

BIO'S VIRTUAL SUMMIT ADVANCES MEDICAL COUNTERMEASURE PARTNERSHIPS FOR COVID-19

Launches Ongoing Initiative to Accelerate and Coordinate Development of Drugs, Vaccines, Preventives, and Diagnostics

On March 24-25, 2020, BIO virtually convened more than 500 leaders from across industry, government, academia, and NGOs to assess the state of the pandemic and accelerate medical countermeasure solutions for COVID-19. BIO CEO Jim Greenwood and Dr. George Scangos, CEO of Vir, hosted the two-day summit to identify pressing technical, funding, regulatory and policy challenges, and enable BIO to catalyze cross-industry collaborations and public-private partnerships to advance development of medical countermeasures. Participants heard from key government officials, including Ambassador Deborah Birx, White House Coronavirus Response Coordinator, Dr. Robert Kadlec, HHS Assistant Secretary for Preparedness and Response, and Dr. Rick Bright, Director, Biomedical Advanced Research and Development Authority.

KEY FINDINGS

Based on Summit discussion, BIO identified the following critical needs and concerns:



Successful development efforts will require the federal government to facilitate sharing of all relevant scientific and epidemiologic data and information as quickly and efficiently as possible.



Many promising solutions will emerge from small and mid-sized companies and research laboratories, but these entities will likely have difficulty navigating the complex government contracting and regulatory bureaucracy; real-time assistance is needed.



Early and rapid decisions from government funders will be essential to support immediate research, development, and clinical trial activity in order to identify the most promising candidates for further R&D and collaboration.



Regulatory, advisory, and reimbursement authorities must be involved with requirement-setting and decision-making early on to prevent bottlenecks and downstream delays.



As the pandemic spreads, companies must develop technologies and scale up manufacturing in parallel, taking significant financial risk with an uncertain market.

Specific findings and challenges identified within three primary countermeasure areas include:

Diagnostics

- A joint approach is required using both laboratory-based diagnostic testing and forward-deployed testing technologies (point-of-care diagnostics). Clearer guidance from funders is needed for point-of-care test development.
- Constraints on supplies of personal protective equipment and laboratory materials limit the ability to develop and execute diagnostic tests.
- The lack of any national diagnostic infrastructure to enable platform interchangeability is a systemic weakness.
- Federal government will need to provide a roadmap for commercialization of diagnostic technologies in the post-Emergency Use Authorization phase.

Vaccines/Preventives

- Uncertainty about viral mutation, disease epidemiology, and the risk of patient reinfection complicate vaccine development.
- The supply of reagents and other materials needed to develop vaccines is constrained, delaying progress. Clinical trial design protocols are needed from FDA to facilitate testing.
- Domestic fill-finish capacity is limited, and manufacturing product to the scale needed for a national or global campaign will require extensive public-private collaboration among companies and U.S. government agencies with essential capacities and infrastructure.

Therapeutics

- BSL-3 lab capacity, and supplies and research material, including patient serum, are difficult to access for testing drug candidates.
- Designing hospital-based studies will pose a challenge due to evolving standards of care and indeterminate numbers of patients; adaptive clinical trial designs will be necessary.
- Myriad therapeutic initiatives in planning or early development require a rapid funding mechanism for small projects.

BIO INTERNAL ACTIONS



BIO is establishing three focused collaborative task forces to address challenges in each of three technical areas and to facilitate industry partnerships. These task forces will consider immediate-impact actions as well as policy and resourcing recommendations that will enable better preparation for future pandemics.



BIO created the Coronavirus Hub (hub.bio.org) to connect companies searching for specific resources or services with others that have them. This new hub enables users to post requests for urgently needed resources and announce the availability of supplies and capacities. The portal connects in real-time through customized and searchable postings. The Coronavirus Hub will also serve as a platform for facilitating research partnering between companies.



BIO has consolidated all federal government grant opportunities on the BIO website for easy access by companies and researchers and will keep this site updated as new announcements are made.

FEDERAL AGENCY NEAR-TERM RECOMMENDATIONS



Federal agencies should engage with BIO's three taskforces to facilitate rapid resolution to shared development and operational challenges.



The Administration must quickly distribute emergency supplemental funds to biotechnology companies and researchers to rapidly advance potential drugs, vaccines and diagnostics.

- **OMB** must act with urgency and apportion funds to **ASPR/BARDA** so that funding allocations can be made without delay.
- **ASPR/BARDA** must use flexible Other Transaction Authority agreements or other innovative approaches, such as quickly implementing a **DRIVE** initiative to get funds out to the researchers on the front lines.
- **DOD's Joint Program Executive Office (JPEO)** must rapidly allocate medical countermeasure emergency supplemental funding.



NIH, CDC, and FDA should establish a platform for data and information sharing on scientific and clinical characteristics of SARS-CoV-2 and COVID-19.

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