, and advanced production systems. Enacted policies and regulations must support life sciences ecosystem development at scale and sustain favorable ecosystem operating conditions.

2. Promotion of collaborations is key to quickly mobilizing and pursuing new medical innovations.

- Public- and private-sector collaborations, and inter-industry collaborations, have played a key role in rapidly advancing innovations for pandemic response.
- These collaborations often build upon public-supported academic research in basic research together with industry expertise in applied discovery, development, and clinical testing that routinely take place in high-functioning life sciences ecosystems.
- The pandemic has demonstrated the benefit of collaboration, even between previous competitors.
- Different, but complementary, R&D, and industrial strengths and capacities can be brought together for advancing medical innovations.

- Recommendation—Policymakers should develop and align incentives to encourage collaborations that will advance and speed the development and commercialization of medical innovations and take advantage of the full capacities found across life sciences research institutions and industry.

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3. The convergence of digital technology with life sciences helps accelerate innovations and supports ecosystem resiliency.

- One broad benefit of the COVID-19 pandemic has been the acceleration in the use of digital technologies across all stages of life sciences development and the industrial value-chain.
- Digital technologies are proving effective in speeding up research insight and innovation, sustaining trials and regulatory oversight, building supply chain transparency, facilitating trade, and supporting safer (remote) clinical healthcare interactions.

- Recommendation—For the future, policymakers should continue to promote the use of digital technologies in R&D, clinical testing, supply chain management, and healthcare delivery and seek ways to further their integration across distinct activities to improve the effectiveness of life sciences ecosystems.

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4. Flexibility in government regulatory approaches is making a difference.

- Given the typical drug and vaccine development timelines of a decade or more, the speed of the overall response mounted by the global life sciences community to COVID-19 is nothing short of astonishing.
- This has been accomplished, in part, because of flexibility shown in regulatory processes by government.
- Perhaps the most-publicized area of flexibility is in the clinical testing of potential vaccines and therapies through mechanisms such as emergency use authorizations, compassionate use, conditional market authorizations, and short timeframe approvals, while still allowing for thorough scientific evaluation of a medicine's benefits and risks.
- Other less publicized forms of flexibility have also been advanced in the use of digital technologies in regulatory monitoring, ability to make changes in suppliers, and allowance for joint ventures and other collaborations.

- Recommendation – Policymakers should consider how increased flexibility with accountability can be achieved on a more regular basis as a means for ensuring that unmet medical needs are addressed to improve patient lives.

5. The existing business environment for innovation in life sciences ecosystems has proven to be highly agile and able to be effectively leveraged through the COVID-19 pandemic.

- In challenging times there is a strong impetus for government to be seen to be "doing something." COVID-19 has certainly required critical government interventions and actions, but it is important to recognize that care must always be taken to avoid actions that may undermine the favorable ecosystem characteristics needed to maintain life sciences advancements and innovation.
- There are multiple "fundamentals" that are influenced by governments that must be sustained for life sciences ecosystems to flourish.
- Recommendation—Policymakers need to ensure that the core elements of high-functioning life sciences business environments are in place to facilitate innovation advancement. Some of the key elements to be advanced include strong IP protections and provision of secure market access for innovative medicines.

- Substantial commitment of government funds to supporting R&D.
- Sustaining effective rules against trade barriers and facilitating international trade.
- Maintaining predictable and sustainable payer pricing system.
- Operation of a flexible, science-based regulatory system.
- Robust intellectual property protections and enforcement.

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