REAGAN-UDALL FOUNDATION FOR THE FDA

COVID-19 Lessons Learned: Clinical Evaluation of Therapeutics

September 28, 2021
1-5:30pm Eastern

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REAGAN-UDALL FOUNDATION FOR THE FDA

Welcome

Susan C. Winckler, RPh, Esq.
Reagan-Udall Foundation for the FDA

REAGAN-UDALL FOUNDATION FOR THE FDA

Thank you for joining

This workshop is being recorded. A transcript will be available on regulations.gov.

If you'd like to ask a question, you may enter it in the Q&A. We will get to as many questions as time allows.

If you signed up to provide a public comment during registration, you will have a minute-and-a-half to provide your statement during that portion of the workshop. We will call speakers to the microphone alphabetically by last name and will unmute you when it is your turn to speak.

Speakers and presenters cannot address questions regarding any pending regulatory action.

Agenda

1pm	**Welcome and Introduction**
1:15pm	**Opening Keynotes**
	Janet Woodcock, MD U.S. Food and Drug Administration
	Francis S. Collins, MD, PhD National Institutes of Health
1:45pm	**Research, Scoping, & Prioritization Panel**
2:45pm	**Infrastructure & Resourcing Panel**
3:45pm	**Clinical Trial Execution Panel**
4:45pm	**Public Comment***
5:15pm	**Closing Plenary**

**Open to those who registered in advance. This is an open public comment forum; neither the Foundation nor FDA will respond.*

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Introduction

Kevin Bugin, PhD
U.S. Food and Drug Administration &
former Federal COVID-19 Response or Countermeasures Acceleration Groups

Welcome and Thank You

Why Are We Here Today?

REAGAN-UDALL FOUNDATION FOR THE FDA

- Why did we conduct lessons learned for therapeutics?
- Timing
- Purpose of workshop
- Goals

Today's Discussion

- **Panel discussions**
  - Research, Scoping, & Prioritization
  - Infrastructure & Resourcing
  - Clinical Trial Execution

Next Steps

- Today is another step in our journey. It is not the end goal.
- There will be a meeting recording posted. The slides are currently available at ReaganUdall.org
- There will be a summary that builds on the pre-read, incorporating today's discussion and public comments
- The docket will remain open (ID:FDA-2021-N-0977), please submit comments and ideas, and we'll be summarizing that public feedback once it closes
- We hope that our panel members, participants, and our leaders across the clinical trial ecosystem will carry forward the lessons learned today and put them in place to ready us for the future of this pandemic and future pandemics response

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Janet Woodcock, MD

Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

Federal COVID-19 Response: Clinical Evaluation of Therapeutics Lessons Learned Public Workshop

Opening Remarks

- September 28, 2021

Operation Warp Speed Therapeutics

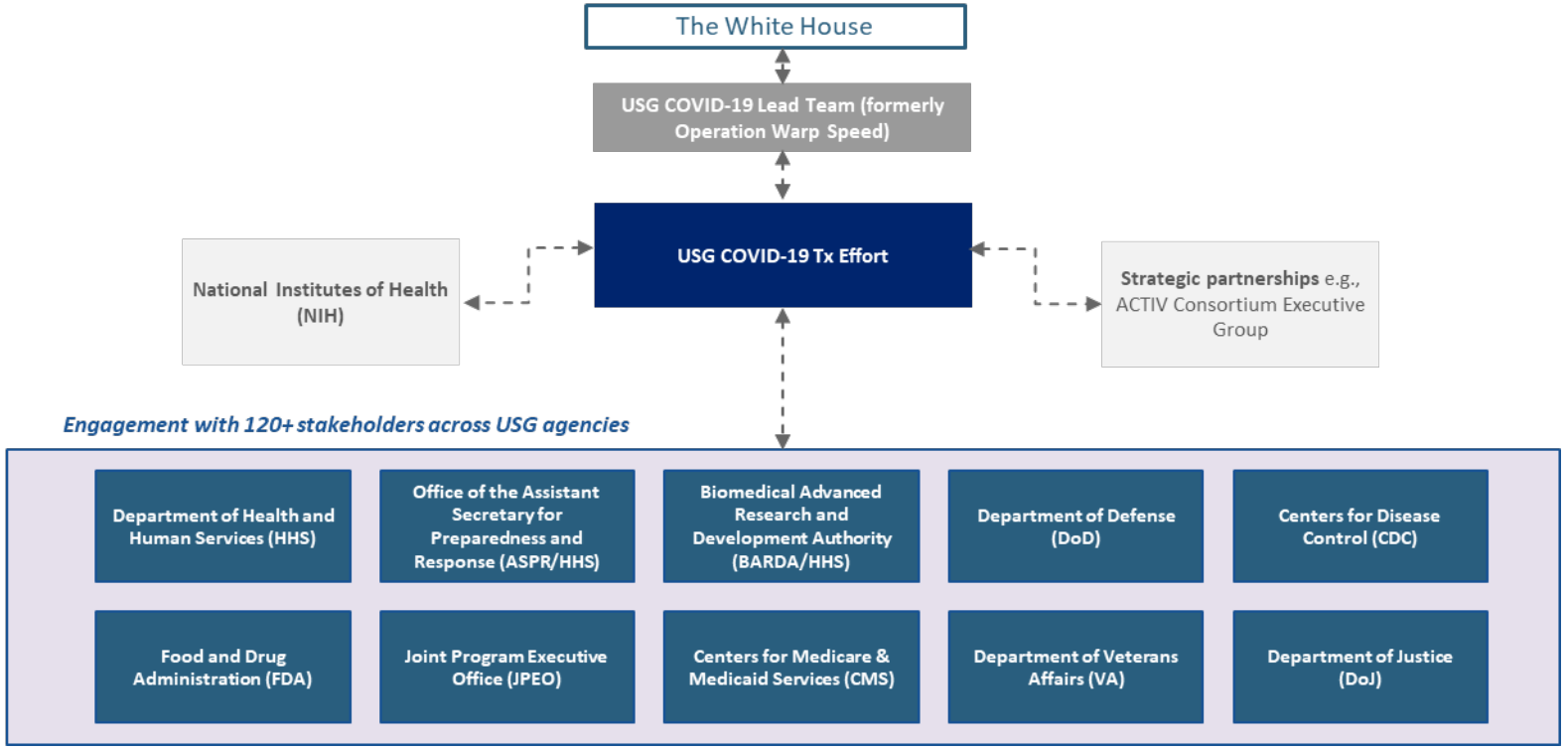
In May 2020, the Operation Warp Speed (OWS) therapeutics effort was established with the following mission:

- Accelerate **clinical development and manufacturing scale-up** of candidates most likely to have a broad public impact
- Enable **broad distribution and availability of Tx** until wide-spread access to a vaccine(s) could be achieved
- Provide **continued access for those infected** with COVID-19

The OWS therapeutic strategy focused on candidates that **attack the virus or prevent/manage complications** associated with COVID-19

In January 2021, OWS was transitioned to the **Federal COVID-19 Response**

The Therapeutics (Tx) effort facilitated broad interagency coordination to enable accelerated Tx development and availability



Context for this Lessons Learned Initiative

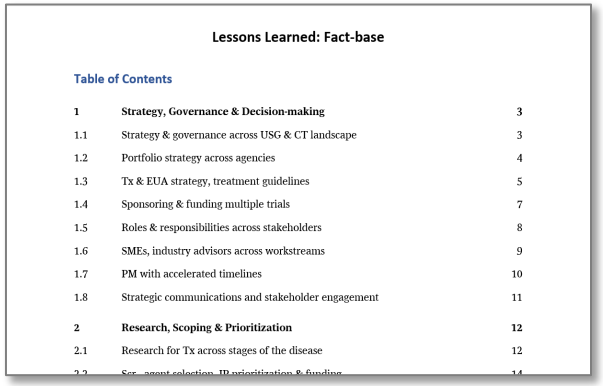
- The coordinated Federal Response for COVID-19 therapeutics produced tremendous insights related to the clinical evaluation of therapeutics
- These insights can be applied to the broader clinical trial landscape and improve the clinical trial ecosystem's preparedness for the next public health emergency
- While there continues to be a public health emergency, there was a need to focus on the clinical evaluation of therapeutics early in 2021 to explore immediate application of lessons and initiation of longer-term efforts
- Analysis and collection of lessons learned took place from January to May of 2021

Over the course of the first half of 2021, we captured lessons learned, developed recommendations, and considerations for implementation

Compiled a **comprehensive 70+ page fact-base** based on interviews with stakeholders and lessons learned documentation with key context, lessons learned, and sources

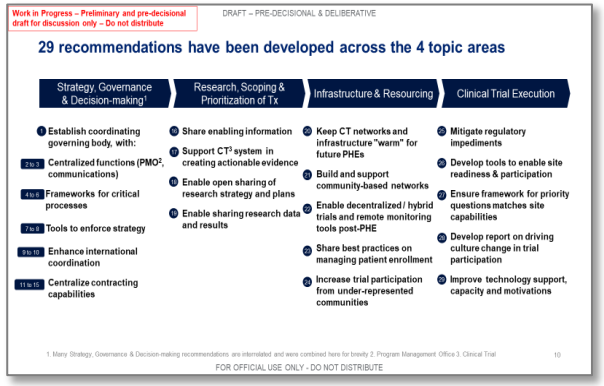
Synthesized **29 key recommendations** based on lessons learned. Process was led by working groups and aligned with leadership

Developed considerations to address recommendations to provide **details and reference for implementation process.** Meant as starting points for discussion.



Lessons Learned: Fact-base

Table of Contents



Work in Progress – Preliminary and pre-decisional draft for discussion only – Do not distribute

DRAFT – PRE-DECISIONAL & DELIBERATIVE

29 recommendations have been developed across the 4 topic areas

Strategy, Governance & Decision-making[1]	Research, Scoping & Prioritization of Tx	Infrastructure & Resourcing	Clinical Trial Execution
1 Establish coordinating governing body, with:	6 Share enabling information	12 Keep CT networks and infrastructure "warm" for future PHEs	20 Mitigate regulatory impediments
2 to 3 Centralized functions (PMO[2], communications)	7 Support CT[3] system in creating actionable evidence	13 Build and support community-based networks	21 Develop tools to enable site readiness & participation
4 to 5 Frameworks for critical processes	8 Enable open sharing of research strategy and plans	14 Enable decentralized / hybrid trials and remote monitoring tools post-PHE	22 Ensure framework for priority questions matches site capabilities
7 to 8 Tools to enforce strategy	9 Enable sharing research data and results	15 Share best practices on managing patient enrollment	23 Develop report on driving culture change in trial participation
9 to 10 Enhance international coordination		16 Increase trial participation from under-represented communities	24 Improve technology support, capacity and motivations
11 to 15 Centralize contracting capabilities			

1. Many Strategy, Governance & Decision-making recommendations are interrelated and were combined here for brevity 2. Program Management Office 3. Clinical Trial

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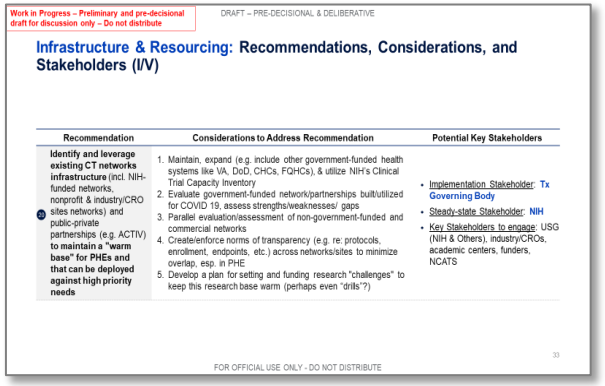

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DRAFT – PRE-DECISIONAL & DELIBERATIVE

Infrastructure & Resourcing: Recommendations, Considerations, and Stakeholders (I/V)

Recommendation	Considerations to Address Recommendation	Potential Key Stakeholders
12 **Identify and leverage existing CT networks infrastructure** (incl. NIH-funded networks, nonprofit & industry/CRO sites networks) and public-private partnerships (e.g. ACTIV) **to maintain a "warm base" for PHEs and that can be deployed against high priority needs**	1. Maintain, expand (e.g. include other government-funded health systems like VA, DoD, CHCs, FQHCs), & utilize NIH's Clinical Trial Capacity Inventory 2. Evaluate government-funded network/partnerships built/utilized for COVID 19, assess strengths/weaknesses/ gaps 3. Parallel evaluation/assessment of non-government-funded and commercial networks 4. Create/enforce norms of transparency (e.g. re: protocols, enrollment, endpoints, etc.) across networks/sites to minimize overlap, esp. in PHE 5. Develop a plan for setting and funding research "challenges" to keep this research base warm (perhaps even "drills"?)	• Implementation Stakeholder: Tx Governing Body • Steady-state Stakeholder: NIH • Key Stakeholders to engage: USG (NIH & Others), industry/CROs, academic centers, funders, NCATS

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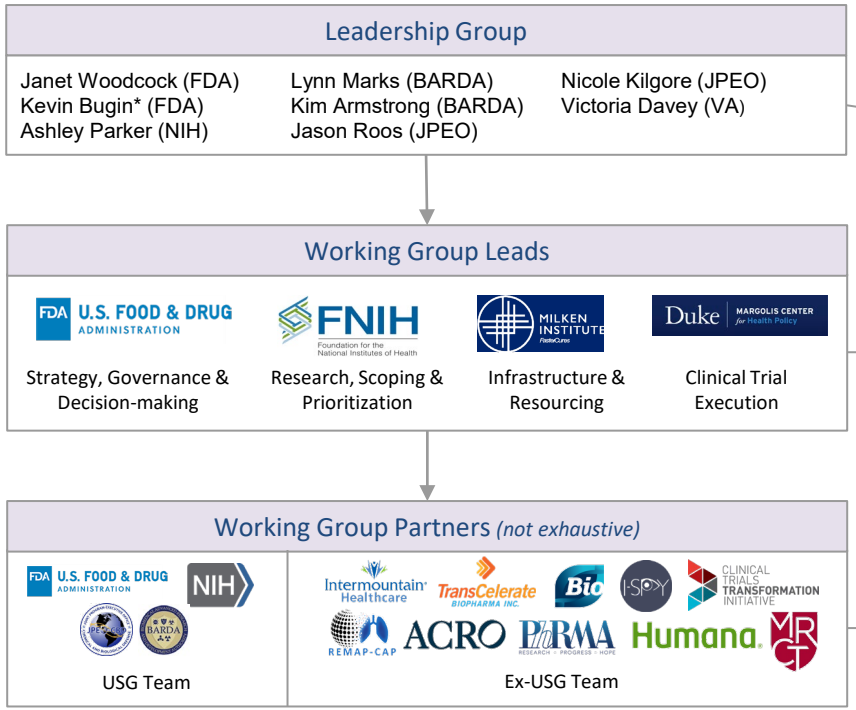
Working groups were formed around key topic areas with oversight from a USG leadership group



Key roles

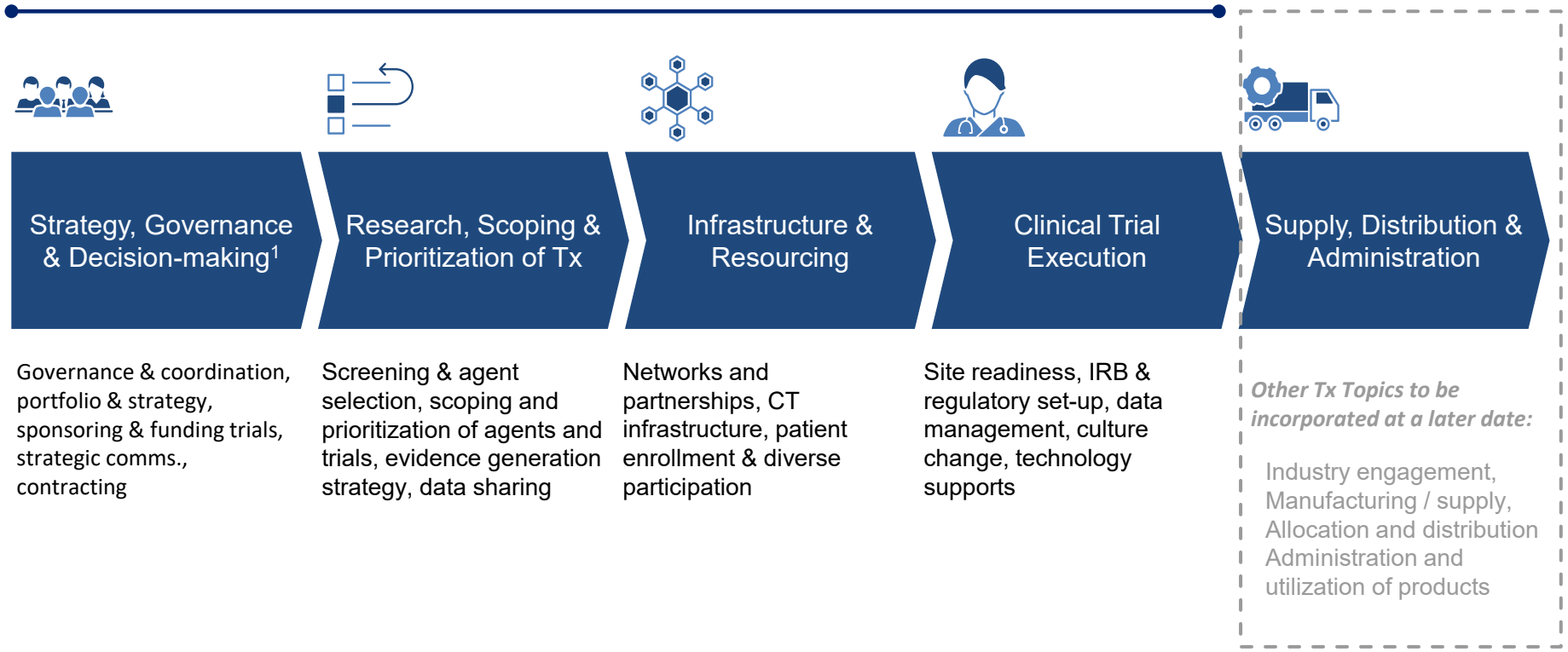
Leadership Group: Oversee overall initiative and provide input on cross-agency & stakeholder buy-in

WG Leads: Coordinate and provide input to the development of lessons learned in the topic areas assigned to them based on expertise

WG Partners: Share lessons learned from their organization's experience and support development of recommendations

*Reach out to Kevin Bugin (PM for initiative) with any further questions: Kevin.Bugin@fda.hhs.gov

Lessons Learned were identified across five topic areas, with four being within scope of this initial effort and discussion today

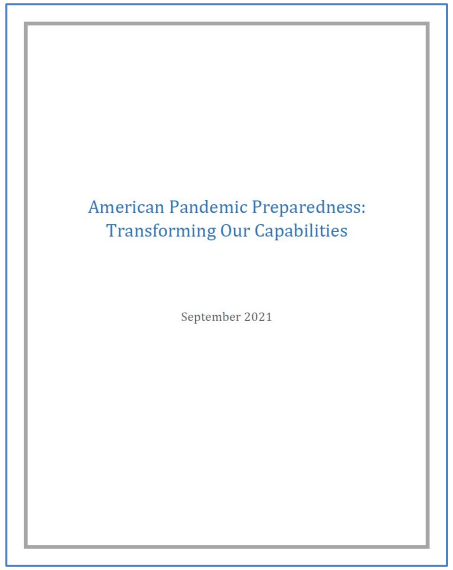


Many of the Tx lessons learned discussed today can be found in the recently shared President's Pandemic Preparedness Plan (Sept. 2021)

- Strength the U.S. Public Health System
  - Invest in public health labs and digital infrastructure
  - Prioritize vulnerable communities
  - Support evidence-based communication

- Improve Regulatory Capacity
  - Platform technologies
  - Clinical trial networks
  - Improved regulatory capacity and approaches at FDA

- Enhanced Program Management
  - Mission Control
  - International Coordination



https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf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Francis S. Collins, MD, PhD

Director
National Institutes of Health

Virtual Public Workshop on COVID-19 Lessons Learned: Clinical Evaluation of Therapeutics

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

September 28, 2021

American Pandemic Preparedness Plan

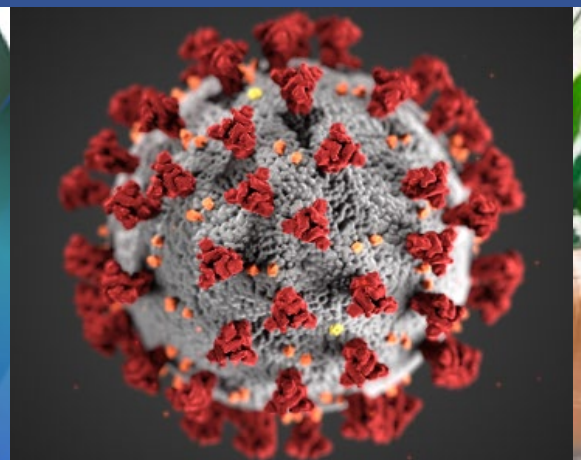
- I. Transforming Medical Defenses
  - Develop vaccines, therapeutics, and diagnostics
- II. Ensuring Situational Awareness
  - Improve real-time monitoring, early warning/predictors and tracking of variants
- III. Strengthening Public Health Systems
  - Invest in digital infrastructure
  - Diversifying scientific workforce
  - Prioritize vulnerable communities and support community engagement
- IV. Building Core Capabilities
  - Improve regulatory approval and capacity for platform technologies and clinical trial networks
  - Secure biosafety and biosecurity measures
- V. Managing the Mission
  - Centralized program management and international coordination

NIH COVID-19 Initiatives:

Experience that can inform the American Pandemic Preparedness Plan

- Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Public Private Partnership
- Rapid Acceleration of Diagnostics (RADx)
- Tracking Resistance and Coronavirus Evolution (TRACE)
- Antiviral Program for Pandemics (APP)
- Community Engagement Alliance (CEAL)






ACTIV Public-Private Partnership

LAUNCH

- On April 17, 2020, 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**
  - Establish a collaborative framework for prioritizing therapeutic candidates and accelerating vaccine evaluation
  - Accelerate randomized clinical trials of promising agents and leverage existing clinical trial networks while maintaining rigorous safety standards
  - Coordinate regulatory processes and leverage assets among all partners

ACTIV Stakeholders

20 INDUSTRY LEADERS

NOVARTIS
Roche
MERCK
RHYTHM THERAPEUTICS
Pfizer
abbvie
AMGEN
moderna
Lilly
Eisai
Takeda
SANOFI
J&J
evotec
AstraZeneca
Bristol Myers Squibb
gsk
NOVAVAX
VIR
GILEAD

8 GOVERNMENT LEADERS

BARDA
CDC
DEPARTMENT OF DEFENSE
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
FDA U.S. FOOD & DRUG ADMINISTRATION
NIH
H-CORE (Formerly Operation Warp Speed)
DEPARTMENT OF VETERANS AFFAIRS

4 NON-PROFIT

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PROGRAM MANAGEMENT

FNIH
Foundation for the National Institutes of Health

ACTIV Focus Area Objectives & Composition

Each focus area is a Working Group that contains several subgroups 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 • Mutational Tracking	• Agent Prioritization • Master Protocol	• Survey Development • Clinical Trial Network Inventory • Innovations	• Vaccines Clinical Trials • Protective Immune Responses • Vaccine-Associated Immune Enhancement • Impact of Vaccines on Transmission • Correlates of Protection

ACTIV Master Protocols:
COVID-19 Therapeutics Prioritized for Testing

- **ACTIV-1 Immune Modulators**
  - Phase 3 inpatient trial: Cenicriviroc, Orencia® (abatacept), Remicade® (Infliximab)
- **ACTIV-2 Monoclonal Antibodies and Other Therapies**
  - Phase 2/3 outpatient trial: AZD7442 (IV)* (IM)*, Brii-196 & Brii-198, BMS-986414 and BMS-986413, LY-CoV-555, SAB-185, Camostat Mesylate, SNG001 IFN-beta
- **ACTIV-3 Monoclonal Antibodies and Other Therapies**
  - Phase 3 inpatient trial: AZD7442, Brii-196 & Brii-198, LY-CoV-555, Zyesami™ (aviptadil acetate) and Veklury® (remdesivir), VIR-7831, Ensovibep (MP0420), Pfizer PF-07304814
- **ACTIV-4 Antithrombotics and Host Tissue Therapies**
  - Phase 3 outpatient trial: Eliquis® (apixaban), Aspirin
  - Phase 3 inpatient trial: Un-fractionated (UF) Heparin, Low Molecular Weight (LMW) Heparin, Unfractionated Heparin and P2Y12 Inhibitors, TXA127, TRV027, APN01, Fostamatinib
  - Phase 3 convalescent trial: Eliquis® (apixaban)
- **ACTIV-5 Big Effect Trial**
  - Phase 2 inpatient trial: Skyrisi™ (risankizumab), Lenzilumab, Danicopan
- **ACTIV-6 Repurposed Drugs**
  - Phase 3 outpatient trial: Ivermectin, Fluvoxamine, Fluticasone

**Enrollment ceased at company's request*
***Denotes** agent lack of efficacy*
***Denotes** proven agent efficacy*

Rigorous Testing is Essential:

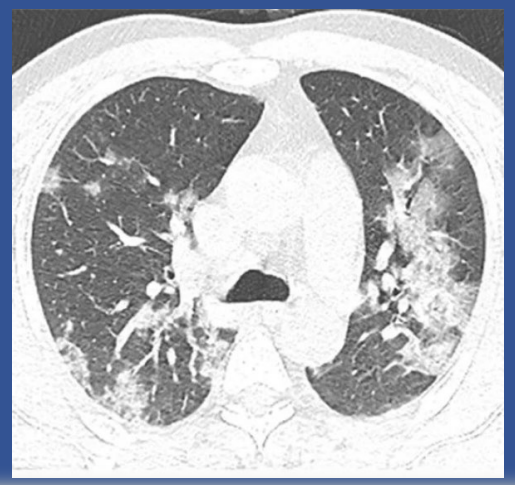
Potentially Promising Therapeutics That Failed In Well-Powered Placebo-Controlled Randomized Trials

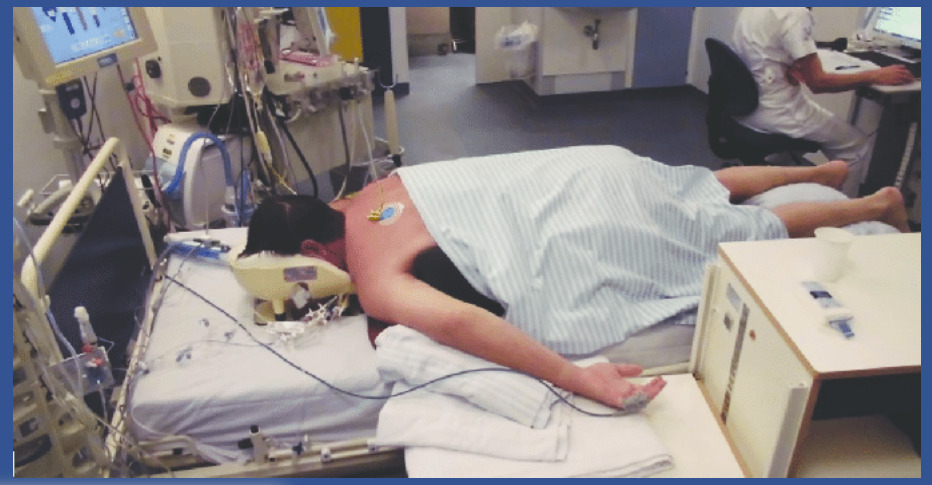
- Hydroxychloroquine (HCQ)
- Chloroquine (CQ)
- HCQ or CQ plus azithromycin
- Lopinavir/ritonavir (HIV drugs)
- Full dose heparin for ICU patients
- Many monoclonal antibodies for inpatients
- Hyperimmune globulin for inpatients

Different Therapies at Different Stages of COVID-19

COVID-19+ Disease Progression

No Symptoms → Outpatient Mild Symptoms → Inpatient No Oxygen → Inpatient Low-flow Oxygen → Inpatient High-flow Oxygen → Mechanical Ventilation





Anti-viral Strategies

Immunomodulatory Strategies

Anti-coagulation Strategies

Antiviral Program for Pandemics (APP)

Accelerate development of a portfolio of safe and effective AVs that directly act against SARS-CoV-2 and other viruses of pandemic potential

Discovery

Build a sustainable platform to discover new antivirals by:

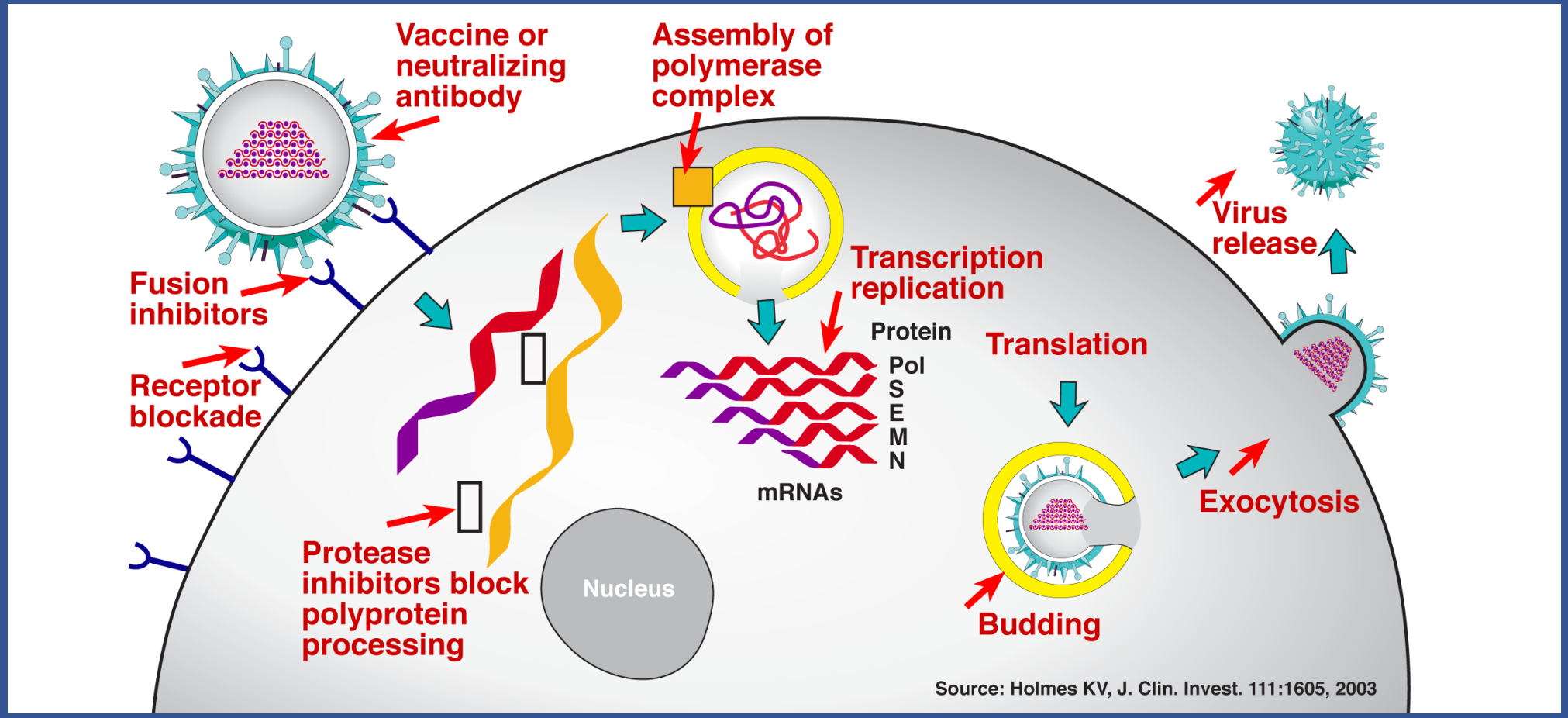
- Establishing multi-investigator, and multi-disciplinary discovery groups (AViDD Centers)
- Using structural and systems methods to identify potential drug targets shared across key viral pathogens
- Progressing promising candidates to IND-enabling work

Development

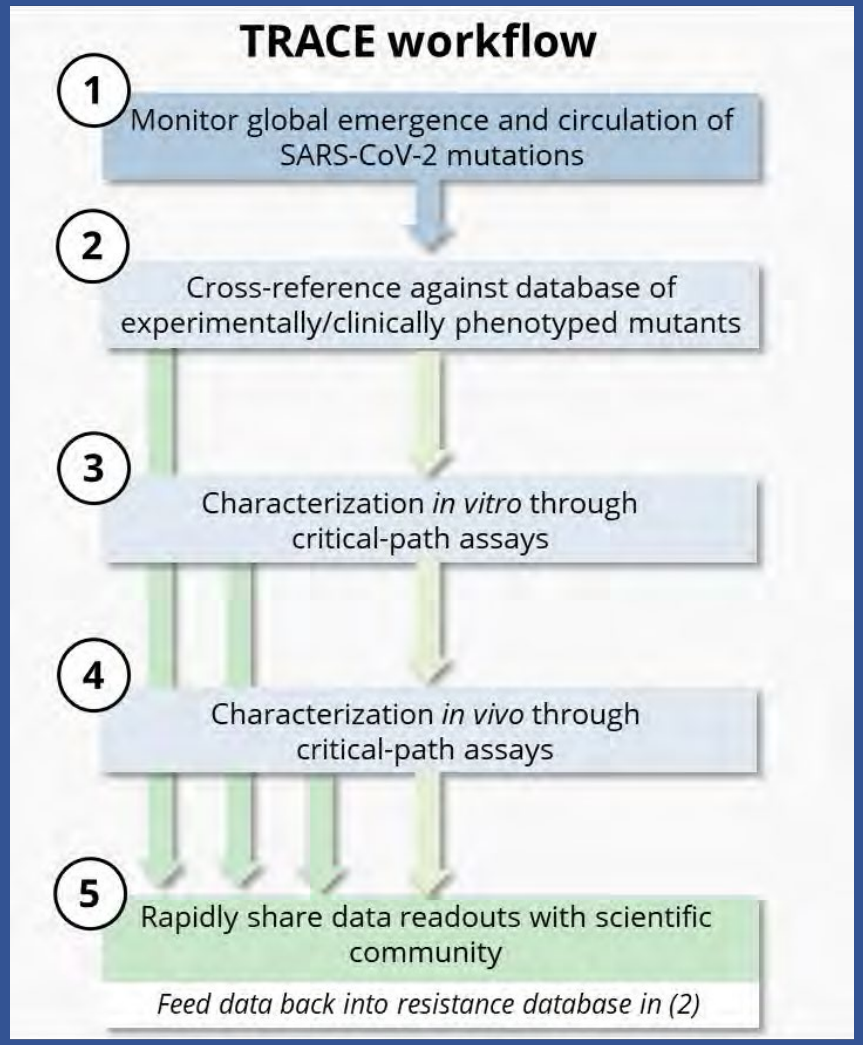
Accelerate clinical testing of promising antiviral candidates by:

- Supporting key non-clinical and early clinical studies
- Establishing public-private partnerships to supplement private sector capabilities (including facilitating third-party collaborations)
- De-risking candidates for further late-stage development

Coronaviruses: Selected Targets for Therapeutics



ACTIV Tracking Resistance And Coronavirus Evolution (TRACE)



TRACE Priorities

- Publish weekly TRACE report summarizing shifting trends in emerging viral variants
- Collect available industry and government agency data on variants in one place
- Generate datasets using standardized protocols and common reference reagents

NIH Community Engagement Alliance (CEAL)

- Community-engaged research and outreach focused on COVID-19 awareness and education to address misinformation and mistrust
- Promote and facilitate inclusion of diverse racial and ethnic populations in clinical trials
  - Prevention, vaccine, therapeutics, diagnostics
- CEAL research teams
  - More than 20 states (Alabama, Arizona, Arkansas, California, Colorado, DC Metro Area, Florida, Georgia, Illinois, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, New Mexico, New York, North Carolina, Pennsylvania, Puerto Rico, Tennessee, and Texas)

Conclusion

- Substantial and rapid progress has been made in prioritizing and testing therapeutics for various stages of COVID-19
- In a pandemic, well-intentioned but poorly designed and underpowered trials can do more harm than good. Academic medical centers must guard against this.
- Through ACTIV and NIH trials, multiple therapies have been proven beneficial; others have been demonstrated to have no value
- Repurposing existing drugs must always be the first approach, and can provide quick “singles” and “doubles”, but generally not “home runs”
- Going forward, the highest priority for coronaviruses is to develop and test targeted antiviral drugs
- Those may need to be used in combination to avoid resistance
- Many lessons have been learned to prepare for future pandemics:
  - Partnerships, master protocols, coordinated trial networks, global reach…

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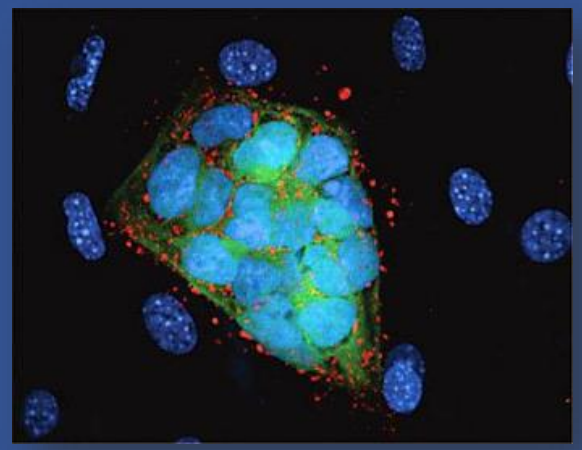
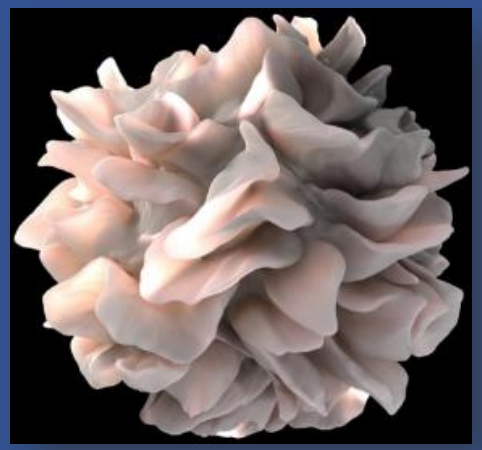
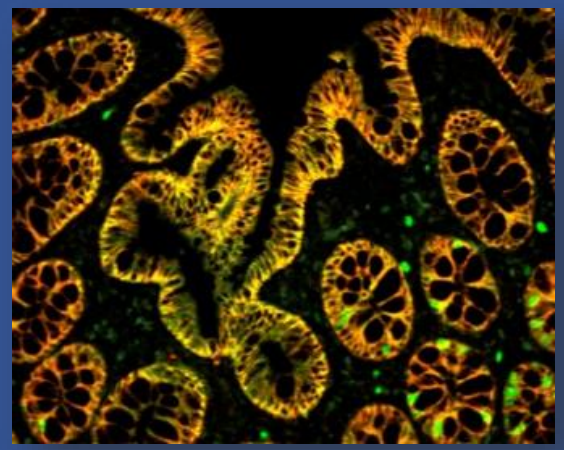

Research, Scoping, & Prioritization

Moderated by

Stacey Adam, PhD
Foundation for the National Institutes of Health

Michael Santos, PhD
Foundation for the National Institutes of Health

Panelists

Janet Woodcock, MD
U.S. Food and Drug Administration

Phyllis Arthur, MBA
BIO

Elliott Levy, MD
COVID R&D Consortium

Sarah Read, MD
National Institute of Allergy and Infectious Diseases
Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Therapeutics-Clinical Work Group Co-Chair

Recommendations

Research, Scoping, & Prioritization

Recommendation 1: Rapidly collect and disseminate enabling information such as pathogen ID, sequencing, and natural history data (through natural history registries).

Recommendation 2: Ensure the clinical trial (CT) ecosystem creates actionable evidence through developing strategy, guidelines, templates, incentives, and capacity building (e.g., prioritize randomized trials).

Recommendation 3: Enable the open sharing of research strategy and plans amongst stakeholders in the CT ecosystem to coordinate activities, including in funding announcements.

Recommendation 4: Establish efficient and effective systems for sharing early research data and results with other researchers outside of publication channels.

Infrastructure & Resourcing

Moderated by

Esther Krofah
FasterCures and Center for Public Health, Milken Institute

Kristin Schneeman
Director, FasterCures

Panelists

Barbara Bierer, MD
Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Michael Kurilla, MD, PhD
National Center for Advancing Translational Sciences, National Institutes of Health

James Mayne, PhD
Pharmaceutical Research & Manufacturers of America

Doug Peddicord, PhD
Association of Clinical Research Organizations and Washington Health Strategies Group

Recommendations
Infrastructure & Resourcing

Recommendation 1: Identify and leverage existing clinical trial network infrastructure (incl. NIH-funded networks, nonprofit & industry/CRO sites networks) and public-private partnerships (e.g., ACTIV) to maintain a 'warm base' for public health emergencies (PHEs) and that can be deployed against high priority unmet needs.

Recommendation 2: Build, engage, and support more community-based institutions/networks to improve the diversity and representativeness of clinical trials and ability to deploy pragmatic trials.

Recommendation 3: Remove post-pandemic barriers to expanded adoption of decentralized/hybrid trials and remote monitoring tools.

Recommendation 4: Research, develop, and share best practices on managing patient enrollment with a focus on prioritized trials/platforms while enabling co-enrollment.

Recommendation 5: Determine best practices for increasing participation in trials from under-represented communities and create action plans for improvement.

Clinical Trial Execution

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Moderated by

Mark McClellan, MD, PhD
Duke-Margolis Center for Health Policy

Sarah Sheehan, MPA
Duke Margolis Center for Health Policy

Panelists

Samuel Brown, MD, MS
Intermountain Medical Center and University of Utah

Janice Chang
TransCelerate BioPharma Inc.

Clark Files, MD
Wake Forest School of Medicine

Monica Webb Hooper, PhD
National Institute on Minority Health and Health Disparities

Kate Zenlea, MPH, CPH
The Global Health Initiative at Henry Ford Health System

Recommendations

Clinical Trial Execution

Recommendation 1: Reform regulatory oversight to avoid impediments in trial conduct and review/ maintain effective public health emergency (PHE) regulatory flexibilities (incl. development of best practices for IRBs/cIRBs, indemnity, streamlining FDA collaboration across centers, fit-for-purpose HRP training).

Recommendation 2: Develop tools, best practices, and resources for timely and effective trial participation, including site readiness assessment tools.

Recommendation 3: Assure that regulatory and prioritization framework for priority questions and data requests will generate optimal and timely clinical site participation.

Recommendation 4: Develop a retrospective assessment report for federal agencies, funders, academic and industry partners on driving culture change in pandemic trial participation, informed by clinical and patient communities. Engage and leverage “early adopter” health systems and community providers to link effort to clinical trial culture change.

Recommendation 5: Improve technology support, capacity, and motivations: capabilities for automated clinical trial data collection via: EHR and EDC integration, automated lab data, tools for remote patient monitoring & data collection, electronic registries (for natural history and conversion to trials), and registry/trial payment incentives to encourage adoption.

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Public Comment

Limited to one-and-a-half minutes per speaker

This is an open public comment forum;
neither the Foundation nor FDA will respond to comments.

Additional comments may be submitted through the public docket (Docket ID:FDA-2021-N-0977) at Regulations.gov.

Closing Plenary

Kevin Bugin, PhD
U.S. Food and Drug Administration & former Federal COVID-19 Response or Countermeasures Acceleration Groups

Takeaways from Opening Keynote

- Important to take time to take stock even when still in the pandemic—we've made substantial progress since April 2020
- Initial clinical research efforts for therapeutics were "scattershot" which created barriers to generating actionable evidence early
- Remarkable collaboration was seen with ACTIV between NIH, FDA, HHS, CDC, academia and industry
- Extraordinary "all-of-government" collaboration in response to COVID-19 and this was carried forward to the collaborative Lessons Learned effort we discussed today
- President's American Pandemic Preparedness Plan lays out an ambitious plan for future pandemics

Takeaways
Panel 1: Research, Scoping, & Prioritization

- In a public health emergency, there is a strong desire to help patients – everyone jumps in and tries to help. A preparedness plan that communicates what can be done from Day 1 and when and how additional information and guidance will be disseminated will improve coordination and efficiency

- When determining criteria for scoping and prioritization, need to consider scientific considerations (e.g., mechanism of action, safety database) as well as scalability (e.g., availability of clinical supply, manufacturing)

- In addition to the immediate-term goals, keep the long-term pipeline and broader view in mind – bridging the 'valley of death' is an important intermediate goal as well

- Must ensure trials are designed to yield actionable evidence

- Systematic communication channels to promote timely information-sharing is critical

- Need strong and continuous investment in pandemic preparedness, including infrastructure at the community-level and therapeutic areas such as antiviral R&D

Takeaways
Panel 2: Infrastructure & Resourcing

- There are networks and infrastructure, but it exists in different states of readiness, and interoperability or rapid coordination that new or larger networks necessitate was difficult in real-time – Key question: how do we keep the needed infrastructure “warm and ready”?

- The underlying infrastructure and resources circumstances were changing.
  - Shifts in more remote/decentralized trial practices, and digital health tools, while needed, were a struggle to implement for new sites in particular
  - Basic need issues, such as PPE and clinical research professionals limited
  - Emerging variants, standard of care evolution, etc.

- Collaboration with and across industry and with regulators, key enabler of the flexibility and progress that was needed during the evolution of clinical trials during the PHE

- We did not have the infrastructure to effectively reach out to underserved / underrepresented patients. We need to engage with more community sites and bring them into the networks. Identifying and addressing their needs may be the answer to the key question

Takeaways
Panel 3: Clinical Trial Execution

- Importance of right-sizing the research question and appropriately matching that up to the capacity at sites from the get-go (including getting capacity at new sites/networks up to a new normal)
  - This requires engagement of community trial sites going forward
  - Beginning with the social determinants of health in mind (i.e., access to high quality healthcare)
  - Keep in mind eligibility criteria and its impact on diversity

- Clinical research needs to be as simplified, standardized, and supported as much as possible (include thinking internationally)
  - Regulatory requirements (central, sIRBs), administrative (informed consent), and legal indemnification should be clearer
  - Address the overhead (payrolls and risk management)
  - Contracting and other agreements
  - Investigational drug/pharmacy management

Takeaways
Panel 3: Clinical Trial Execution cont'd

- "What do clinicians and healthcare providers do: Do they treat? Or do they respect, treat and learn?"

- Training the next generation is an opportunity to accelerate culture change for the next gen of clinical care providers and clinical researchers

- Integrating novel tools and technology into the clinical care (needs to be widely available)

- Culture change is needed. We need:
  - True stories that demonstrate a real value proposition for communities
  - Adjustments to broader systems, frameworks, and incentives to enable research in clinical care
  - Relationships that reinforce changes over time

Next steps

- Again, today is another step in a journey and not intended to be the end of this conversation
- We hope that our panel members, participants, and our leaders across the clinical trial ecosystem will carry forward the lessons learned today and put them in place to ready us for the future of this pandemic and future pandemics response

Reminders:

- There will be a meeting recording and the slides (updated) will be available at ReaganUdall.org
- There will be a summary that builds on the pre-read, incorporating today's discussion and public comments
- The docket will remain open (ID:FDA-2021-N-0977), please submit comments and ideas, and we'll be summarizing that public feedback once it closes

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Thank you