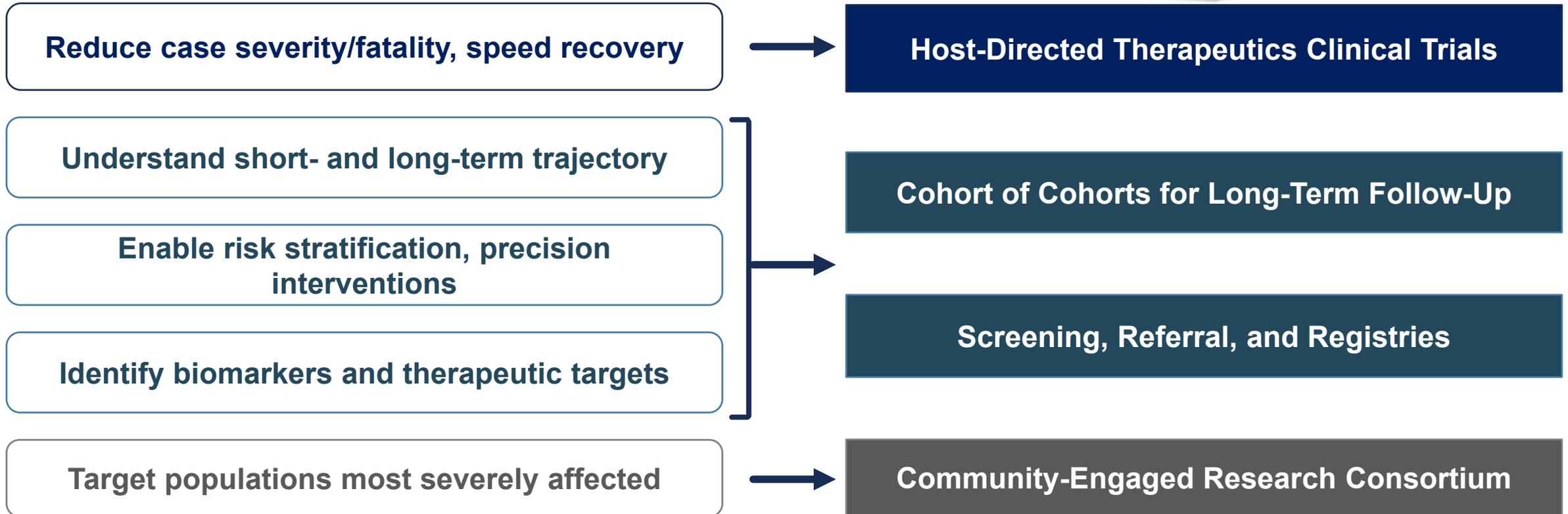


# NHLBI COVID-19 Clinical Research Framework



## Goals



# CONNECTS

## “Collaborating Network of Networks for Evaluating CCOVID-19 and Therapeutic Strategies”

Goal: Leverage and expand NHLBI’s national clinical research networks to rapidly and nimbly respond to emerging research and clinical needs for COVID-19

- **Leveraging existing assets, data, and studies**
- Comprehensive, **expandable platform** linking trial network, registries, and cohorts
- Facilitating case finding, **clinical trial accrual, longitudinal studies, and community engagement**



# CONNECTS Clinical Trial and Registries Platform: Driving Toward COVID-19 Host-Directed Interventions Before, During, and After Hospitalization

COVID-19+ Progression →



## Host-Directed Therapeutics Clinical Trials & Case Registries

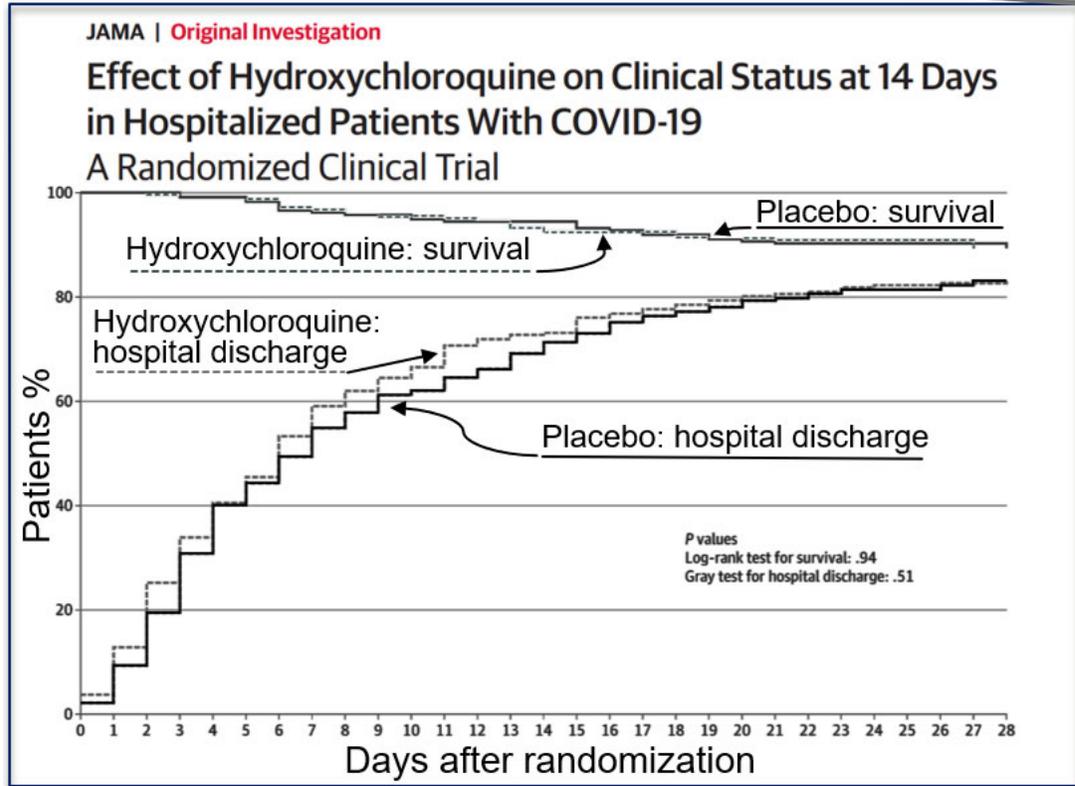
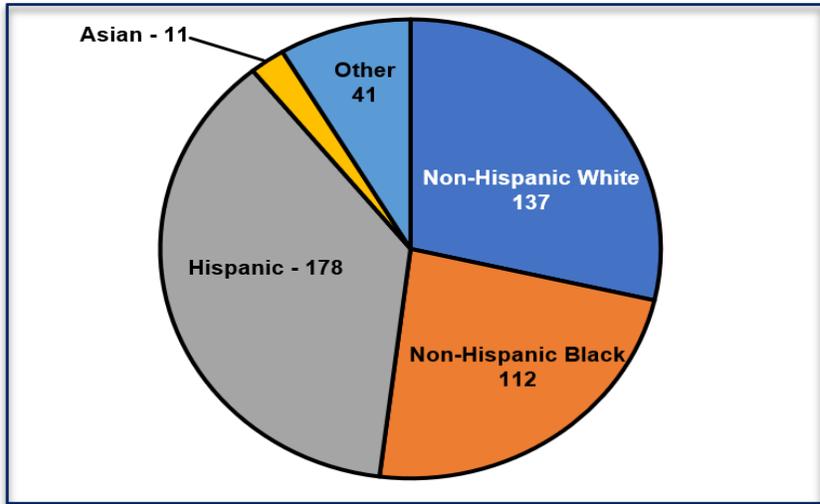
<i>Patient Populations</i>	Pre-hospital Outpatient	Hospitalized Patients (+/- ventilatory support)	Post-hospital Convalescent Patients
<i>Anti-Inflammatory</i>	COLOCORONA Colchicine vs. Placebo	ORCHID Hydroxychloroquine vs. Placebo	
<i>Passive Immunity</i>	C3P0 – Convalescent Plasma vs. Placebo		
<i>Anti-Thrombotic</i>	ACTIV – 4B	ACTIV – 4A	ACTIV – 4C

# Outcomes Related To COVID-19 Treated With Hydroxychloroquine Among Inpatients With Symptomatic Disease (ORCHID) Trial



Hospitalized Patients (+/- ventilatory support)

Patient Demographics



Addressed early question about Hydroxychloroquine effectiveness. Study was stopped on June 19 because there was no benefit or harm.

# The Clinical Trial of COVID-19 Convalescent Plasma of Outpatients (C3PO)



*Patient Populations*

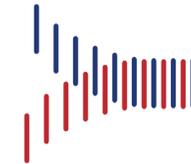
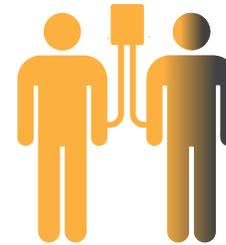
Pre-hospital Outpatient

*Passive Immunity*

**C3PO:**  
Convalescent Plasma vs. Placebo

- **Population:** Adults presenting to the ED:
  - Mild, symptomatic, lab confirmed COVID-19
  - High risk for progression to severe/critical illness
  - Clinically stable for outpatient management at randomization
- **Planned Enrollment:** 600 in total (300 per arm)
- **Intervention:** A single dose of convalescent plasma (CP) or saline placebo

## CONNECTS



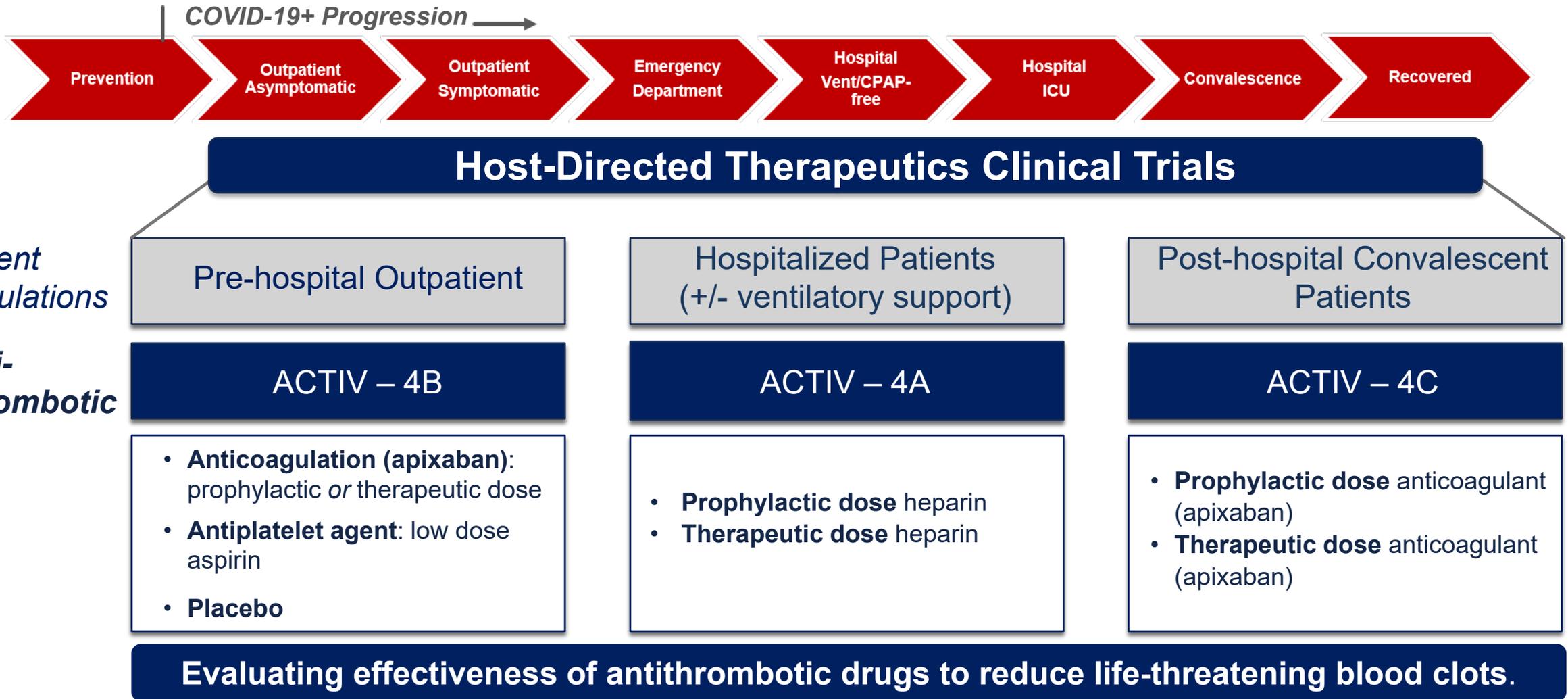
SIREN

**C3PO**

Clinical Trial of COVID-19  
Convalescent Plasma in  
Outpatients

Evaluating the use of **convalescent plasma** to treat non-hospitalized patients with mild COVID-19.

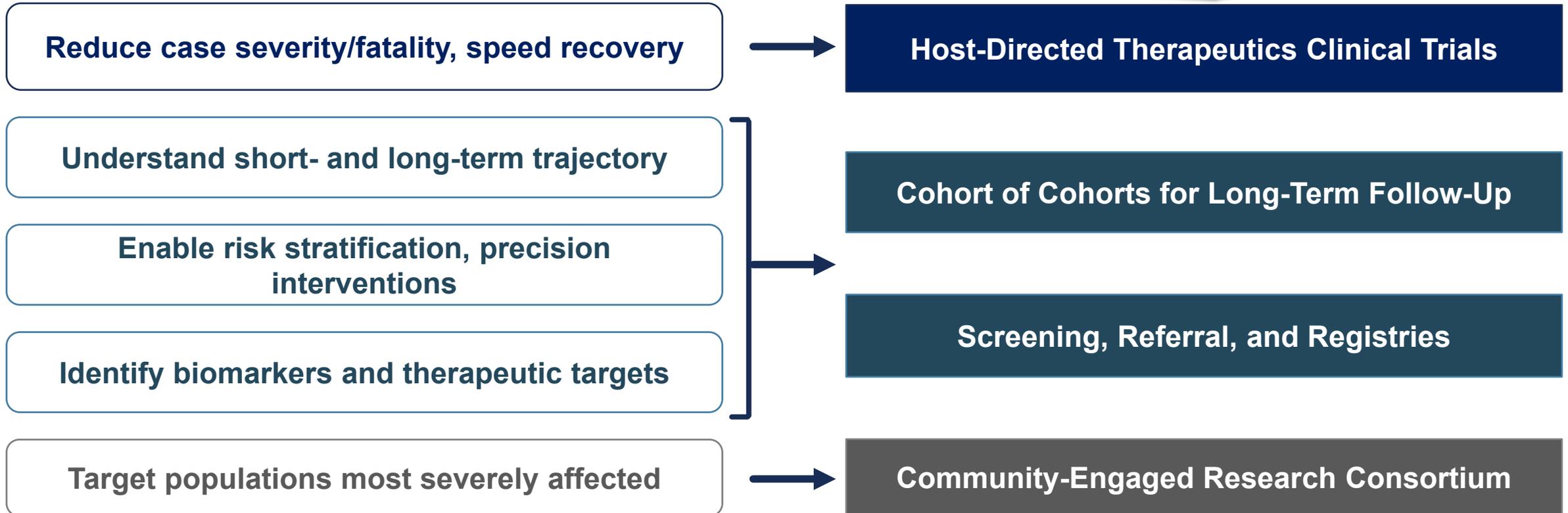
# Accelerating COVID-19 Therapeutic Interventions and Vaccines 4 (ACTIV-4)

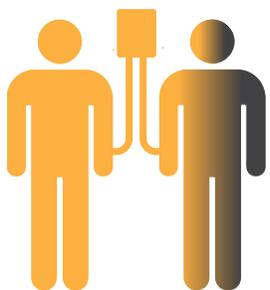


# NHLBI COVID-19 Clinical Research Framework



## Goals





**C3PO**  
Clinical Trial of COVID-19  
Covalescent Plasma in  
Outpatients



**ORCHID Trial**