



VA and National/International Research Partnerships on COVID-19

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OUTLINE

- ORD's COVID-19 Goals
- National Security Council, BARDA
- ACTIV
 - Leadership
 - Trials
- Operation Warp Speed
 - Leadership
 - Vaccine Trials
- NIH/NIAID/INSIGHT
- Summary

ORD's COVID-19 Goals

1. Keep research staff and participants safe
2. Support the clinical mission by:
 - a) Providing access to investigational therapies, which are only available through research
 - b) Collecting and evaluating the scientific literature and real world evidence to support operational decision-making
 - c) Contributing to national research efforts to combat the pandemic

VA Interagency Collaborations

- Contributing to national research efforts
- Demonstrating VA's research capabilities
- Coordinating to fill in gaps, avoid overlap



U.S. DEPT OF DEFENSE



U.S. Department of Health and Human Services



National Security Council COVID Insights Task Force



- Lead participant in the National Security Council COVID Insights Task Force
 - Bringing together data from VA, DoD, HHS, and others at DOE for analysis using artificial intelligence.
 - OI&T, Office of Informatics & Analytics, and National Data Systems are key participants.
 - Initial mission is to provide real-world data to support FDA's COVID-19-related decision-making:
 - Which drugs are being used to treat COVID-19
 - What are risk factors and protective factors
 - Safety and effectiveness of repurposed COVID-19 therapeutics
 - Providing insights back to VHA operations partners

HHS Assistant Secretary for Preparedness and Response (ASPR): 4 missions



U.S. Department of Health and Human Services



Providing Strong Leadership



Building a Regional Disaster Health Response System



Sustaining Public Health Security Capacity



Enhancing the Medical Countermeasures Enterprise

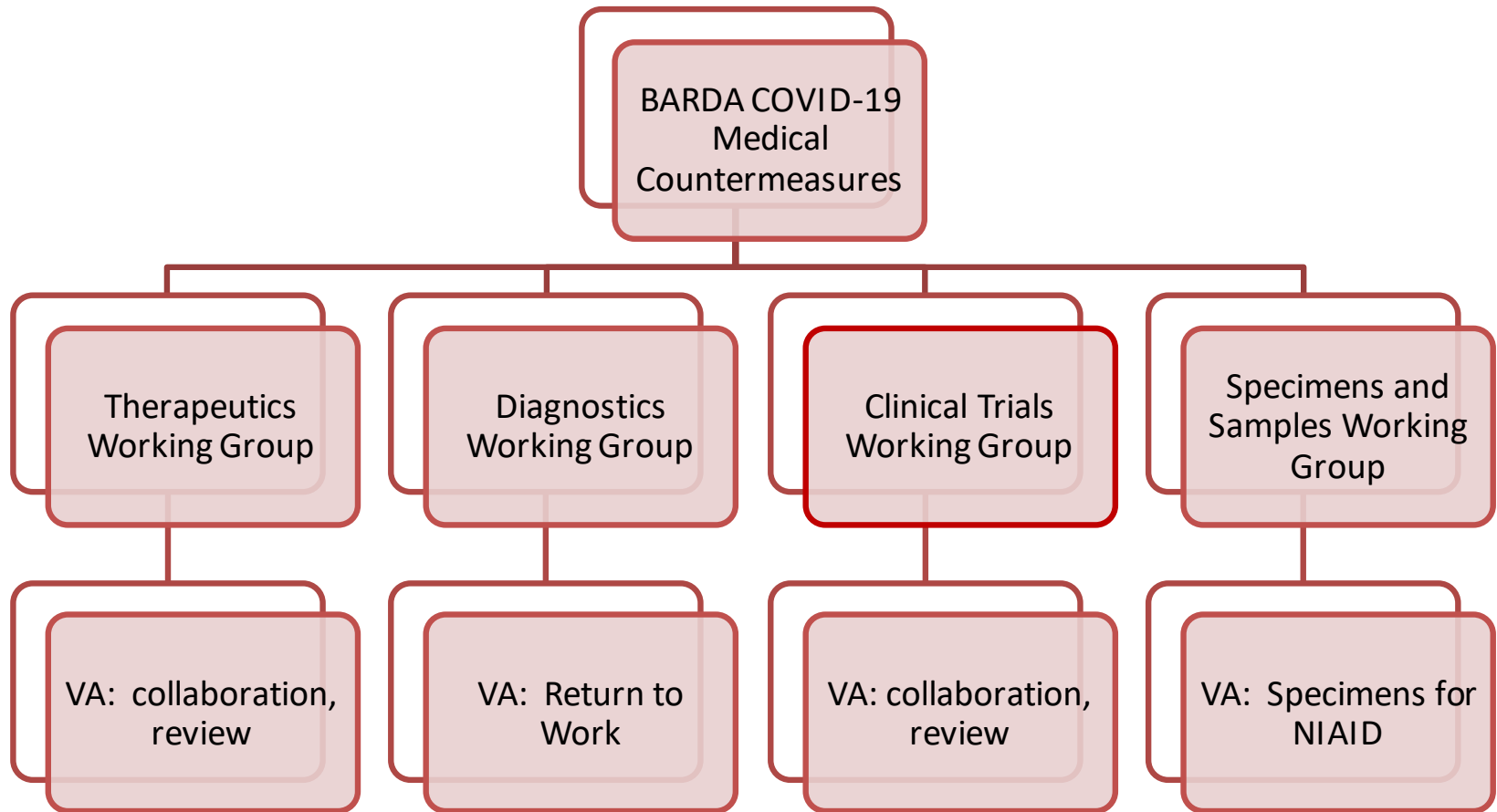


Biomedical Advanced R & D Authority: BARDA

- Develops and procures innovative medical countermeasures
- Has flexible, nimble authorities
- Uses multi-year advance funding
- Develops public-private partnerships
- In COVID-19, BARDA initially served as U.S. government interagency organizer beginning in Jan 2020



BARDA Initially Organized Interagency Efforts



Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

- Announced April 17 to coordinate and streamline processes to make the best use of biomedical research resources
- Unprecedented collaboration among NIH, other Federal agencies, academia, and industry, led by Francis Collins (NIH Director) and Paul Stoffels (Johnson & Johnson).
- Viewed as essential to our country's national security, due to the health and economic impacts of COVID-19.



See: <https://jamanetwork.com/journals/jama/fullarticle/2766371>

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Working Groups

Pre-Clinical

Therapeutics

Clinical Trials Capacity

Vaccines

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

ACTIV Master Protocols

ACTIV-1 immune modulators

ACTIV-2 monoclonal antibodies (outpatient)

ACTIV-3 monoclonal antibodies (inpatient)

ACTIV-4 anticoagulants (inpatient)

ACTIV-5 other promising compounds

ACTIV-2 / A5401

**Adaptive Platform Treatment Trial for Outpatients with COVID-19
(Adapt Out COVID)**

A Multicenter Trial of the AIDS Clinical Trials Group (ACTG)

**Sponsored by:
National Institute of Allergy
and Infectious Diseases**

**Industry Support Provided by:
Lilly Research Laboratories, Eli Lilly and Company**

Protocol Chair: David (Davey) Smith, MD, MAS

**Protocol Vice Chair(s):
Kara Chew, MD, MS
Eric Daar, MD
David Wohl, MD**

ACTIV-3 / INSIGHT 014

A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for Hospitalised patients with COVID-19

Short Title: Therapeutics for Inpatients with CCOVID-19 (TICO)

Funder and holder of US IND:
National Institute of Allergy and Infectious Diseases,
National Institutes of Health

and carried out by the

International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)
in Collaboration with Other NIAID and NHLBI-supported Trials Networks

2nd June 2020



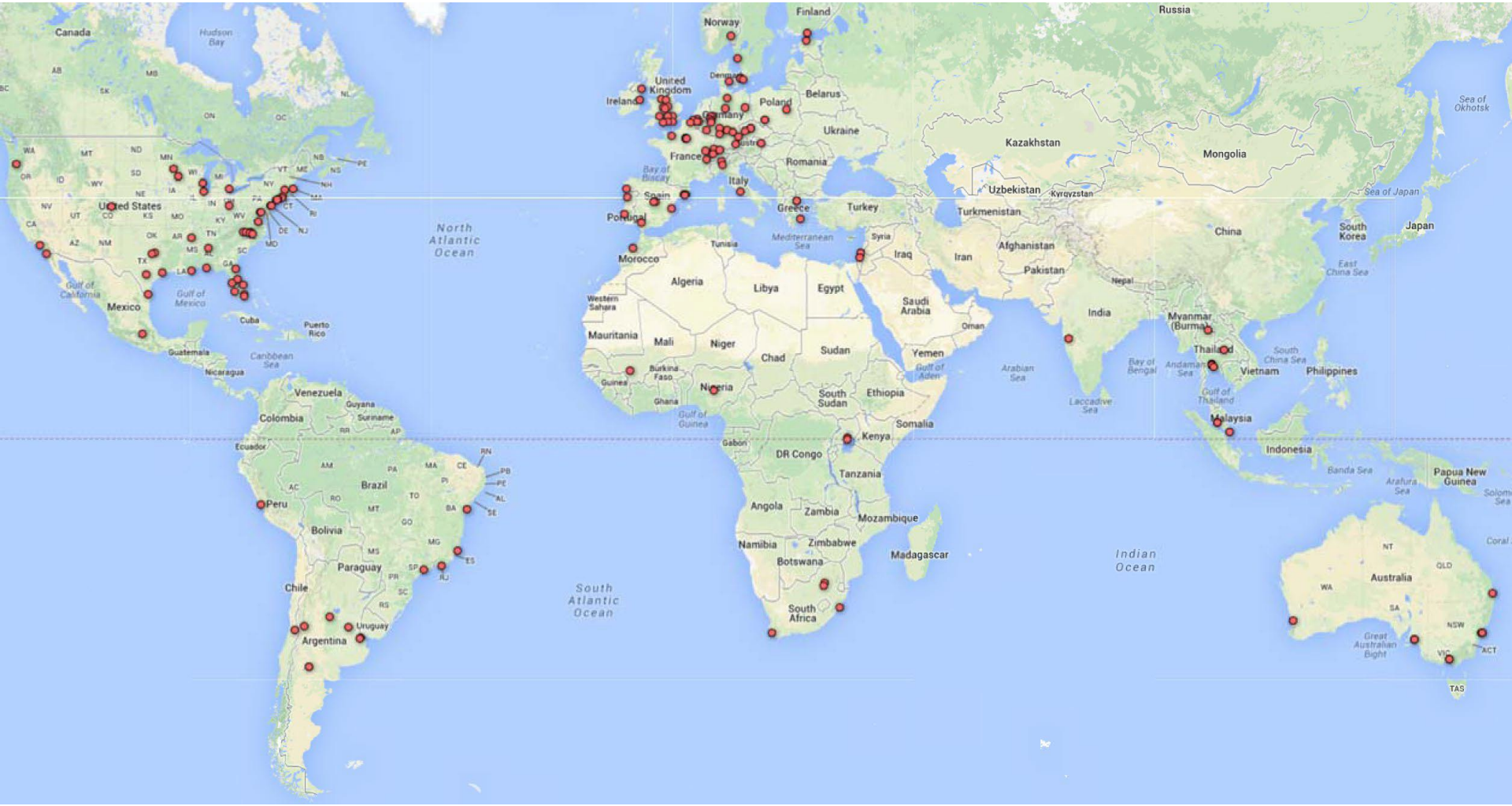
OPERATION WARP SPEED

- Announced May 15 to fund, coordinate, and offer regulatory support to enable the rapid development and distribution of novel diagnostics, therapeutics, and vaccines
- Federal-wide, led by HHS Secretary Alex Azar and Defense Secretary Mark Esper, with Dr. Moncef Slaoui as chief advisor and General Gustave F. Perna as chief operating officer
- OWS will swiftly implement a series of vaccine trials including in VA research network, first in July, thousands of participants
- Five vaccine candidates slated to be in trials before the end of the calendar year:
- First 3: Moderna, AstraZeneca, Janssen

NIAID/NIH/University of Minnesota: International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)

- >20 year old international network for HIV and other infectious diseases research, now active in COVID-19 clinical research
- Some VA researchers already in INSIGHT network
- New: ORD will assist ACTIV-3 and INSIGHT studies with support from a VA cooperative study coordinating center
- Adding VA research sites
- INSIGHT trial: COVID-HIG in inpatients and outpatients
- COVID-HIG is a human hyperimmune product of purified gamma globulin (IgG) fraction of human plasma containing antibodies to SARS-CoV-2

INSIGHT's Global Presence: 37 Countries on 6 Continents



Summary

- ORD serves on interagency teams and working groups to advise on SARS-COV-2 and COVID-19 research initiatives
- ORD is implementing national and international trials in VA: central funding, regulatory support, trial coordination assistance are key
- ACTIV and OWS implementation timelines are fast—unprecedented demand on our research system
- VA's national/international research collaborations are in addition to VA-funded studies and participation in industry trials
- VA research network is pivotal to ACTIV/OWS success because of our clinical research capabilities and at-risk Veteran population

THANK YOU

‘In the absence of proven treatments, clinical trials can be part of clinical care’

-Martin Landry, PhD, FRCP
RECOVERY (UK)

For COVID-19 research questions:

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