Policy Brief

Pandemic R&D Agenda for Action:

Fostering Innovation To End This Pandemic and Prepare for the Next One

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PANDEMIC ACTION NETWORK

Introduction

As the world commences the third year of the COVID-19 pandemic, the case for investment in research and development (R&D) for medical countermeasures to prevent and combat emerging global health threats is stronger than ever. In 2020-21, scientists around the globe raced to develop and deploy new vaccines, diagnostics, therapeutics, and other tools in record time to help stop the spread of the virus and save lives. Yet despite these tremendous scientific accomplishments, systemic gaps in pandemic-related R&D systems, supply chains, manufacturing, and delivery continue to stymie the roll-out of urgently needed technologies to *all* people who need them, *everywhere,* and are prolonging the pandemic.

COVID-19 has exposed longstanding market and systems failures and fragilities that pose barriers to timely and effective pandemic R&D. New variants like omicron underscore the continued risk of a pandemic R&D system that is not based on proactive and sustainable investment, scalability, and equity and human rights for the collective global good. Not only do these persistent gaps threaten to undo progress achieved through the scientific breakthroughs, but they also exacerbate entrenched inequalities that leave the most vulnerable and disadvantaged people around the globe without access to lifesaving medical countermeasures and essential health services, and perpetuate gross power imbalances between high- and low-income nations. COVID-19 has also unleashed a multitude of actors in pandemic-related R&D across the innovation spectrum and across the globe, underscoring the growing need for more purposeful alignment, coordination, information-sharing, and transparency.

The world urgently needs a fit-for-purpose, proactive, and resilient pandemic R&D ecosystem. There is broad consensus that R&D is a vital component of building a world better equipped to prevent, prepare for, and respond to pandemic threats. Yet new investments in innovation will fail to meet their promise to save lives, prevent future global health emergencies, and build a healthier, safer world for all unless governments, international institutions, and industry are willing to heed the hard lessons of this pandemic and work together to fix these systemic failures and challenges. **We are calling on world leaders to prioritize action in four areas:**

1. **End the COVID-19 crisis for everyone**
2. **Strengthen global, regional, and national pandemic-related R&D capacity**
3. **Increase long-term, sustainable financing for pandemic-related R&D**
4. **Coordinate and align pandemic-related R&D stakeholders**

Contributors

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End the COVID-19 Crisis for Everyone

New vaccines, therapeutics, and diagnostics have been indispensable tools in the COVID-19 response, but the science continues to evolve on their effectiveness. Continued investments in R&D are critical to ensure these tools remain effective and respond to new data on immune response, dosing and boosters, and new virus variants. Countermeasures are useless if they cannot be delivered to, and used by, populations in need, which makes solving the persistent downstream R&D and supply chain bottlenecks of paramount importance. Global and regional manufacturing capacities must be leveraged and maximized to step up the speed and scale of global vaccination, while at the same time ramping up delivery of tests and therapeutics to save lives in the interim. Additionally, vaccines and other medical countermeasures must be fit-for-purpose, appropriate, and accessible for all populations. This requires not only continued, iterative innovation as needs and circumstances change, but also an innovation process that prioritizes global needs and applicability.

World leaders should:

- **Fully and urgently fund the Access to COVID-19 Tools Accelerator (ACT-A) across all pillars and close the R&D funding gap.** ACT-A, the global mechanism set up to collaborate and help ensure that all countries have equitable access to COVID-19 tests, treatments, vaccines, and other lifesaving tools, remains critically underfunded. In 2022, ACT-A needs US$23.4 billion to implement its part of the global COVID-19 response, of which US$840 million is needed to close upstream R&D gaps for vaccines, diagnostics, and therapeutics. A fully resourced ACT-A, across all pillars and across R&D, manufacturing, and delivery needs is vital to ending the crisis phase of this pandemic. These funding gaps are a small fraction of the trillions that the pandemic is costing the global economy and must be closed immediately.

- **Support continued R&D, surveillance, testing, and trials to develop and maintain technologies to respond to COVID-19 mutations and variants.** As seen with the delta and omicron variants, COVID-19 can mutate and spread quickly, hampering our ability to detect, stop, and treat the virus. Sustained surveillance and testing to detect and report on these and other new variants, R&D to adapt or design new countermeasures, and ready-to-mobilize clinical trials capacity are essential to an effective rapid response. The Coalition for Epidemic Preparedness Innovation (CEPI) is playing a leading role in advancing next-generation COVID-19 and pan-coronavirus vaccines and requires full and sustained funding to carry out this mission.

- **Resolve supply chain barriers and increase transparency to speed and scale up global access and delivery of COVID-19 countermeasures.** Supply chain bottlenecks have challenged the scale-up of COVID-19 countermeasure manufacturing, as well as delivery of tools to end-users. Export restrictions and other limitations in accessing countermeasure inputs have slowed production, and shortages of adjunct materials like vials, needles, and syringes continue to challenge last-mile delivery. They also threaten delivery of routine immunizations and other basic health services. These constraints are being felt everywhere and are especially acute in lower-income nations with already limited supplies. Governments should end all use of export controls and ensure the free flow of goods so that medical countermeasures can be manufactured and distributed more efficiently and equitably. Greater transparency from industry and governments on supply and demand data can also help shine light on bottlenecks before they become major challenges and help promote policy or product design solutions to mitigate.

- **Ensure diverse, global representation in the R&D process to ensure COVID-19 medical countermeasures are fit-for-purpose and universally accessible.** Many of the tools currently available to fight COVID-19 have presented significant challenges for access and deployment in low- and middle-income countries (LMICs). Some of the leading mRNA vaccines require consistent freezing or refrigeration through ultra-cold chain capabilities, and until the recent introduction of antiviral pills and injectable antibody therapies, treatment options were limited to monoclonal antibody therapies which had to be administered intravenously in a health care setting. All of these treatments remain hard to access quickly enough to be effective, even in wealthy countries. To ensure products are safe, effective, and globally accessible for diverse populations, it is important that LMIC populations are included in clinical trials and represented in R&D governance and decision-making processes.

Strengthen Global, Regional, and National R&D Capacity

Health R&D capacities at the global, regional, and national levels need to be significantly up-leveled to match the size, scope, and scale of pandemics. At the global systems level, a top priority is to invest in platform technologies that can be readily adapted to emerging infectious disease threats. At the regional and national levels, R&D capacities need to be built and maintained so that every country can mobilize to stop outbreaks at their source. Every country may not need to develop a full suite of R&D capabilities — such as advanced laboratories, clinical trials infrastructure, and quality-assured manufacturing — for the full spectrum of medical countermeasures and innovations; it may be more cost-effective and efficient to pool these capacities at a sub-regional or regional level. But every country should have a clear plan and pathway to gain rapid access to needed tools at affordable prices when new threats emerge.

World leaders should:

- **Support LMICs to implement their national and regional priorities for R&D capacity strengthening and technical assistance.** Local governments and communities know best the weaknesses and gaps in their own pandemic R&D systems — and their assessed and articulated needs must inform the global pandemic preparedness agenda and shape investments by international funders. While some countries may need to bolster surveillance capacities, others may need to build up laboratory capacity, manufacturing, or supply chain management. There is no one-size-fits-all template, so tailored support and technical assistance is required. African Union-led initiatives launched to fight COVID-19, such as the African Vaccine Acquisition Trust and Partnership for African Vaccine Manufacturing to build regional capacities in supply chain, procurement, and manufacturing, show the power and potential of locally- and regionally-driven solutions for pandemic preparedness and response. These efforts should be supported and strengthened for the long-term.

- **Scale up globally distributed manufacturing with associated technology transfer and workforce development.** COVID-19 has shown a bright light on the lack of globally diversified manufacturing for pandemic countermeasures. Governments and industry should work in partnership to build and maintain globally distributed manufacturing capabilities

that are on deck and can be revved up quickly to respond to surges in global demand. These investments must have long-term economic viability to be sustainable and effective when the next pandemic strikes, which means building intra-pandemic markets for vaccines and other countermeasures is vital to ensure new facilities can be operational during emergencies. These manufacturing investments must be coupled with commitments by private sector companies and governments to step up support for technology transfer and workforce development so that new manufacturing capacities have the equipment, expertise, know-how, and power to produce and deliver new innovations safely and rapidly at scale.

- **Strengthen national and regional regulatory bodies to coordinate and expedite review and approval of new products and manufacturing facilities.** While many regulatory authorities have moved swiftly to review and approve new COVID-19 vaccines, differences in labeling, dossiers, and other requirements between countries, as well as the need for review of technologies in individual countries after approval by a stringent regulatory authority, has slowed global access. Similar, often unremediated, regulatory bottlenecks have been seen for COVID-19 diagnostics and therapeutics. Coordination and alignment of review and harmonization of standards across regulatory bodies — particularly at the regional level — could streamline product approval during a health emergency and help speed access when speed is of the essence. In particular, increased coordination between the World Health Organization (WHO) and regional regulatory bodies, such as the European Medicines Agency and the newly formed African Medicines Agency, may help to streamline safety and efficacy reviews and result in faster uptake of products at a national level. Additionally, as new manufacturing facilities come online around the world, increased national and regional regulatory capacities will be needed to ensure these facilities are up to global standards, producing high-quality, safe products.

- **Bolster global platform R&D capabilities to rapidly respond to the next pandemic.** Decades of investment in platform technologies enabled the development of COVID-19 vaccines in record time. Now that proof-of-concept has been achieved, we must double down on the promise of these and other platform technologies to dramatically reduce timelines for future product development to fight novel pandemic threats. Leveraging platform technologies to accelerate development of a library of prototype vaccines for the top viral families with pandemic potential, as proposed by CEPI, the U.S. National Institutes of Health (NIH), and the European Union's Health Emergency Preparedness and Response Agency (HERA), is a good place to start. Bolstering coordinated platform surveillance capabilities across countries and regions is also needed. This requires not only increased investment, but also prioritization, coordination, and alignment on research agendas to prioritize emerging infectious disease vaccines as a global good, leverage available resources and expertise, build on promising science, and commit to ensure technologies are readily available and accessible to the world.

- **Prioritize national health system strengthening in tandem with R&D to ensure ready pathways for end-to-end product development and delivery.** Strong health systems are the backbone of global health security and pandemic preparedness — from upstream disease detection and surveillance, to downstream supply chain management and product delivery, they are vital to pandemic-related R&D. Investing in health systems is critical to fostering a strong enabling environment for end-to-end pandemic countermeasure development and delivery, including having the systems, policies,

structures, and personnel in place to flex and nimbly respond during health emergencies and deliver technologies to the last mile. Domestic and international investments to advance primary health care and Universal Health Coverage can help achieve these goals and improve delivery of health services in non-pandemic times.

Increase Long-term, Sustainable Financing for Pandemic-Related R&D

A strengthened pandemic R&D agenda must be matched with additional, predictable, and sustainable financing. Much like traditional defense, health security R&D is a long game; it requires continual investment and enhancement in surveillance, readiness, and training, year-in and year-out. For too long, emerging infectious disease R&D has been subject to reactive, boom-and-bust funding that fades as soon as a health crisis abates, often without bringing promising new tools over the finish line. These resources are highly dependent on a small group of donor countries, primarily through overseas development assistance (ODA) budgets vulnerable to political and economic swings. In non-crisis times, this financing has not been delivered at the speed or scale necessary to accelerate R&D and universal global access when it is needed.

World leaders should:

- **Secure new, multisectoral sources of funding for pandemic R&D.** R&D for emerging infectious diseases benefits the national and global defense, economic, and health objectives. As such, pandemic R&D should be funded as a strategic, multisector endeavor and should not rely on domestic health or development assistance budgets alone. Governments, multilateral institutions, and the private sector *all* must upscale investments across countermeasure technologies and across the pandemic R&D lifecycle. COVID-19 shows the importance of sustaining investments in platform technologies and also making sufficient capital available for "at-risk" investments to seed the development and manufacturing of a new technology before it has passed regulatory review, so that it can quickly be used to save lives and help stop the spread of a deadly virus. A near-term top priority for world leaders should be to fully fund CEPI's US$3.5 billion replenishment to ramp up R&D to significantly reduce the threat of future outbreaks with pandemic potential and ensure equitable access to lifesaving vaccines. Leaders should also invest in FIND and other leading R&D partners with a primary mission of accelerating development and global access and equity to vaccines, diagnostics, and therapeutics.

- **Include R&D capacity strengthening as a priority area for additional financing through a new global fund for pandemic preparedness.** At their October 2021 Summit, G20 leaders heeded the call by the Independent Panel on Pandemic Preparedness and Response, the G20 High-level Panel on Financing the Global Commons for Pandemic Preparedness and Response, the Pandemic Action Network, and others for creation of a new international financing mechanism for pandemics. The aim of the fund is to mobilize at least US$10 billion in additional annual financing to close critical gaps in global and national preparedness for pandemic threats. Financing priorities should be informed by country capacity assessments and include investments in pandemic R&D infrastructure such as surveillance, laboratory capacity,

clinical trials, manufacturing, regulatory strengthening, pharmacovigilance, and supply chain management. The Global Health Security Agenda (GHSA) is a ready-made platform for countries to identify and articulate their financing gaps, and its new R&D Taskforce is actively working to develop tools to assess R&D gaps and align with the new mechanism.

- **Prioritize global access in domestic and regional R&D investment strategies.** As high-income countries and regions consider scaling up their capacity for pandemic R&D, they should ensure that these additional investments produce innovations designed for global application as well as for domestic use. COVID-19 has shown that nationalistic approaches will fail to stop pandemics. New or forthcoming investments in the NIH and Biological Advanced Research and Development Authority (BARDA), the European Union's HERA, and other national and regional R&D agencies should be explicitly structured to support global response and preparedness, and work in close partnership with CEPI and other R&D institutions with global access missions.

- **Ensure access principles are applied to all future pandemic R&D investments.** Ensuring global equity and universal access to lifesaving medical countermeasures in the face of a health crisis is not only a moral imperative, it is critical to stop deadly infectious diseases from spreading. Public sector funding for pandemic R&D should be clearly linked to adherence to access principles, and governments should better define global public goods, as well as access provisions for global public goods. Government and industry also need to forge new public-private partnerships for pandemic R&D that promote and incentivize equitable, affordable, and universal public access to novel medical countermeasures while also respecting intellectual property.

Coordinate and Align Pandemic-Related R&D Stakeholders

Global efforts in R&D for pandemic- and epidemic-risk diseases remain highly fragmented and uncoordinated. This has led to missed opportunities to align R&D efforts at the regional and global level to improve early outbreak detection and inform public health policies, or to generate shared learnings and promote best clinical practices for different interventions and therapies. Some recent progress has been made in improving global coordination of R&D through the WHO's R&D Blueprint, and, in the midst of the COVID-19 pandemic, through the establishment of the Solidarity Trial and the ACT-A. Yet, outside the high-level agenda setting of the R&D Blueprint, these mechanisms were designed as temporary structures specifically for COVID-19, are funded through emergency resources, and lack the capacity to compete with national actors. There is currently no standing global body that is empowered and equipped to oversee pandemic-related R&D before and during a global crisis and ensure equitable access.

- **Conduct an independent, multi-stakeholder review of ACT-A to draw lessons for future global coordination for R&D in health emergencies.** As noted above, ACT-A was stood up quickly as a temporary solution to coordinate international organizations around global delivery of lifesaving tools to respond to COVID-19. The challenges and limitations of this model have been discussed in recent articles and papers. To their credit, ACT-A leaders have listened to these critiques and attempted to adapt the platform over the course

of the pandemic, as reflected in their recent strategic review. However, some stakeholders are already talking about the "future of ACT-A." Any decisions about the future of this, or a similar entity, should be informed by an independent, inclusive review and consultation process that brings in the perspectives of LMIC governments, industry, and civil society.

- **Define and align roles and responsibilities of stakeholders at the global, regional, and national levels and across the R&D spectrum.** Many of the systems or procedures to coordinate and facilitate R&D during the COVID-19 pandemic have been improvised. This experience points to the need to more clearly define organizational roles and responsibilities, coordination, and hand-off mechanisms that can be activated quickly, operate efficiently, and prevent redundancies. Priorities include defining the role for WHO and its regional offices, outside of its normative role in agenda setting through the R&D Blueprint, as well as the R&D activities and responsibilities of regional bodies like the Africa Centers for Disease Control (Africa CDC) and Pan American Health Organization (PAHO) vis-à-vis their member states and global actors. The NIH, HERA, and CEPI have all proposed to do work on a library of vaccines for novel pathogens; their efforts should be aligned and coordinated to prevent unnecessary duplication and achieve cost savings. Product developers across the public and private sectors should also coalesce around a global action plan to support equitable development and deployment of medical countermeasures for future pandemics. In addition, there is a need for greater co-investment and alignment between clinical development, regulatory review, manufacturing, and supply chain to support a holistic, end-to-end strategy.

- **Promote open and timely data sharing to accelerate R&D and inform future innovation.** Transparent, accessible data sharing on surveillance, pathogen sequencing, clinical trials, and research in the pre-commercial space from all partners engaged in pandemic-related R&D is important so that researchers, scientists, and innovators around the world can leverage this information to iterate on and develop new medical countermeasures for existing and emerging threats. Research teams have been more ready to share data during the COVID-19 crisis, but permanent systems and long-term commitment is needed to promote global scientific collaboration and best leverage experience and resources.

- **Integrate R&D into global health security and pandemic preparedness governance and coordination bodies.** While COVID-19 has pushed pandemic R&D into the spotlight, a global framework or process to assess country or global R&D readiness for pandemic threats is not included in the tools we currently have to govern and coordinate global health security. R&D is not yet included in the International Health Regulations, the Joint External Evaluations (JEEs), or the GHSA Action Packages. The GHSA is a useful platform for supporting countries to assess and articulate gaps in pandemic preparedness, and its new R&D Task Force should be leveraged to support countries' assessments of R&D gaps and needs. Longer-term, R&D indicators should be formally incorporated into the International Health Regulations. As world leaders debate the establishment and adoption of new pandemic governance mechanisms, such as the proposed Global Health Threats Council or Pandemic Accords, coordination and financing pandemic R&D should be high on their agenda.

- **Engage end-users of medical countermeasures in the R&D process.** The need for suitable, adaptable tools for low-resource settings is not unique to COVID-19, but is a persistent challenge in product development for global health security that requires greater attention at the upstream R&D stage. Governments, civil society, and industry

stakeholders from countries at all income levels — especially those from low-resource settings who have traditionally been excluded — must be engaged to inform the development and design of medical countermeasures so that they are accessible and appropriate for all populations and settings. Product development processes should reflect the perspectives and needs of end-users and decision makers in LMICs from the outset to ensure resulting products are appropriate or adaptable for use in low-resource settings.

Conclusion

The prolonged COVID-19 pandemic and the emergence of infectious virus variants like omicron underscores the risks of the longstanding global failure to prioritize investments in pandemic R&D, global solidarity, and universal access to lifesaving innovations. Yet, the greater awareness and appreciation today by policymakers and their publics of the importance of pandemic R&D to their lives and livelihoods also presents an opportunity to drive systemic change.

This paper has identified a menu of priority actions to close the critical R&D, manufacturing, and delivery gaps necessary to end the acute COVID-19 crisis and build a more resilient, equitable pandemic R&D ecosystem for the future. R&D stakeholders from all sectors — governments, multilateral and regional organizations, industry, philanthropy and investors, and civil society around the globe — should convene in 2022 to forge consensus on what it will take to guarantee timely, affordable, and equitable development and delivery of novel tools and technologies in the face of the next pandemic threat.

The cost of inaction has never been more clear. Political will must catch up to science: to end this pandemic and prevent the next one.