



INTREPID ALLIANCE

INTERNATIONAL READINESS FOR PREVENTING INFECTIOUS VIRAL DISEASE



INTREPID ALLIANCE ANTIVIRAL SUMMIT

AVERTING THE NEXT PANDEMIC NOW

March 22, 2023

EXECUTIVE SUMMARY

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EXECUTIVE SUMMARY

The inaugural INTREPID Alliance Antiviral Summit, “Averting the Next Pandemic Now,” took place in Washington, D.C. on March 22, 2023, and involved almost 100 international participants, most of them in person, from the pharmaceutical and biotech industries, academia, government, regulatory bodies, foundations, and NGOs.¹ The Summit was characterized early on as an opportunity for hopeful collaboration in a post-pandemic world, which set the tone for the day. The response was positive and constructive, but speakers recognized the risk of pandemics has never been as great as it is today. The discussion reinforced the need for the INTREPID Alliance to act as a convenor, a catalyst, and a voice of the pharmaceutical industry, emphasizing the important role industry has in driving antiviral research for pandemic preparedness.

The [INTREPID Alliance](#) is a group of innovative biopharmaceutical companies committed to accelerating antiviral research, aiming to ensure that we have a stronger pipeline and are better prepared for future pandemics. As described in opening remarks by James Anderson, the Chair of INTREPID², and Ruxandra Draghia-Akli, an INTREPID board member,³ the goals for the Summit were three-fold:

1. Build on the collaborations and good practices developed during the SARS-CoV-2 pandemic among companies,

academics, regulators, policy makers, philanthropies and NGOs.

2. Identify gaps in antiviral research and opportunities for INTREPID to add value.
3. Foster personal interactions between thought leaders in the field,

In her opening remarks, Susan Dentzer, program moderator and CEO of America’s Physician Groups, underscored the importance of the 100 Days Mission (100DM) set forth by the G7 global leaders by observing that if the United States had met the 100 day target during the COVID-19 pandemic, the nation would have had a suite of countermeasures in place by the second week of April 2020, a month into the initial lockdown, at a time when the



Bridging the gap in antiviral solutions to viral pathogens with the greatest pandemic potential, requires innovation, commitment and collaboration across sectors. The INTREPID Alliance brings the experts and the platform needed to help ensure we are better prepared in the future.

—JAMES ANDERSON

Chair, INTREPID Alliance, Executive Director of Global Health, IFPMA

global infection rate was estimated at two million and global deaths at 137,000. Vaccines approved in December 2020 and an antiviral being authorized in May 2020 were record-breaking developments, but the number of cases and deaths was more than an order of magnitude higher by then. We must aim to be faster in the future.

In a video address, Victor Dzau⁴ challenged the participants to build a sustainable pipeline of 25 phase-2 antivirals as proposed in the 100DM; to create an overarching view of the R&D landscape against the top 10 pathogens of pandemic potential; and to work together to shape a roadmap for building the pipeline of therapeutics to tackle future pandemics.

Speakers from the International Pandemic Preparedness Secretariat (IPPS), the White House, National Institutes of Health (NIH),

the Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Health Emergency Preparedness and Response Authority (HERA), Industry and others identified the need for a united R&D therapeutics community to shape a future antiviral landscape for pathogens of pandemic concern, as well as for a future Disease X scenario, and for developing a centralized list of treatments that could save countless lives. Speakers discussed lessons from the COVID-19 pandemic, including: continuing collaborations such as ACTIV,⁵ the need for accelerated clinical trials and prepositioned clinical trial networks, convergent regulatory pathways and early consultation with regulators, manufacturing innovation with capacity located around the world and close to populations, global access strategies that are created early in the R&D process with emphasis on low- and middle-income countries (LMICs), the importance of prioritization of antivirals by countries and their health care systems to support rapid delivery. Government and industry speakers also highlighted current research efforts targeting key viral families, including the development of Target Product Profiles (TPPs). More than 20 key unmet needs and recommendations in R&D, regulatory, manufacturing, access, policy and advocacy were identified.

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Therapeutics are vital in the fight against pandemics, and we believe the world needs a strong armamentarium of therapeutics in the pipeline ready to tackle future pandemic threats.

—VICTOR J. DZAU, M.D.

President, U.S. National Academy of Medicine, IPPS, Science & Technology Expert Group Co-Chair

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Specific therapeutic needs were identified by the NIH/National Institute of Allergy and Infectious Disease (NIAID). In the near term, for SARS CoV-2 infection, there is a need for additional 3CL protease inhibitors with non-overlapping resistance patterns and fewer drug-to-drug interactions; an oral polymerase inhibitor; other agents with different mechanisms of action; agents for pre-exposure prophylaxis for special populations; agents for post-exposure prophylaxis; pediatric and pregnant people dosing; and therapies to prevent or treat long COVID. Specifically, there is a strong need for broad-spectrum antivirals that could treat multiple pathogens or all variants and subtypes of a given pathogen. Combination therapies were called for by several speakers, and INTREPID is well positioned to enable early assessment of combinations.

Viral families with the potential to cause future pandemics were identified by NIH: coronaviridae (e.g., SARS, MERS),



orthomyxoviridae (e.g., influenza viruses, including avian flu), bunyavirales (e.g., hemorrhagic fevers, hantavirus, Lassa fever), filoviridae (e.g., Ebola, Marburg), flaviviridae (e.g., West Nile, Dengue, yellow fever), paramyxoviridae, (e.g., Nipah, RSV), picornaviridae (e.g., Enterovirus D68), and togaviridae (e.g., Chikungunya). It was acknowledged that the World Health Organization's (WHO) soon-to-be-released prioritized viral families would be a helpful update for alignment on the most urgent pathogens.

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During COVID-19 we had this unique moment of focus between all aspects of the private sector, our public health community, our government...if we can capture that goodness... where everyone was working together for that common goal, that's going to be how we achieve the 100 Days Mission going forward.

—**MATT HEPBURN, M.D.**
Senior Advisor to Director, White House Office of Science and Technology Policy for Pandemic Preparedness

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An integrated plan for pandemic preparedness addresses key research gaps in top viral families; accelerates development of vaccines, therapeutics, and diagnostics for prototype and priority pathogens; coordinates closely with USG partners, key global stakeholders, and industry.

—**CARL DIEFFENBACH, PH.D.**
Director, Division of AIDS at NIAID/NIH

A final call to action. Underscoring the theme of “expecting the unexpected,” the Summit closed with the acknowledgment that emergency science can function well when multiple sectors step up to the plate and align, and a call to sustain that infrastructure as we move beyond SARS-CoV-2; a call for investment in biosecurity commensurate with the threat, which has never been greater, and for a leadership mindset ensuring the coordination of the end-to-end relay to move things from discovery to target to R&D to manufacturing to approval and availability. Product approvals and availability can be accelerated by regulatory harmonization, supply in a predetermined equitable process, availability of countermeasures and diagnostics at

the local level, and ultimately acceptability and trust among the people who could benefit. Finally, recommendations were made to partner with regional leaders such as the Africa CDC; utilize digital technology to build better predictive models of biodetection and emerging disease threats and to build a Coalition for Epidemic Preparedness Innovations (CEPI)-like organization for antivirals.

INTREPID Alliance response. Following the Summit definition of the end-to-end roadmap needed for antivirals in future pandemics, the INTREPID Board reaffirmed its focus on the creation and stewardship of a diverse and centralized listing of antiviral compounds with potential utility



A final call to action for multi-sector investment in biosecurity commensurate with the scale of the threat—which has never been greater—and for a leadership mindset that fosters collaboration across the the end-to-end relay from new target discovery, accelerated development, and innovative manufacturing to streamlined approval, global availability and trusted uptake.

—JULIE GERBERDING, M.D., M.P.H.
President and CEO, Foundation for the FNIIH



against key pandemic viral families and targets. In our judgment, this is where the expertise and capabilities of the INTREPID membership can have most impact. We will work with other stakeholders who will drive progress on the other key elements of the end-to-end pathway.

To this end, INTREPID intends to publish and frequently update a landscape of antiviral global R&D efforts and will build on the NIH TPPs, which may serve as entry criteria into the centralized listing. As a steward of this public listing of promising compounds, INTREPID intends to provide advice and consultation to academic and other early stage researchers to help prioritize promising compounds for further development.

After the Summit, INTREPID was invited by the 100DM IPPS to participate in a subgroup of their Science Technology Expert Group working with the Rapidly Emerging Antiviral Drug Development Initiative (READDI), the Pandemic Antiviral Discovery (PAD) initiative and others to develop a detailed therapeutics roadmap integrating lessons from the current and



The hundred-day term can distract people in thinking ‘it’s just about the sprint,’ when really, it’s all about the marathon of preparedness.

—HEULWEN PHILPOT
Head of IPPS

past pandemics and capturing what must be done by all stakeholders, ranging from TPPs to clinical trial design, manufacturing needs, and smoothing the handover at each stage of research.

Finally, INTREPID will develop clear industry policy perspectives on the subsequent enablers of the end-to-end pathway, including financing for pandemic preparedness R&D, clinical trials, regulatory approaches, manufacturing and equitable access. We will engage with the stakeholders working on these areas to provide input from INTREPID and support a fit-for-purpose pathway that could help enable delivery within 100 days in future pandemics.

¹ Please refer to page 31 of the full report for a list of participating organizations.

² and Executive Director of Global Health, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

³ and Head, Global Public Health Research & Development, Johnson & Johnson

⁴ President of the National Academies of Sciences, Engineering, and Medicine and member of the IPPS (informally the “100 Days Mission”), steering group, and co-chair of the IPPS Science and Technology Expert Group, which provides technical input and assurance to the 100 Days Mission.

⁵ In April 2020 the NIH announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, coordinated by the Foundation of the NIH, “to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines.” <https://www.nih.gov/research-training/medical-research-initiatives/activ>

It is imperative that we work to strengthen relationships and partnerships between the industry, government agencies, academic research organizations, philanthropies, procurement agencies, and multilateral organizations as a national and international community in order to strengthen the global antiviral ecosystem for pandemic preparedness and response.

On March 22, 2023, 100 thought leaders convened at the inaugural INTREPID Alliance Antiviral Summit, and many made recommendations on ecosystem strengthening—a list of these recommendations is below.

This list of recommendations does not necessarily represent a consensus or the views of the INTREPID Alliance. It is simply a report of recommendations made by thought leaders and stakeholders in attendance at the Summit to address the overall pandemic ecosystem. They address overall ecosystem gaps and will require multi-sectoral action to address.

RESEARCH AND DEVELOPMENT

- 1. Roadmap.** Develop a roadmap to facilitate coordination of the end-to-end “relay” of biothreat prevention and countermeasure development: moving candidates from discovery to target to clinical development to approval to reliable manufacturing at scale to supply reliability and ultimately uptake at the point of care.
- 2. Viral families and Antiviral Listing.** Determine research focus on viral families based on the WHO priority list. Create a centralized system of promising investigational candidates and encourage investment in those therapies and diagnostics, ensuring that gaps are addressed and innovations from small companies are included.
- 3. Target Product Profiles (TPPs).** Collaborate to develop TPPs to guide research into antiviral agents for possible pandemic pathogens, reflecting the needs of patients in low-resource countries.
- 4. New generation of products meeting LMIC needs.** Encourage public- and private-sector, and philanthropic organizations to work together on TPPs appropriate for low- and middle-income countries (LMICs). Catalyze product development in areas the commercial market may ignore.
- 5. Scientific collaboration.** Adopt best scientific collaborative practices such as those demonstrated by the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership: e.g., maintenance of a centralized inventory of pre-clinical and clinical resources. Provide broad access to repositories of standardized sequence data, viruses, assays, and animal models.
- 6. COVID-19’s unmet needs.** Foster public-private partnerships to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines addressing the SARS-CoV-2 pandemic. Align on a quality case definition of long COVID.
- 7. Sustain capabilities developed during COVID-19.** Maintain an active, effective clinical trial network that can be pre-positioned for the next pandemic. Develop systems for organizational learning and talent management within companies to further enhance and retain talent. Sustain scientific and manufacturing capabilities post-development.
- 8. Clinical trials.** Build a prepositioned network of antiviral trial sites and flexible platform capabilities for rapid response, such as those developed by CEPI for vaccines, building on the ACTIV, RECOVERY, and Solidarity trials and consistent with HERA’s planning.
- 9. Predictive, exploratory, and pre-clinical scientific investments.** Build better predictive models of where new pathogens are most likely to emerge and improve “One Health” biodetection. Invest in basic science to develop medical countermeasures against prototype pathogens. Invest in optimized medicinal chemistry to reduce manufacturing barriers. Advance the development of small molecules and monoclonal antibodies that target more conserved regions of the virus, beginning early in parallel with vaccine development.

REGULATORY

- 1. Global alignment.** Aim for global alignment across regulatory agencies on protocols, clinical trial design, and criteria for authorizing of medicines in the context of an emergency. Streamline and harmonize regulatory processes to the extent possible, considering national and regional laws. Promote regulatory reliance to speed approvals and deliver authorized medicines to populations faster.
- 2. Early guidance.** Seek earlier interactions and guidance from regulators under a pre-Investigational New Drug (IND) Application meeting request or other advice mechanisms.

ACCESS

- 1. Approval, availability, allocation, and acceptance.** Conceive of and plan for access as the four A's: Approval, Availability in country and at the point of care where people need it most, Allocation of the prioritization of ample supply, and Acceptance.
- 2. Early access implementation.** Improve operationalization of early access in low resource countries by aligning and coordinating among procurement agencies, companies, and local governments. Improve capability and capacity of procurement and prequalification agencies from lessons learned during the SARS-CoV-2 pandemic.
- 3. Early access planning by companies.** Call for earlier plans by companies on innovative access strategies for low-resource countries, with special attention to the last mile.
- 4. Clinical workforce.** Address shortages in the infectious disease clinical workforce both in high- and low-resource countries.

MANUFACTURING

- 1. Manufacturing capacity.** Ensure manufacturing capacity is globally distributed, close to populations, and sustainable to speed products to patients, including early licensing arrangements. Once created, sustain this between pandemics.
- 2. Secure distribution.** Include distribution chains all the way down to the last mile to ensure access, involving communities, and strengthening health systems.

POLICY AND ADVOCACY

- 1. Collective industry advocacy voice.** Shape the environment for antiviral preparedness through a collective advocacy voice that reframes pandemic preparedness and response in a national and global security context and sustains investment in medical countermeasures for known and as-yet-unknown viral threats. Governments should provide incentives for discovery, development, and manufacturing of antivirals with limited commercial interest and be clear about proposed solutions and the funding required.
- 2. Stakeholder advocacy.** Encourage advocacy from patient advocates, clinicians, and researchers on antivirals to demonstrate the public mandate to policy makers.
- 3. Global alignment and national leadership.** Sustain U.S. leadership and diplomacy on pandemic preparedness. Advocate for government-sponsored investments in antiviral discovery. Reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA) and President's Emergency Plan for AIDS Relief (PEPFAR). Coordinate with HERA and other leading country and regional platforms, e.g., those of Japan and the UK, Africa, and the G20.
- 4. Country prioritization of antivirals.** Work to increase antiviral prioritization by countries and their health care infrastructures to support rapid delivery, including test-and-treat programs. Obtain country feedback on what it will take to facilitate rapid uptake of antivirals and to strengthen health systems to diagnose and deliver interventions.
- 5. Public health empowerment.** Empower public health systems and a network of collaborators coordinating efforts to be ready for Day 1 of the next pandemic and support them with sustained investment.
- 6. Streamline contracting process.** Streamline governments' contracting systems that could be activated during a pandemic, working end-to-end across the value chain including manufacturing and final product procurement.
- 7. Protect IP.** Ensure that multiple years of early- to late-stage scientific investment that resulted in the rapid development of antivirals during COVID-19 is valorized and supported by strong intellectual property protections.
- 8. Address politicization of science.** Strategize to address the politicization of science, public health, and preparedness. Overcome disinformation with robust and clear science-based communication.