

## NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options

*Health agencies, leading pharmaceutical companies to join forces to accelerate pandemic response*

The National Institutes of Health and the Foundation for the NIH (FNIH) are bringing together more than a dozen leading biopharmaceutical companies, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. The planned Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics. This is part of the whole-of-government, whole-of-America response the Administration has led to beat COVID-19.

“We need to bring the full power of the biomedical research enterprise to bear on this crisis,” said NIH Director Francis S. Collins, M.D., Ph.D. “Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic.”

Coordinated by the FNIH, ACTIV government and industry partners will provide infrastructure, subject matter expertise and/or funding (both new and in-kind) to identify, prioritize and facilitate the entry of some of the most promising candidates into clinical trials. Industry partners also will make available certain prioritized compounds, some of which have already cleared various phases of development, and associated data to support research related to COVID-19. The partnership is being developed with input from a steering committee managed by the FNIH which includes leaders from NIH, FDA and the research and development organizations of the companies.

“COVID-19 is the most significant global health challenge of our lifetime, and it will take all of us working together as a global community to put an end to this pandemic,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. “We will need to harness the best ideas from multiple stakeholders, including governments, regulatory authorities, academia, NGOs and industry to stop COVID-19. At Johnson & Johnson, we are committed to working closely with FNIH, IMI and are part of other important consortia to speed solutions to stop this pandemic.”

“Battling the COVID-19 pandemic is far too great a challenge for any one company or institution to solve alone,” said Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer and President, Worldwide

### Participating Organizations

#### Government

- National Institutes of Health
- HHS Office of the Assistant Secretary for Preparedness and Response
- U.S. Food and Drug Administration
- Centers for Disease Control and Prevention
- European Medicines Agency

#### Non-Profit

- Foundation for the National Institutes of Health

#### Industry

- AbbVie
- Amgen
- AstraZeneca
- Bristol Myers Squibb
- Evotec
- GlaxoSmithKline
- Johnson & Johnson
- KSQ Therapeutics
- Eli Lilly and Company
- Merck & Co., Inc.
- Novartis
- Pfizer
- Roche
- Sanofi
- Takeda
- Vir Biotechnology

Research, Development and Medical, Pfizer. “We are seeing an unprecedented level of collaboration across the innovation ecosystem to address this global health crisis, and this potentially powerful NIH initiative may allow us to further accelerate the delivery of much needed therapies to patients around the world.”

The research community is currently striving to sift through more than 100 potential preventives and therapeutics for COVID-19. ACTIV will aim to provide guidance which can be used to prioritize the plethora of vaccine and therapeutic candidates in development and connect clinical trial networks to test new and repurposed candidates quickly and efficiently.

“Using the most advanced clinical trial methods to rapidly test multiple interventions will help get the answers we need as soon as possible to expedite potential prevention and treatment approaches to fight COVID-19,” said FDA Commissioner Stephen M. Hahn, M.D. “Collaboration is a critical ingredient for success and the FDA will continue to use every tool possible under our [Coronavirus Treatment Acceleration Program](#) to speed the development of safe and effective medical countermeasures.”

ACTIV will have four fast-track focus areas, each of which will be led by a highly motivated working group of senior scientists representing government, industry and academia:

- 1) *Standardize and share preclinical evaluation methods in an open forum that allows for comparison and validation by:*
  - Establishing a centralized process and repository for harmonizing and sharing methods and evaluating models
  - Extending access to high-throughput screening facilities, especially in biosafety level-3 laboratories, with a goal of testing all compounds that have been in human clinical trials to identify the potential to apply these compounds to COVID-19
  - Increasing access to validated animal models
  - Enhancing comparison of approaches to identify informative assays
- 2) *Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential by:*
  - Establishing a steering committee with relevant expertise and objectivity to set criteria for and rank potential candidates submitted by industry partners for first wave and subsequent evaluation
  - Developing a complete inventory of potential candidates with different mechanisms of action and acceptable safety profiles
  - Designing, launching and openly sharing master protocols with agreed upon endpoints, sampling and analysis for evaluating candidates
  - Using a single control arm to enhance trial efficiency
- 3) *Maximize clinical trial capacity and effectiveness by:*
  - Connecting existing networks of clinical trials to build capacity and capabilities, including specialization in different populations and disease stages

- Leveraging infrastructure and expertise from across NIH networks, including:
  - Adjuvant Discovery and Adjuvant Development Programs
  - AIDS Clinical Trials Network
  - Clinical and Translational Science Awards Program
  - Clinical Trials in Organ Transplantation
  - Cooperative Centers on Human Immunology
  - HIV Prevention Trials Network
  - HIV Vaccine Trials Network
  - Human Immunology Project Consortium
  - International Network for Strategic Initiatives for Global HIV Trials (INSIGHT) Network
  - National Cancer Institute Clinical Oncology Research Program
  - National Cancer Institute Clinical Trial Network
  - Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network
  - Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN)
  - T and B Cell Discovery Programs and Immune Epitope Database
  - Vaccine Treatment and Evaluation Units
- Establishing a coordination mechanism across networks to expedite trials, track incidence across sites and project future capacity

4) *Advance vaccine development by:*

- Creating a collaborative framework to share insights into natural immunity and vaccine candidate-induced immune response by:
  - Mapping epitopes and developing assays
  - Establishing protocols for sampling and immunological analyses and reagents
  - Collecting clinical data on immunological responses and endpoints, to enable meta-analysis of correlates of protection
  - Engaging with regulators on surrogate endpoints for clinical evaluation

“This powerful public-private partnership will focus and expedite R&D activities required to combat COVID-19,” says Maria C. Freire, Ph.D., President and Executive Director, FNIH. “Working in lock-step, the public and private sectors will maximize the chances of success and provide a roadmap to pre-emptively manage future threats.”

**About the Foundation for the National Institutes of Health:** The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world’s premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate biomedical research and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of

health issues. Established by Congress in 1990, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit [fnih.org](http://fnih.org).

**About the National Institutes of Health (NIH):** NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit [www.nih.gov](http://www.nih.gov).

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