



INTREPID ALLIANCE

INTERNATIONAL READINESS FOR PREVENTING INFECTIOUS VIRAL DISEASE



INTREPID ALLIANCE ANTIVIRAL SUMMIT

AVERTING THE NEXT PANDEMIC NOW

March 22, 2023

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- James Rosen, MBA, M.S.P.H., *CEO, Rapidly Emerging Antiviral Drug Development Initiative (READDI), Inc.*
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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.

“

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

[CLICK TO READ THE RECOMMENDATIONS](#)



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.

“

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

“

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.

PROCEEDINGS

James Anderson, INTREPID Chair and Executive Director of Global Health, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and Ruxandra Draghia-Akli, Global Public Health R&D, J&J, and INTREPID board member, welcomed all the participants and delivered opening remarks emphasizing the importance of working together to accelerate the antiviral pipeline against future pandemics. As the impact of COVID-19 continues to decline, James said, it was timely to bring the participants together and start driving the progress for better preparation ahead of the next pandemic. He noted that the seven founding member companies¹ of INTREPID are committed to playing their part. James also proposed the goals of the summit: to maintain the collaborations and good practices that developed during the SARS-CoV-2 pandemic among companies, academics, regulators, policymakers, philanthropies, and NGOs; to identify gaps in antiviral research and opportunities for INTREPID to add value; and to foster personal interactions between thought leaders in the field.

PANEL 1

Fireside Chat: Collaboration, Coordination, and Partnerships Across Sectors for Pandemic Preparedness

Moderator: Susan Dentzer, *President & CEO, America's Physician Groups*

- Victor J. Dzau, M.D., *President, U.S. National Academy of Medicine; Co-chair, 100 Days Mission Science & Technology Expert Group (100DM STEG); and Member, IPPS Steering Group (pre-recorded video)*
- Heulwen Philpot, *Head of the IPPS*
- Matthew Hepburn, M.D., *Senior Advisor to the Director, White House Office of Science and Technology Policy (OSTP) for Pandemic Preparedness*

OPENING REMARKS

Susan Dentzer, Program Moderator and President & CEO, of America's Physician Groups, joined James and Ruxandra in welcoming the participants to this urgent and extremely important Summit on antiviral preparedness. In her opening remarks, Susan underscored the importance of being well prepared to battle a pandemic by 100 days after the pathogen in question is first identified. She observed 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 global infection rate was estimated at 2 million, U.S. deaths at 31,000, and global deaths at 137,000. The reality of vaccines being approved in December 2020 and an antiviral being approved in May 2020 was still a record-breaking speed of development, but we should aim to be faster in the future with an even broader set of countermeasures, including antivirals.

Susan then led the first panel discussion on how best to partner across sectors to achieve the 100-day mark for pandemic preparedness. She introduced a video from **Dr. Victor Dzau**, Co-chair of STEG for

EXHIBIT A

— What is the 100 Days Mission?

As shown during the response to COVID-19, the faster we can develop safe, effective and affordable vaccines, therapeutics and diagnostics for an escalating infectious disease, the more lives we can save.

The goal of the 100 Days Mission is to prepare as much as possible so that within the first 100 days that a pandemic threat is identified, the following interventions can be made available, safe, effective, and affordable:

- Accurate and approved rapid point of care diagnostic tests
- An initial regimen of therapeutics
- Vaccines ready to be produced at scale for global deployment

In June 2021, G7 Leaders welcomed the "100 Days Mission" (100DM) in Carbis Bay, building on the collaborative scientific efforts which led to the development of Diagnostics, Therapeutics, and Vaccines (DTVs) for COVID-19.

Source: <https://ippssecretariat.org/>

Source: Victor Dzau's presentation

the 100DM, an initiative endorsed by the G7 and G20 leaders that aims to increase global preparedness so that affordable vaccines, diagnostics, and therapeutics can be available within 100 days of a pandemic threat being identified.

Victor 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 ten pathogens of pandemic potential; and to create a framework or roadmap for building the pipeline of therapeutics to tackle future pandemics. Achieving these objectives would detail the end-to-end development of therapeutics all the way through to manufacturing and access, for a smooth handoff of phase-2 ready therapeutics to go into phase 3 clinical trials. He raised awareness that a central convening organization for antivirals (akin to CEPI for vaccines or FIND for diagnostics) doesn't currently exist, and that therapeutics are vital in the fight against future pandemics, particularly when there are obstacles to vaccine development and uptake. He concluded with a call to action for volunteers across sectors to develop a therapeutics roadmap that would take the United States, and the world, closer to achieving the 100DM.

Heulwen Philpot, Head of the [IPPS](#), identified the need for a unified therapeutics R&D community to feed into and shape a sustainable and coordinated R&D antiviral landscape. She proposed creating a multi-sectoral subgroup of the IPPS STEG, which Victor heads, to develop a roadmap to build prototype libraries for therapeutics against the top ten pathogens of pandemic potential. WHO's prioritized viral families (currently under review) would be a helpful

starting point for alignment on prioritized pathogens. These prototype libraries would provide the best R&D building blocks for rapidly developing treatments in a future Disease X scenario, and in the inter-pandemic periods could save countless lives currently lost to outbreaks of diseases for which treatments are currently unavailable. For therapeutics, the IPPS has three main goals to deliver the 100DM mission for therapeutics: having 25 phase-2-ready therapeutic candidates by 2026; ensuring a sustainable and coordinated R&D ecosystem for therapeutics, and creating programmable therapeutic platforms that can be as flexible as mRNA is for vaccines.

Matthew Hepburn, M.D., Senior Advisor to the Director, White House OSTP for Pandemic Preparedness, started with the statement that the nation and the world need to “be prepared to be surprised.” Lessons from Operation Warp Speed must be carried into early preparation for the next pandemic, he said. Key imperatives for early planning include identifying incentives that will promote collaboration across sectors and geographies. There is an opportunity to better partner with low-resource countries to promote equitable access by optimizing existing country-level collaboration incentives and connecting people to research that is being done locally. Government support will be needed to catalyze product development for diseases the commercial market does not prioritize. Multiple solutions are needed, including small molecule drugs, monoclonal antibodies (mAbs), and combination therapies, particularly for the immunocompromised. Other critically important ingredients include having the collective political will to achieve key objectives including expedited

contracting, regulatory harmonization, flexible and innovative manufacturing, and last-mile solutions to get products to people worldwide. INTREPID or a similar organization can take accountability for achieving these objectives to both boost the R&D infrastructure and support the 100DM.

KEY TAKEAWAYS

- ▶ The speakers challenged participants at the conference to build a sustainable pipeline or prototype libraries of 25 phase-2 antivirals to meet the 100DM against key pathogens of pandemic concern.
- ▶ It is critically important to develop a roadmap to facilitate coordination of the end-to-end “relay” of biothreat prevention and countermeasure development. Achieving this goal would entail moving candidates as expeditiously as possible from discovery to target, to clinical development, to regulatory approval, to reliable manufacturing at scale, to ensuring supply reliability, and ultimately to achieving uptake by patients at the point of care.
- ▶ Another key goal is to have a sustainable and coordinated global R&D ecosystem for therapeutics and diagnostics, and programmable therapeutic platforms that can be as flexible as mRNA is for vaccines.
- ▶ Improved collaborations between high and low-resource countries are needed to promote equitable access by optimizing incentives to address the needs of low-resource countries. Target product profiles should be co-designed with affected communities, who should also be engaged with local research and development activities—specifically, in clinical trials.

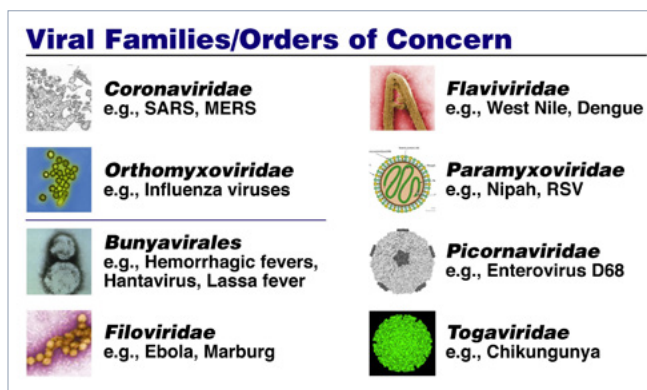
Non-industry Research Stakeholders, Priority Viral Families, Targets, and Research Programs

Moderator: John Young, *Global Head of Infectious Disease Research and Early Development, Roche Pharma*

- Carl W. Dieffenbach, Ph.D., *Director, Division of AIDS at NIAID / NIH*
- Philip Sanderson, Ph.D., *Scientific Program Manager, Division of Preclinical Innovation Early Translation Branch, National Center for Advancing Translational Sciences (NCATS)*
- Jimmy Rosen, MBA, *CEO, READDI, Inc.*
- David Wholley, *EVP, Strategy & Business Development, Foundation for the National Institutes of Health (FNIH)*

John Young, Global Head of Infectious Disease Research and Early Development at Roche Pharma, moderated a panel of NIH, FNIH, and funded academic-sector leaders to identify perspectives on unmet research needs, determine what is required from non-industry research partners, and discern what level of investment must be sustained to achieve the 100DM for therapeutics.

EXHIBIT B



Source: Carl Dieffenbach's presentation

Carl Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH, spoke about the *Pandemic Response to SARS-CoV-2 to Pandemic Preparedness Against RNA Viruses of*

Pandemic Potential and identified the near-term therapeutic needs to be at a minimum: 3CL protease inhibitors with nonoverlapping resistance patterns and fewer drug-to-drug interactions, an oral polymerase inhibitor, agents for pre-exposure prophylaxis for special populations, agents for post-exposure prophylaxis, pediatric dosing, and therapies to prevent or treat long COVID.

To move from response mode to an integrated plan for pandemic preparedness, NIAID is addressing key research gaps in top viral families; working to accelerate the development of vaccines, therapeutics, and diagnostics for prototype and priority pathogens; and coordinating closely with USG partners, key global stakeholders, and the industry.

NIH has prioritized eight viral families on which to focus efforts (see Exhibit B). To achieve this, NIH has developed the flagship Antiviral Program for Pandemics (APP), which aims to catalyze the development of new medicines to combat COVID-19 and prepare for future pandemic threats. APP

created, and provides large grants to, nine Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern, which were established as multidisciplinary centers bringing together a consortium of investigators and industry leaders focused on discovery and development of antivirals against coronaviruses and other viruses with pandemic potential. The original budget for APP was projected to be around 3.2 billion U.S. dollars over five years, of which one billion dollars was to be allocated to the [AViDD centers](#). So far, one billion dollars has been secured for APP and three years of the AViDD funding has been guaranteed. NIAID is also taking the lead on developing TPPs for priority viruses with pandemic potential, as a useful resource for the field.²

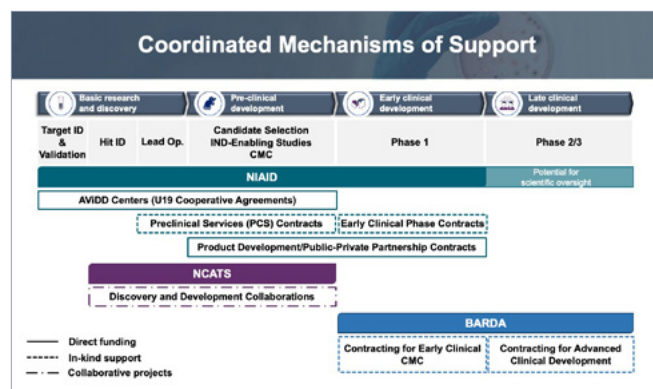
Philip Sanderson, Ph.D., represented APP within the NCATS' Division of Preclinical Innovation. While NIAID focuses on extramural research, NCATS' role in the antiviral pandemic preparedness ecosystem is to provide, in a coordinated fashion, in-kind support of discovery and preclinical development activities, including assay development through high-throughput screening, target validation, medicinal chemistry for lead optimization, BSL-3 high-containment, high-throughput screening labs, manufacturing, and toxicology through

to IND. NCATS' model is collaborative, as depicted in Exhibit C, which shows the coordinated mechanisms of support across NIAID, NCATS, and the Biomedical Advanced Research and Development Authority (BARDA).

In response to the earlier panel's calls for rapid manufacturing, Philip explained that small molecule chemistry is very different from vaccine or antibody manufacturing, a reality that makes the process of streamlining difficult.

Jimmy Rosen, MBA, MSPH, is CEO of READDI, Inc., a 501(c)(3) non-profit biotech company spun out from the University of North Carolina. The goal of READDI is to establish a robust drug-development pipeline of antivirals by accelerating new antiviral discovery and development, aggregating, and advancing existing assets, and expediting treatment access globally. READDI has committed to ensuring that on Day 1 of the next pandemic, the world will be provided with a) effective antiviral therapies that are "phase 2 ready," b) robust phase 2 and 3 randomized clinical trial designs, c) established manufacturing plans, and plans for equitable distribution and access. READDI has committed to sharing insights from its proprietary database that categorizes antivirals by stage of development, chemical, and class. READDI has completed a landscape survey of all antiviral-development programs in priority virus families across industry and academia on the basis of a 10-year review of proprietary data and publicly available information. The philosophy of this pandemic preparedness approach is that *being approximately right is better than being exactly wrong*.

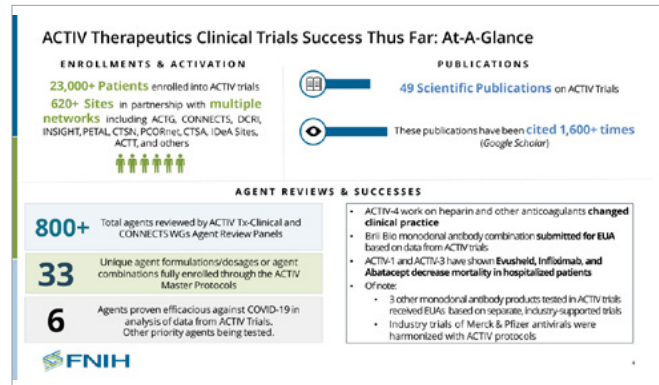
EXHIBIT C



Source: Philip Sanderson's presentation

David Wholley, EVP, Strategy and Business Development at the FNIH, reflected on the role of the ACTIV initiative^{3,4} in the COVID-19 pandemic and lessons learned to carry into preparations for the next pandemic. More than 100 scientists from NIH, the industry, academia, and private foundations came together in ACTIV. They formed four major working groups for vaccines, preclinical therapeutics, clinical therapeutics, and clinical trial capacity, working to select the most promising candidates and to create an infrastructure to provide accelerated robust clinical testing and master protocols. ACTIV is currently focused on completing ongoing clinical trials, characterizing emerging viral variants, and gaining a better understanding of long COVID. ACTIV worked very closely with Operation Warp Speed and already had relationships across the ecosystem, thus streamlining the ability to build rapidly and effectively. As seen in Exhibit D, ACTIV has been a driving force in developing a coordinated therapeutics research response to COVID-19 and serves as a useful template to help guide future pandemic preparedness efforts.

EXHIBIT D



Source: David Wholley's presentation

Lessons learned by ACTIV are that it is critical to achieve the following:

1. Pursue an active, transparent, coordinated system of global surveillance for emerging and ongoing threats. Said system must be capable of effectively sharing data with scientists across international borders.
2. Invest now to develop a robust pipeline of new, qualified, early-stage therapeutic candidates to meet future pandemic threats.
3. Have a centralized system for selecting and prioritizing promising investigational therapies (new and repurposed). Said system must integrate public and private scientific expertise.
4. Provide broad access to repositories of standardized sequence data, viruses, assays, and animal models. Such access can greatly accelerate preclinical research.
5. Integrate community care settings into our clinical trial ecosystem to improve equity and diversity of clinical trial populations.
6. Coordinate robust public-private partnerships to mount an effective pandemic response.



It's essential to have an effective and efficient centralized system for the communities to select and prioritize promising investigational therapies to work on. Said system must integrate public and private scientific expertise.

—**DAVID WHOLLEY**
EVP, Strategy and Business Development at the FNIH



KEY TAKEAWAYS

- ▶ The NIH / NIAID is playing a leading role in future pandemic preparedness, has also defined priority virus families, established multiple AViDD Centers, and has developed draft antiviral TPPs.
- ▶ Sustained investment in antiviral R&D over the coming years, combined with policy changes, is essential to ensure that the goals of the 100DM can be met.
- ▶ It is essential to advocate for government-sponsored investments in antiviral discovery.
- ▶ Research enterprises should determine which viral families to focus on based on the WHO priority list.
- ▶ A proprietary landscaping analysis of antiviral therapeutics has already been performed and this will be complemented by an effort to publicly release a landscape that will be led by the INTREPID Alliance.
- ▶ ACTIV provides a useful framework and playbook for how best to tackle future pandemic preparedness.
- ▶ Best scientific collaborative practices should be broadly adopted, such as those demonstrated by the ACTIV partnership—e.g., maintenance of a centralized inventory of preclinical and clinical resources. Broad access should be provided to repositories of standardized sequence data, viruses, assays, and animal models. Resources located within NIAID and NCATS can be used to support preclinical antiviral R&D.
- ▶ It is important to create a centralized system of promising investigational therapies and encourage investment in those therapies and diagnostics, ensuring that gaps are addressed and innovations from small companies are included.
- ▶ It is essential to collaborate to develop TPPs to guide research into antiviral agents for the treatment of possible pandemic pathogens, reflecting the needs of patients in low-resource countries.
- ▶ Public-private partnerships should be fostered to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines addressing the SARS-CoV-2 pandemic.
- ▶ The biomedical research and medical fields should align on a quality case definition of long COVID.
- ▶ It is essential to sustain U.S. leadership and diplomacy on pandemic preparedness. PAHPA and PEPFAR must be reauthorized. U.S. entities must coordinate with the European Commission's HERA department and other leading country and regional platforms, e.g., those of Japan and the United Kingdom, African nations, and the G20.

Optimizing Health for Patients: Innovation in Antivirals and Innovation in Access

Moderator: Phyllis Arthur, *Senior Vice President for Infectious Diseases and Emerging Science Policy, BIO*

- James Class, Ph.D., *Executive Director, Policy, Gilead Sciences*
- Greg Frank, Ph.D., *Director, Global Public Policy, Merck*
- Gareth Morgan, *SVP and Global Head of Portfolio Management and AMR Policy, Shionogi Inc.*

Essentials for Access Innovation:

- Charles Gore, *Executive Director of the Medicines Patent Pool (MPP)*
- Cathal Meere, *Manager, Global Sourcing Pharmaceuticals, The Global Fund (virtual participant)*

Phyllis Arthur, Senior Vice President for Infectious Diseases and Emerging Science Policy at BIO, moderated a discussion on optimizing the progress of innovation in antivirals and the innovation needed to accelerate worldwide access to antiviral therapeutics. The panel highlighted what went well during the pandemic and what lessons can be brought forward to achieve the key goals: stemming or stopping an outbreak from a known or unknown pathogen by developing and getting products rapidly and equitably to patients. This agenda includes incorporating access strategies into antiviral pandemic preparedness planning as early as possible; ensuring regulatory infrastructure and the relationships needed to promote access at the country level; shaping markets to expedite licensing for generics; and linking R&D efforts to patient advocacy.

James Class, Ph.D., Executive Director of Policy at Gilead Sciences, discussed his

experience with Gilead's commitment to emerging viruses research and lessons learned from remdesivir development and global access planning. Starting with the precursor to remdesivir in 2009, all the way through clinical testing of remdesivir against COVID-19 in 2020, Gilead was evaluating the precursor compound and eventually the drug for activity against emerging viruses such as RSV, MERS-CoV, SARs-CoV, Nipah, and Ebola. After confirming remdesivir's antiviral activity against coronaviruses, Gilead also collaborated with governmental, academic, national, and international institutions. James described this timeline of drug development as a marathon that enabled Gilead to pivot and nearly achieve the 100-day goal of putting remdesivir into clinical development by Feb 2020. The Government Accountability Office (GAO) even reported on the development of remdesivir, calling out the importance of Gilead's commitment to maintaining substantial resources for scientists.

Early in 2020, James said, another company commitment was achieved: investing at risk in manufacturing and scale-up. The remdesivir manufacturing timeline was reduced from 12 to six months despite scarcely available, novel raw materials and complex manufacturing processes involving an internationally diversified coordination network. James spoke of the importance of intellectual property as having created a system that enables investment in science over a long period of time, as in the case of remdesivir. Globally, remdesivir was made available to more than thirteen million people around the world; more than 60 percent of those people, or eight million patients, were in lower-income and lower-middle-income countries. Voluntary royalty-free licensing was established early to facilitate access. These accomplishments involved commitment (resources from the top), collaboration (appropriate strategic public-private incentives), and speed (a framework to streamline and accelerate processes).

Greg Frank, Ph.D., Director of Global Public Policy at Merck, discussed how Merck & Co. (known as MSD outside of the U.S. and Canada), implemented a three-pronged strategy to accelerate access to the company's investigational oral antiviral, molnupiravir, discovered by Emory University and developed in partnership with Ridgeback Biotherapeutics, LP.

The first prong of the strategy was to (1) make Merck-produced molnupiravir available as quickly as possible through at-risk manufacturing, ensuring 10 million courses available at the time of the first Emergency Use Authorization (EUA) in December 2021; (2) establish tiered pricing such that the countries that had the ability to finance a health response paid the most; and (3) provide best access price

to UNICEF, USAID and to low- and lower-middle income countries.

In the strategy's second prong, Merck engaged generic manufacturers early to facilitate access in lower resource countries through bilateral voluntary licensing to supply generic molnupiravir to more than 100 LMICs in April 2021, well in advance of regulatory authorization. Merck supported its voluntary licensees' efforts, such as regulatory dossier development and prequalification submissions. Merck also entered into an MPP agreement to broaden the molnupiravir manufacturing footprint to 20 additional sublicensees, which brought molnupiravir manufacturing capability to every major continent in the world.

In the strategy's third prong, to reserve supply to provide timely availability to LMICs and bridge availability of WHO pre-qualified generics, Merck signed an agreement with UNICEF for up to 3 million courses (30 percent of available supply) at best access price across more than 100 LMICs. Merck also donated 100,000 courses to Direct Relief in February 2022 and committed to make available up to 2 million courses to USAID in March 2022. With this rapid-access plan, Merck's licensed generic manufacturers supplied more than 5 million courses by the end of 2022; as of March,



more than 4 million patients worldwide have received Merck-produced molnupiravir. Despite ample supply and donor funding to support procurement, uptake of molnupiravir was slow. Many countries did not prioritize antivirals, leverage funding for procurement, or have adequate infrastructure to support test-and-treat programs to inform patient eligibility to receive treatment. For future pandemics, it will be necessary to work with government and global agencies to plan and implement rapid deployment of antivirals that address these last mile-barriers.

Gareth Morgan, SVP and Global Head of Portfolio Management and AMR Policy at Shionogi, introduced Shionogi as a mid-sized global company with a long history in infectious disease research. Currently, Shionogi is developing an investigational oral antiviral for COVID-19 called ensitrelvir, an antiviral 3CL protease inhibitor. Although ensitrelvir remains an investigational drug outside of Japan, it was granted emergency regulatory approval in Japan for treatment of SARS-CoV-2 on November 22, 2022.

Gareth discussed some lessons learned during the process of developing this drug related to the rapidly changing viral dynamics during a pandemic. He reported on a recently completed phase 2/3 study in which 90 percent of the patients had been vaccinated and during which the dominant SARS-CoV-2 variant changed from Delta to Omicron. Gareth reported that Shionogi has partnered successfully with NIH/NIAID to further evaluate ensitrelvir for both outpatient and inpatient use through two currently enrolling global studies. Experience in antibiotic R&D and AMR has also generated lessons learned. R&D talent management and retention have been instrumental in the successful development

of a key compound that targets some of the most difficult-to-treat Gram-negative bacterial pathogens.

Turning to innovation in access, Gareth described Shionogi's commitment to protect people worldwide from the threat of infectious disease. Shionogi's access strategy for LMICs has been to execute voluntary licenses for both their antibiotic and COVID-19 antiviral products. In June 2022, Shionogi, the Global Antibiotic Research & Development Partnership (GARDP), and the Clinton Health Access Initiative (CHAI) announced landmark license and collaboration agreements to expand access to 135 countries for an antibiotic developed to treat certain serious Gram-negative bacterial infections. In October 2022, Shionogi and the MPP signed a voluntary license agreement to allow access to Shionogi's investigational oral antiviral for COVID-19 in 117 LMICs.

Going forward, Shionogi's experience suggests the need for rapid partnering with NGOs for LMIC access; improved regulatory harmonization across all countries, especially in the case of pandemics; developing turnkey options for rapid manufacturing scale-up; creating improved and efficient supply chains; country healthcare infrastructures that support rapid delivery of new medicines to patients; and liability protection for pandemic response products that may be introduced with limited data under EUA schemes. In addition, antiviral innovation will benefit from R&D talent management, better monitoring and sharing of new pathogen data, harmonizing regulatory pathways for rapid approval, planning for resistance, and determining appropriate incentives to keep R&D financially attractive for the biotech and pharma industries.

ESSENTIALS FOR ACCESS INNOVATION:

Charles Gore, Executive Director of the MPP, delivered a presentation on how the licensing process for LMICs was expedited during the COVID-19 pandemic but still took too long. He described MPP as a public health organization established in 2010 to accelerate access to new health technologies and facilitate the development of new formulations needed in LMICs. MPP operates through voluntary licenses to aid in the early market entry of generics in LMICs. Initially focused on HIV medicines, its mandate was expanded to include hepatitis C and tuberculosis in 2016, and other patented essential medicines in 2018.

In response to the COVID-19 pandemic, MPP has been working to facilitate access to new treatments and support the development of vaccine manufacturing capacity in LMICs. To date, it has signed agreements with 18 patent holders for 14 HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a cancer treatment, four long-acting technologies, three oral antiviral treatments for COVID-19 and 12 COVID-19 technologies.



MPP believes that early licensing agreements in emergency conditions could enable the development of generic versions within 100 days from approval of innovators' products.

—CHARLES GORE
Executive Director of the MPP

Although the licensing of antivirals prior to regulatory approval of the originators' products has reduced the time to regulatory filing by generic manufacturers, and technology transfer packages created opportunities for accelerated product development for manufacturers that needed it, it took one year from the time of a signed license for generics to become available, which is too long during a pandemic. To make expedited access a reality, Charles implored the audience to put in place the maximum possible arrangements now, such as a pre-selected network of manufacturers, depending on drug type; license templates to shorten negotiations; and templates or at least broad terms for market shaping (volume guarantees, etc.). These discussions have to begin among originators, generics, market-shaping organizations, and procurement agencies now.

EXHIBIT E

Lessons Learned: Licensing

- Licensing of antivirals prior to regulatory approval of originator products helped to reduce time to regulatory filing by generic manufacturers
- The availability of technology transfer packages created an opportunity for accelerated product development for manufacturers that needed it
- Expediting access to reference listed drug (RLD) as soon as license is signed was important to ensure faster development of generics
- Implementation of criteria for selection of licensees that enabled recruitment of licensees from a broader range of jurisdictions expanded manufacturing base to improve supply security
- Demand uncertainties due to the unpredictable nature of the pandemic risk discouraging investment in development/production by some manufacturers
- BUT IT ALL TOOK TOO LONG
- MPP believes that under emergency conditions, IP and technology transfer could enable development of generic versions within 100 days from approval of innovator products (see next slide)

medicines without borders

MEDICINE WITHOUT BORDERS

Source: Charles Gore's presentation

Cathal Meere, Manager of Global Sourcing Pharmaceuticals at the Global Fund, discussed the critical importance of taking a step back and learning from the current pandemic, and continuing the conversations that were begun among stakeholders so that the world is prepared for the future. The Global Fund was contacted early on by antiviral manufacturers and did see a

commitment and alignment on principles of supply in the early stages to make molecules available as soon as possible to the LMICs and to license manufacturing. Cathal commended pharmaceutical companies and generic companies on their willingness to manufacture at risk and in anticipation of higher uptake.

Cathal reported, as did others at the summit, that “we stumbled a bit” in the last mile from the originators to the procurement agencies. To improve access, a good understanding is needed of the working models and policies for procurement when collaborators are working together for the first time, and of manufacturers’ contracting concerns, such as liability or diversion. He closed by suggesting that when looking for external partners for expanded generic manufacturing, organizations in Africa and in LMICs be considered that are capable of producing material closer to where the demand is.

KEY TAKEAWAYS

- ▶ It is essential to improve operationalization of early access in low-resource countries through alignment and coordination of procurement agencies, companies, and local governments. Improve readiness of procurement and prequalification agencies from lessons learned during the SARS-CoV-2 pandemic.
- ▶ Companies should plan as early as possible to adopt innovative access strategies for antivirals for low-resource countries, with special attention to the last mile.
- ▶ Countries should increase their work on antiviral prioritization and build their healthcare infrastructures to support rapid delivery, including test-and-treat programs. It will be important to obtain country feedback on what it will take to facilitate rapid uptake of antivirals and to strengthen health systems to diagnose, treat, and deliver.
- ▶ Equitable access requires community buy-in in LMICs. Thought leaders can work with community healthcare workers and leaders to prime populations for future antiviral use.
- ▶ Effective global pandemic response planning should ensure that there is manufacturing capacity that is globally distributed, close to populations at risk, and sustainable to speed products to patients, including early licensing arrangements. Once created, it will be essential to sustain this infrastructure between pandemics.
- ▶ Distribution chains must be created all the way down to the last mile to ensure access, involving communities and strengthening health systems.
- ▶ Rapid tech transfer before outbreaks is vital to pandemic preparedness.
- ▶ License templates to shorten negotiations are essential to accelerating the drug to market.
- ▶ The multiple years of early-to-late-stage scientific investment that resulted in the rapid development of antivirals during COVID-19 should be valorized and supported by strong intellectual property protections.

Luncheon Speaker

Susan Dentzer introduced Keynote Luncheon speaker Nicole Lurie, M.D., MSPH, Executive Director for Preparedness and Response, CEPI, as an expert with a long history of pandemic and disaster preparedness experience—including having served as the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services (HHS) from 2009 to 2016. Susan noted that CEPI, where Dr. Lurie serves now, originated the 100DM for vaccines and has much to share about making a comparable effort happen for antivirals.

Nicole opened her session by noting that as the world continues to learn lessons from COVID-19, there have been cholera outbreaks in nearly 35 countries in recent months and a shortage of vaccines. She pointed to outbreaks of Ebola in Sudan and to a new outbreak of Marburg in Tanzania. CEPI will take responsibility for helping with the development of vaccines in these crises and is working with many of the Summit participants to do so. She reported that even with the aid of large and small developers, the world is still not where it needs to be with respect to vaccines and antivirals.

Regarding the 100DM, she observed that the time frame allows for authorization of a vaccine but does not encompass the rollout of the billions of doses needed for the world. Echoing Charles Gore, she noted that the second 100 days are the time frame for ensuring equitable access, requiring clinical trials, practicing pharmacovigilance, scaling manufacturing, and rolling out and delivering products. Because scarcity is the enemy of equitable access, scaling is very important. Assuring adequate and equitable supplies of vaccines and antivirals thus requires pre-positioning capabilities in advance—working on priority viral families and developing the prototypes to obtain as much of a head start as possible while also working to advance regulatory innovation.



Preparedness is ultimately about a lot more than surveillance and countermeasure development. It is also about health system strengthening . . . and having the right public health system in place to help ensure equitable access in the second 100 days, once those countermeasures are developed and manufactured.

—NICOLE LURIE, M.D.

MSPH, Executive Director for Preparedness and Response, CEPI

Nicole recommended that as the field embraces the 100DM as well as the milestones required during the second 100 days, participants should assess their organizations' roles in these processes, and collaborate to ensure successful handoffs of responsibilities to others. TPPs for vaccines and antivirals should be developed in collaboration with affected countries with usability and manufacturability standards also in mind. She suggested exploiting scientific synergy among vaccine, therapeutic, antibody, and diagnostic discovery and development as target viral families are

prioritized. Country readiness and health system strengthening are also essential: for example, in the United States, a strengthened public health infrastructure would have improved the nation's response to COVID-19.

Nicole cited these examples of innovative CEPI efforts to foster collaboration among organizations:

- A joint coordination group involving CEPI's end-to-end partners to ensure smooth handoffs,
- A regulatory advisory group of large global regulators,
- A preferred manufacturing network involving every continent with manufacturers contractually bound to work on technology transfer and manufacturing in a crisis,
- Identification of financial resources from donors and others to avert "passing the tin cup" in the middle of a pandemic, and

- A research and development project to develop monoclonal antibodies, as these are therapeutic vaccine adjacent technologies.

KEY TAKEAWAYS

- ▶ CEPI works to ensure that there is end-to-end "connective tissue" for vaccines. INTREPID and other groups can work to ensure the end-to-end "connective tissue" for therapeutics.
- ▶ Serving as the "connective tissue" means maintaining smooth handoffs between partners—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.



Advancing Antivirals Through Public Sector and Philanthropic Leadership

Moderator: Tomas Cihlar, Ph.D., *Senior Vice President of Virology, Gilead Sciences*

- Patrizia Cavazzoni, M.D., *Director, Center for Drug Evaluation and Research (CDER) FDA*
- Marco Cavaleri, Pharm. D., *Head of Office, Health Threats and Vaccine Strategy, EMA (participating virtually)*
- Ken Duncan, Ph.D., *Deputy Director of Discovery & Translational Sciences, Global Health Program of the Bill & Melinda Gates Foundation*
- Wolfgang Philipp, Ph.D., *Acting Deputy Head of HERA, European Commission (participating virtually)*

Tomas Cihlar, Ph.D., SVP of Virology at Gilead Sciences, moderated a panel of public-sector and philanthropic leadership to gain a better understanding of the role that philanthropy will play in averting the next pandemic, as well as the power created when public-sector, private-sector, and philanthropic organizations work together. He remarked on the importance of staying connected and strengthening networks even as the COVID-19 pandemic is receding, as these collaborative networks will be the foundation for building strong preparation for the next pandemic.

Patrizia Cavazzoni, M.D., Director, CDER, represented the FDA to discuss Lessons from *COVID-19: A View to the Future with an Eye on the Past*. She reported on how the FDA had to quickly adapt to work with platform trials,⁵ such as RECOVERY,⁶ to advance them and deal with their complexities, advantages, and disadvantages. She stated that properly designed trials can allow for efficient evaluation of drugs for outpatient or inpatient use and that very large,

simple trials can detect relatively modest effects with high statistical significance. Platform trials may assess the benefits of active therapeutics used in combination or compare the effectiveness of alternative therapeutics. She cautioned several disadvantages and stated that efficiency is key. An established clinical trial infrastructure is needed; a one-size-fits-all approach can be challenging. Safety data collection needs may differ by molecule, and appropriate endpoints may differ by stage of disease. Overly complicated trial designs can lead to feasibility and interpretability issues.

If the next pandemic also involves an acute respiratory viral illness, it is likely that vaccines will play a critical role, and mAbs may also play an important early role because they may be developed for prevention or treatment. They may be particularly useful for patients who are not expected to respond to vaccination. However, mAbs that target relatively non-conserved regions of a virus will probably have limited durability during a pandemic,

if we assume a virus capable of rapid evolution. The development of small-molecule drugs (which may have greater resilience to changes in the virus) and mAbs targeting more conserved regions of the virus should begin early, in parallel with vaccine development.

Throughout the pandemic, CDER closely coordinated with its USG partners, including the NIH, CDC, and BARDA / Administration for Strategic Preparedness and Response (ASPR). CDER also worked closely with global regulatory bodies, including the EMA, to help address challenging scientific and regulatory issues involving drug development. Under the FDA's confidentiality agreements, CDER and EMA met frequently to discuss specific COVID-19 development programs with the goal of harmonizing advice, but the FDA and EMA have different statutory and regulatory paradigms.

With respect to conducting a foreign clinical study under an IND, under 21 CFR 312.120, the FDA will accept a well-designed, well-conducted, non-IND foreign study as support for an IND or application for marketing approval if the study was conducted in accordance with good clinical practice (GCP) and if the FDA is able to validate the data from the study through an onsite inspection, as necessary. The FDA strongly encourages sponsors to seek advice from the Agency under a pre-IND meeting request or other advice mechanism during the planning stages of a clinical trial. The FDA's Coronavirus Treatment Acceleration Program (CTAP), which the agency adopted to facilitate the development of drugs and biologics (other than vaccines) for COVID-19 therapeutics, accelerated the timeline for advice from the agency during the COVID-19 pandemic, to the extent feasible.

The issues that arose with trials conducted outside the United States during the COVID-19 pandemic have generally been related to Agency concerns with elements of trial design, such as the endpoint definition or adequacy of safety data collection. Unfortunately, the Agency is often approached for regulatory advice about trials conducted outside the U.S. after a trial is completed and the results are known.

Marco Cavaleri, Pharm. D., Head of Office, Health Threats and Vaccine Strategy, EMA, joined virtually to discuss successes during COVID-19 and ambitions for the future of EMA's Emergency Task Force (ETF). ETF was established as an advisory and support body on medicines for public health emergencies and preparedness. ETF provides a platform for scientific advice on the development of new antiviral agents before and during emergencies. ETF is ready to engage with academia, regulators, and other clinical trial networks globally. This cooperation is fundamental for rapid development of promising antivirals.

Marco reminded the audience that medicinal products for treatment of viral diseases must be approved by EMA in the EU and that antivirals need to be developed and approved for the prevention and/or treatment of specific viral diseases. Approval of broad-spectrum antivirals for specific viral disease use enhances potential rapid use during outbreaks and epidemics due to other viruses, depending on the availability of commercial product manufacturing, characterization of safety, and dosage. ETF provides scientific advice on the development of new antiviral agents before and during emergencies and is ready to engage with academia and clinical trial networks on platform clinical trials. International cooperation among

regulators (e.g., the International Coalition of Medicines Regulatory Authorities (ICMRA), WHO, and the FDA, along with stakeholders is crucial for the rapid development of promising antivirals.

Ken Duncan, Ph.D., Deputy Director of Discovery and Translational Sciences, represented the Bill & Melinda Gates Foundation (BMGF) Global Health Program. Partnering with Novo Nordisk Foundation and Open Philanthropy, the Gates Foundation established the Pandemic Antiviral Discovery (PAD) initiative. Its mission is to catalyze discovery and early development of antiviral medicines for the next pandemic. To better prepare, PAD is investing in closing key knowledge gaps throughout the global pipeline of small-molecule antiviral therapeutics and providing support via discovery and early development. A top priority of PAD is to ensure equitable access in LMICs by supporting the generation of new products meeting LMIC-appropriate TPPs. PAD partners provide grants to support research spanning target discovery, assay development, lead generation and optimization, and non-clinical and clinical development through phase 1. In return, partners are required to commit to making the products and information accessible globally.

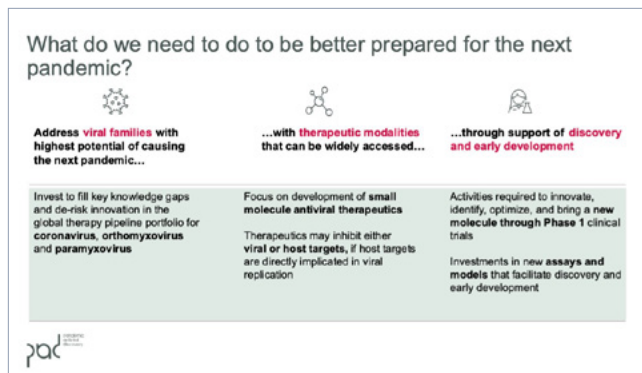


A top priority of PAD is to ensure equitable access in LMICs by supporting generation of new products meeting LMIC-appropriate Target Product Profiles.

—KEN DUNCAN, PH.D.

Deputy Director of Discovery and Translational Sciences, BMGF

EXHIBIT F



Source: Ken Duncan's presentation

Wolfgang Philipp, Ph.D., Acting Deputy Head of the European Commission's HERA, reported that HERA was created in September 2021 with a budget of six billion euros. He spoke about the international collaboration needed to transition seamlessly from preparedness mode to crisis mode for broad-spectrum antivirals. The main components of HERA's strategy are rapid implementation of clinical trials for crisis response and clinical data collection, flexible funding tools for such clinical trials, and coordinated global cooperation. Wolfgang remarked that we need strong clinical trial networks that do not need to be newly activated amid a pandemic, that work in specialized ways, and that have prepared capacities in case of need.

HERA has reserve production capacities for pandemic vaccines—EU FAB—and has invested 160 million euros a year into creating warm manufacturing facilities to ensure access to a large number of vaccines as early on as possible. HERA wants to ensure that supply chains are reliable and effective for critical medical countermeasures. The organization also works to identify threats and sensitive areas in supply chains.

KEY TAKEAWAYS

- ▶ International cooperation among regulators such as International Coalition of Medicines Regulatory Authorities (ICMRA), WHO, EMA, the FDA, and stakeholders is crucial for the rapid development of antivirals.
- ▶ There should be global alignment across regulatory agencies on protocols, design of clinical trials, and criteria for authorization of medicines in the context of an emergency. Regulatory processes should be streamlined and harmonized to the extent possible, considering national and regional laws. Regulators should be prepared to speed approvals and get authorized medicines to populations faster.
- ▶ Regulators and product developers should have earlier interactions so that regulators can provide guidance under a pre-IND meeting request or other advice mechanisms. The FDA strongly encourages sponsors to seek advice from the agency under a pre-IND meeting request or other advice mechanism during the planning stages of a clinical trial.
- ▶ Academic researchers, governments and international agencies, public, the private sector, and philanthropic organizations should all work closely on rapid development of promising fit-for-purpose antivirals meeting TPPs appropriate for LMICs. They should catalyze product development in areas that the commercial market may ignore.
- ▶ Platform trials have advantages as well as challenges. They can quickly assess the benefits of active therapeutics used in combination or compare the effectiveness of alternative therapeutics, but overly complicated designs can lead to feasibility and interpretability issues. Platform trials also need to reconcile local regulatory guidance, a reality that could be challenging in the case of larger multinational trials.
- ▶ There should be active, effective clinical trial networks in place globally that are pre-positioned for the next pandemic.
- ▶ All sectors should develop systems for organizational learning and talent/expert pool building, management, and retention of personnel and expertise to enable productive and expert-level interaction and partnerships in pandemic preparedness.
- ▶ Scientific and manufacturing capabilities should be expanded and maintained for the post-development period.
- ▶ There should be prepositioned networks 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.

Policy Landscape and Advocacy for Antiviral Preparedness

Moderator: Lydia Ogden, M.P.P., Ph.D., *Global Public Health R&D Lead, Johnson & Johnson*

- Christopher Houchens, Ph.D., *Director, Division of Chemical, Biological, Radiological & Nuclear Countermeasures, BARDA, ASPR, DHHS*
- Amanda Jezek, *Senior Vice President, Public Policy and Government Relations, Infectious Diseases Society of America (IDSA)*
- Jeremy Knox, *Head of Policy, Infectious Disease, Wellcome Trust*
- J. Stephen Morrison, Ph.D., *Senior Vice President, Center for Strategic and International Studies (CSIS)*

Lydia Ogden, M.P.P., Ph.D., Global Public Health R&D Policy and External Engagement lead at Johnson & Johnson, led a panel on the biggest challenges for policy and advocacy in the current U.S. political environment, including pandemic “amnesia,” the politicization of pandemic preparedness, risks to intellectual property (IP), and constrained access to pathogens.

Amanda Jezek, SVP for Public Policy and Government Relations, Infectious Diseases Society of America, representing the views of 12,000 infectious disease physicians, laid out what frontline clinicians need in their toolboxes to avert the next pandemic: vaccines, antivirals, diagnostics, and antibiotics. To optimize the use of antivirals, it will be necessary to focus on the end-user experience for patients and their clinicians. Areas for improving this experience, whether for the clinician or the patient, include ease of use and administration, equitable distribution to under-resourced communities, and empowering clinicians with the data packages used for emergency-use authorization and robust guidelines.

Despite the devastating politicization of science, preparedness, and public health, there is a strong desire to find ways forward on both sides of the aisle. The big opportunity this year is the reauthorization of PAHPA, which is an enormous chance to strengthen pandemic R&D. On the appropriations side, Amanda reported that the nation has the opportunity to provide more resources to both basic science at NIH, more of the work BARDA does, and to public health.

Jeremy Knox, Head of Infectious Disease Policy at Wellcome Trust, reflected on how vaccines—while very successful when provided in great numbers—were not the single solution for COVID-19. Antivirals will always be essential in pandemics, so their development must be accelerated. Successful pandemic preparedness involves multiple steps, including mounting clinical trials that quickly generate evidence; having powerful collaborations between companies and funders for the same purposes; and building on the experience with antimicrobial resistance (AMR) to incentivize R&D and encourage risk-taking. Amid a



crowded political agenda, there must also be careful thought about integrating pandemic preparedness planning within the wider global health environment.

Christopher Houchens, Ph.D., Director at BARDA, ASPR, and the HHS, observed that an essential component of pandemic preparedness is knowing whom to call and with whom to partner. Knowing which organizations to partner with before a pandemic happens allows researchers to get to work on day 1. Strengthening these partnerships elevates investments in basic science, platform capabilities, and secured availability of clinical material for rapid discovery. Investing in the basic science and gaining a clear understanding of prototype viruses allows us to respond quickly and nimbly to variants and to new species within their families.

J. Stephen Morrison, Ph.D., SVP, CSIS, discussed challenges to therapeutic adoption in low-resource countries as well as in the United States. CSIS formed a bipartisan alliance on global health security with Dr. Julie Gerberding and Senator Richard Burr as co-chairs. As has been noted, therapies were becoming increasingly important during the pandemic but remained highly problematic for LMICs to obtain and use. The barriers due to regulatory, testing, capacity, and budgetary constraints meant that the demand side simply did not materialize in the way people predicted.

In the U.S., misinformation is a deterrent to progress toward antiviral pandemic preparedness. A compounding factor is the great shortage of healthcare personnel, who are pivotal to combating misinformation.

There is a need for a global coordination mechanism and communication strategy to rebuild trust and confidence in the sciences that have been decayed by misinformation. As the nation moves beyond COVID, U.S. leadership and diplomacy must sustain investment in pandemic preparedness and vigilance in combating misinformation.

KEY TAKEAWAYS

- ▶ The pandemic preparedness agenda must be integrated within the wider global health environment and strengthening health systems in particular. Quality primary care is a part of pandemic preparedness.
- ▶ Strategies should be devised and adopted to address the politicization of science, public health, and preparedness. The effects of disinformation and misinformation must be overcome with robust and clear science-based communication.
- ▶ Bipartisan opportunities in the U.S. exist in 2023 to strengthen R&D through the reauthorization of PAHPA and through appropriations for basic, clinical, and translational research at NIH and BARDA.
- ▶ Critical investment in basic science is needed so that there is a clear understanding of prototype viruses, which will allow a quick and nimble response to variants of those or new species within their families.
- ▶ Public health systems and a network of collaborators coordinating public health efforts should be strengthened considerably to be ready for Day 1 of the next pandemic and supported with sustained investment.
- ▶ Shortages in the infectious disease clinical workforce both in high and low-resource countries should be addressed.
- ▶ The environment for antiviral preparedness should be shaped through collective advocacy that reframes pandemic preparedness and response in a national and global security context. Investment must be sustained over time in medical countermeasures for known and as-yet-unknown viral threats. Governments should provide incentives for the discovery, development, and manufacturing of antivirals with a limited commercial interest, and should be clear about proposed solutions and the funding required.
- ▶ It will be necessary to invest in platform capabilities that allow for the rapid discovery, development, and delivery of effective antivirals against emerging events.
- ▶ Advocacy should be encouraged from patient advocates, clinicians, and researchers on antivirals to demonstrate to policymakers that there is a public mandate for change.

Closing Plenary Session: Wrap-Up and Reflections on the Day

- Julie Gerberding, M.D., M.P.H., *President and CEO, FNIH*
- Susan Dentzer, *President & CEO, America's Physician Groups*

A FINAL CALL TO ACTION

Underscoring the theme of expecting the unexpected and the coordinated chain of events needed in preparedness, Susan asked Julie how best to prioritize the work that needs to be done.

Julie Gerberding, M.D., MPH, President and CEO, FNIH, responded with a final call to action for biopharmaceutical leadership: biosecurity is national security. Leaders must ensure 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.

She highlighted that the world has never faced greater biosecurity threats than now, due to factors such as the incursion of humans into animal ecosystems and the threat of spillover, urbanization and crowding, climate change and its impact on pathogens and their reservoirs, war, social disruption, and increasing global travel and migration. She acknowledged that the recent pandemic emergency motivated multiple sectors to “step up to the plate” and invent new ways to conduct unprecedented emergency research

and development—but warned that the new emergency science infrastructure must be kept “warm” to enable an agile response to future threats. She challenged the group to move upstream: to build better predictive models of where new pathogens are most likely to emerge, and to improve “one health” surveillance that includes humans, animals, and the environment to improve the odds that threats can be contained at their source.

Julie emphasized the importance of engaging with partners such as the Africa CDC to expand global collaboration for antiviral development and manufacturing in a manner similar to that used by CEPI. She concluded with a framework for a comprehensive access strategy: approvals accelerated by regulatory harmonization, allocation of available supply in a predetermined equitable manner, availability of countermeasures and diagnostics at the local level, and ultimately, acceptability and trust among the people who could benefit. She advised INTREPID to build a broader constituency and make a stronger case for leaders to avoid the “crisis to complacency” trap and sustain efforts to fully prepare for the next inevitable biosecurity threats.

KEY TAKEAWAYS

- › Biosecurity is national security.
- › The emergency science infrastructure built under COVID-19 must be maintained or “kept warm.”
- › It is critical to build better predictive models of where new pathogens are most likely to emerge and improve “One Health” surveillance. In addition, it is important to invest in basic science to develop medical countermeasures against prototype pathogens; to invest in optimized medicinal chemistry to reduce manufacturing barriers; and to advance the development of small molecules and monoclonal antibodies that target more conserved regions of the virus, beginning early in parallel with vaccine development.
- › All parties should conceive of and plan for access as the four A’s—Approval; Availability (both within a given country, and where the supply is most needed at the point of care;) Allocation of the prioritization of ample supply; and Acceptance.
- › INTREPID should build a broader constituency of members.

¹ AbbVie, Amgen, Gilead Sciences, Johnson & Johnson, Roche, Novartis, Takeda Pharmaceuticals

² On June 1, 2023, the NIAID posted draft TPPs for “potential direct-acting antiviral therapeutics candidates targeting several key viruses of pandemic potential potential.” <https://www.niaid.nih.gov/research/target-product-profiles-antivirals>

³ Buchman, T. G., Draghia-Akli, R., Adam, S. J., Aggarwal, N. R., Fessel, J. P., Higgs, E. S., Menetski, J. P., Read, S. W., Hughes, E. A., & Accelerating Coronavirus Disease 2019 Therapeutic Interventions and Vaccines (ACTIV) Therapeutics Clinical Working Group (2021). Accelerating Coronavirus Disease 2019 Therapeutic Interventions and Vaccines—Selecting Compounds for Clinical Evaluation in Coronavirus Disease 2019 Clinical Trials. *Critical care medicine*, 49(11), 1963–1973. <https://doi.org/10.1097/CCM.0000000000005295>

⁴ LaVange, L., Adam, S. J., Currier, J. S., Higgs, E. S., Reineck, L. A., Hughes, E. A., Read, S. W., & ACTIV Therapeutics-Clinical Working Group (2021). Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV): Designing Master Protocols for Evaluation of Candidate COVID-19 Therapeutics. *Annals of internal medicine*, 174(9), 1293–1300. <https://doi.org/10.7326/M21-1269>

⁵ “In a platform trial, patients with a single disease are randomly assigned to a group of different therapies on the basis of a decision algorithm to determine whether any therapy has benefit. The principle underpinning such trials allows for the execution of efficient, less expensive designs by enrolling populations quickly and collecting minimal data to answer more than one question.” <https://www.nejm.org/doi/full/10.1056/NEJMe2025674>

⁶ Investigators designed the RECOVERY trial involving hospitalized patients with coronavirus disease 2019 (COVID-19) in the United Kingdom to assess the efficacy of various treatments by using a single end point: mortality within 28 days after randomization. <https://www.recoverytrial.net/>

ANTIVIRAL SUMMIT PARTICIPATING ORGANIZATIONS

AbbVie Inc.	Foundation for the National Institutes of Health	National Institutes of Health (NIH)
Accenture	Frederick National Lab/ Integrated Research Facility at Fort Detrick	National Institute of Allergy and Infectious Disease (NIAID), NIH
Administration for Strategic Preparedness and Response (ASPR), Health and Human Services (HHS)	Genentech	Novartis
Airfinity Ltd	Gilead Sciences, Inc.	Novo Nordisk Fonden
Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern	GSK	Pandemic Antiviral Discovery (PAD) Initiative
A-VAN-TI, Inc.	Health Emergency Preparedness and Response Authority (HERA), EU Commission	Pharmaceutical Research and Manufacturers of America (PhRMA)
Amgen	IGM Biosciences, Inc	PostEra
America's Physician Groups	Infectious Diseases Society of America (IDSA)	READDI, Inc.
Baruch S. Blumberg Institute	Invivyd	Roche
Biomedical Advanced Research and Development Authority (BARDA), Health and Human Services (HHS)	International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)	Shionogi
Bill & Melinda Gates Foundation	INTREPID Alliance, Inc	Scripps Research
Biotechnology Innovation Organization (BIO)	International Pandemic Preparedness Secretariat (IPPS)	Softbank
Bristol Myers Squibb	Food & Drug Administration (FDA)	Stanford University
Center for Strategic & International Studies (CSIS)	Foundation for the National Institutes of Health (FNIH)	Takeda Pharmaceuticals
Center for Discovery and Innovation	Georgia State University	The Global Fund
Coalition for Epidemic Preparedness Innovation (CEPI)	Janssen R&D BE, US	The HEVER Group
Covington & Burling LLP	JNC Consulting	The Rockefeller Foundation
Eli Lilly and Company	Johnson & Johnson	The White House Office of Science and Technology (OSTP)
Emory University	Medicines Patent Pool (MPP)	University of North Carolina at Chapel Hill
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Merck	University of Texas Medical Branch
European Medicines Agency (EMA)	Midwest Antiviral Drug Discovery Center	US Army Medical Materiel Development Activity
European Commission	NanoViricides, Inc.	United States Army Medical Research and Development Command
Exscientia	National Academies of Sciences, Engineering, and Medicine	Vir Biotechnology
FIND. Diagnostics for All	National Center for Advancing Translational Science (NCATS), NIH	Walter Reed Army Institute of Research
		Wellcome Trust
		WomenHeart



INTREPID ALLIANCE

INTERNATIONAL READINESS FOR PREVENTING INFECTIOUS VIRAL DISEASE