

# **ACCELERATING COVID19 THERAPEUTIC INTERVENTIONS AND VACCINES [ACTIV]**

## **CDA FREQUENTLY ASKED QUESTIONS (FAQ)**

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*Additional information on ACTIV is provided after the FAQ slides*

# FAQs (1/5)

## What is ACTIV?

- **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)** is public-private partnership that develops coordinated research strategies for prioritizing and speeding development of the most promising treatments and vaccines for COVID-19.

## Why am I being contacted by ACTIV and asked to sign a CDA?

- You submitted a compound via the ACTIV COVID-19 Clinical & Preclinical Candidate Compound Portal and either (1) your survey submission indicated that data essential to evaluate your candidate compound requires a CDA, or (2) your candidate compound was already reviewed, and the panel is asking for additional data for consideration.

## Can I make modifications to the CDA?

- The ACTIV CDA is a standard template used for all submissions that require confidentiality agreements. The legal team at FNIH will review any proposed modifications to the CDA, however, this will delay the review process of your candidate compound.

## Does the ACTIV prioritization process and CDA guarantee reviewer confidentiality?

- Our reviewers have a confidentiality agreement that binds them to the confidentiality within the CDA.

## FAQs (2/5)

### Is the intellectual property portfolio surrounding my submission protected?

- ACTIV has no interest in generating or acquiring intellectual property (IP). Any IP generated during an ACTIV Trial or ACTIV-sponsored preclinical studies will be wholly owned by the submitter. Our goal is to accelerate promising candidates to save lives.

### What is the expected timeline for a review cycle?

- Our panel operates on a 3-4 week review cycle. This is contingent on having all the information from you, the sponsor available for review.

### What is my candidate compound evaluated for?

- ACTIV Phase II/III trials: Please visit this webpage for additional information on the clinical trials <https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>
- As shown in [slide 12](#), ACTIV reviewers are also considering potentially interesting preclinical compounds that are close to the clinic to offer 'Matchmaking' support and help the sponsor identify a site that can support additional studies required

### Are the master protocols available for review?

- Yes, the master protocols without the drug specific appendices are available upon request. Please email [activ\\_submission@fnihi.org](mailto:activ_submission@fnihi.org) with any inquiries.

## FAQs (3/5)

### **What criteria are the reviewers using to assess my candidate compound?**

- The reviewers are evaluating the data provided across several categories including: 1) Rationale, 2) existing preclinical data to support COVID-19 rationale inclusive of in vitro and in vivo model efficacy and 3) PK/PD, 4) existing clinical data to support COVID-19 rationale inclusive of clinical data in COVID-19 patients, 5) PK/PD, 6) safety, 7) manufacturing capabilities to support a 1000 person Phase II trial, etc. Lacking any of these data categories will not disqualify you from the review process, however, reviewers may provide specific recommendations on how to close those gaps.

### **Who is part of the review panel?**

- ACTIV is formed by 31 partners inclusive of government agencies, industry partners and non-profit partners. In addition to members of these partner organizations, we have engaged experts from different aspects of drug development including animal model experts, in vitro screening experts, preclinical and clinical experts across different fields (e.g. virology, immunology, hematology, critical care, pulmonology, etc.)

### **Is there any preference for compounds being developed by Large pharmaceutical companies, small pharma/biotech companies or academic institutions?**

- The review panel evaluates candidate compounds based on the quality of the data provided. If a therapy is being sufficiently studied already, it will be deprioritized for an ACTIV trial. However, there is no preference based on the type of institution that owns the candidate compound.

## FAQs (4/5)

### **If my candidate compound is selected for clinical trials, does my company or lab need to come up with the funds for the clinical trial?**

- If your candidate compound were to get selected for a Phase II clinical trial, those are funded through government programs. You will need to provide however, enough material for a 500-1000 person study. Furthermore, you will need to provide placebo for the study (although not as much as active). If your compound is selected, the team will reach out to provide a detailed explanation on requirements.

### **Does ACTIV offer funding to address gaps in preclinical or clinical data?**

- ACTIV is not a grant funding mechanism. If your candidate compound were to get selected for a clinical trial, it will be tested in an ACTIV trial. If ACTIV reviewers recommend additional studies before consideration for a Phase II clinical trial, the Preclinical ACTIV leads teams can 'match' you with BSL 3/4 facilities that have study resources needed to address the gaps (paid by the candidate compound sponsor) or 'match' you with other groups within NIH that may have contracts or funding mechanisms to support preclinical or Phase I studies.

### **I received a note stating my candidate compound will not be considered for additional review. Can I submit a rebuttal?**

- The ACTIV review panel welcomes re-evaluation as long as there are new data or clarifications on the existing data submitted via the survey. The candidate compound sponsor can submit a new survey or edit the existing one.

## FAQs (5/5)

**I have an idea for a candidate compound that may target a pathway implicated in COVID-19, but I don't have any preclinical data and don't know where to start. Could the panel provide guidance?**

- Our team has published two manuscripts on this subject: (1) Grobler et al. Accelerated preclinical paths to support rapid development of COVID-19 therapeutics [https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30522-9](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30522-9) (2) Hewitt et al. ACTIVating Resources for the COVID-19 Pandemic: *In vivo* Models for Vaccines and Therapeutics [https://www.cell.com/cell-host-microbe/fulltext/S1931-3128\(20\)30521-7](https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(20)30521-7)
- We are also maintaining an up-to-date the NCATS OpenData portal with the latest information on animal models for COVID-19 <https://opendata.ncats.nih.gov/covid19/animal>

**Where can I go for more information?**

- For more information, please email [activ\\_submission@fnihi.org](mailto:activ_submission@fnihi.org) with any questions. We will get back to you as soon as possible.

# ACTIV Overview

## LAUNCH

On April 17, NIH announced the launch of a public-private partnership, **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)**

## MISSION

Develop a coordinated research response to **speed COVID-19 treatment and vaccine options**

<https://fnih.org/what-we-do/programs/activ-partnership>  
<https://www.nih.gov/research-training/medical-research-initiatives/activ>



# ACTIV Stakeholders

ACTIV is being coordinated by the Foundation for the National Institutes of Health (FNIH), and has brought together multiple partners from government, industry and non-profits.

8  
Government Partners

20  
Industry Partners

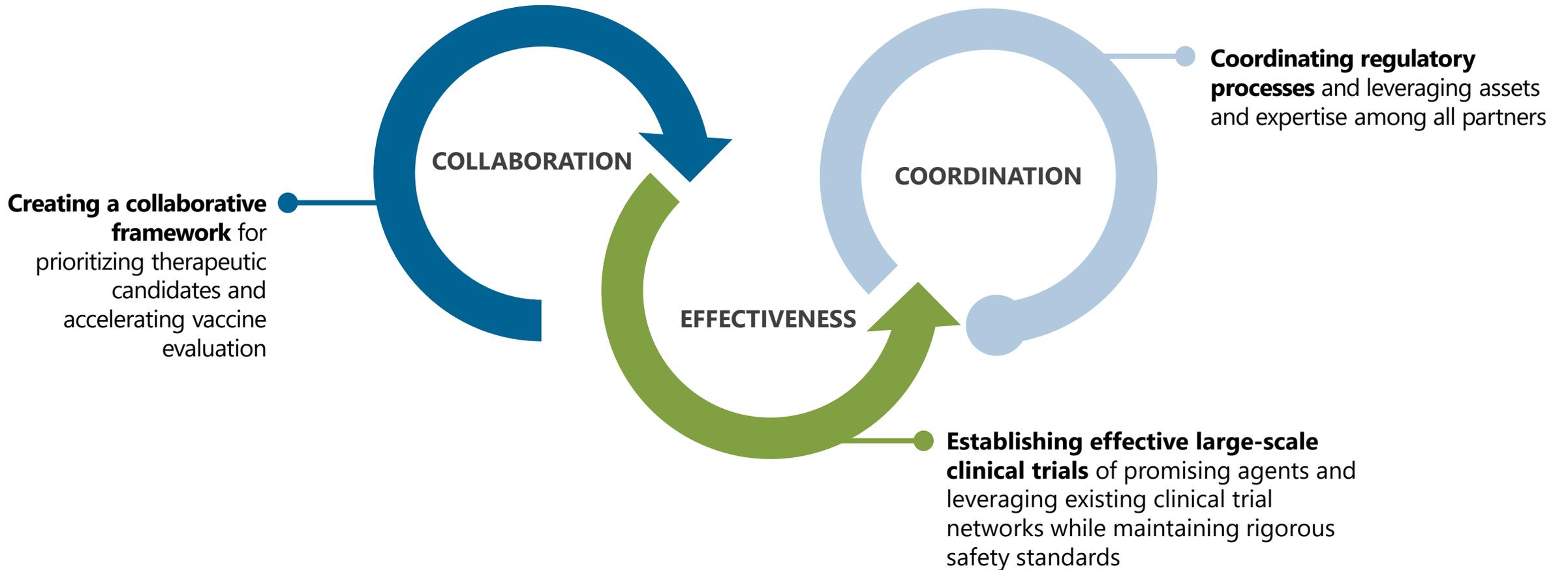
3  
Non-Profits



BILL & MELINDA  
GATES foundation



# ACTIV Program Objectives



# ACTIV Fast-Track Focus Areas

The ACTIV partnership consists of four fast-track focus areas, consisting of Working Group membership of both public and private sector representatives:



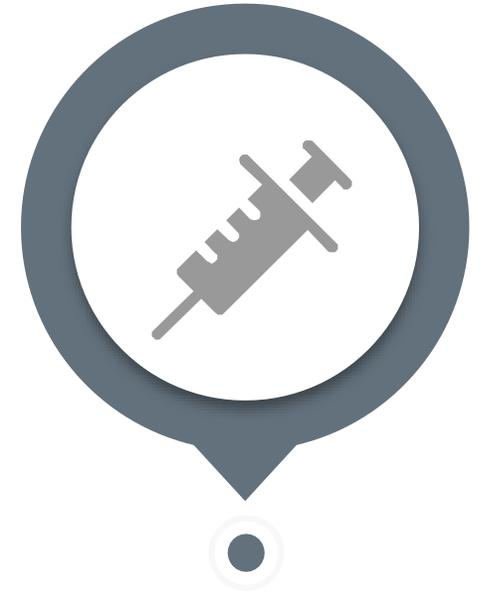
**Preclinical**



**Therapeutics –  
Clinical**



**Clinical Trial  
Capacity**



**Vaccines**

# Focus Area Objectives & Composition

Each focus area is a Working Group that contains several sub groups to oversee tactical operations :



## Preclinical



## Therapeutics – Clinical



## Clinical Trial Capacity



## Vaccines

### Objective

+ Develop a collaborative, streamlined forum to identify preclinical treatments

+ Accelerate clinical testing of the most promising vaccines and treatments

+ Improve clinical trial capacity and effectiveness

+ Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval

### Sub-Groups

+ Animal Models  
+ In Vitro Assays

+ Agent Prioritization  
+ Master Protocol

+ Survey Development  
+ Clinical Trial Network Inventory  
+ Innovations

+ Vaccines Clinical Trials  
+ Protective Immune Responses  
+ Vaccine-Associated Immune Enhancement

# ACTIV COVID-19 Clinical & Preclinical Candidate Compound Portal: Review Process

