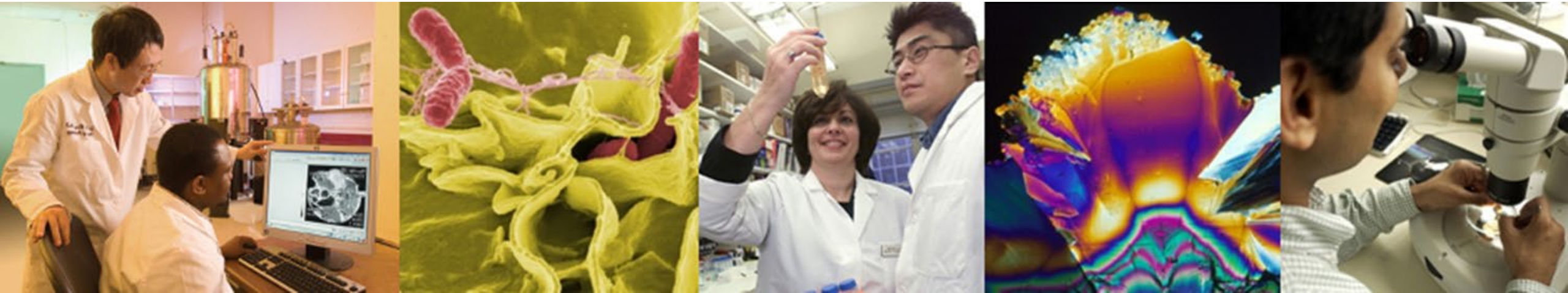# Lessons Learned During the SARS-CoV-2 Pandemic

121st Meeting of the Advisory Committee to the Director (ACD)
National Institutes of Health

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observations

People

- Paramount concern for the health and safety of NIH staff and extramural workforce
  - How best to ensure:
    - Work/life balance
    - Mental health
    - Dependent Care
    - Safe return to Work
  - Concerns of professional women are much more serious than some had previously appreciated
- Enhancing work flexibility for NIH staff and increasing empathy towards those with challenges -> creative, timely results!
  - Once again, NIH staff rose to the occasion!
- Have attempted to provide maximum flexibility to extramural workforce

Innovation

- Extraordinary value in working with Industry, FNIH, other USG entities (ACTIV; OWS) – can these partnerships be maintained going forward or is a crisis required?

- Does the RADx *Innovation Funnel* represent a new model for SBIR/STTR? For other awards?
  - Opening opportunities for new players
  - Stress forces "early failure"

- The importance and value of IRP when a rapid scientific response is needed was underscored
  - Vaccine Research Center (VRC) - the investigational COVID-19 vaccine, mRNA-1273, was co-developed by the biotechnology company Moderna, Cambridge, MA, and the VRC in NIAID/NIH

NIH Clinical Trials

- Unprecedented response by NIH to a global crisis
  - But also revealed some of the challenges of activating academic centers; CROs proved to be generally more nimble
- The ACTIV Clinical Trials WG created "shovel-ready" network of networks for COVID trials
  - But harmonization/interoperability between networks, both within and among ICs was/is challenging

NIH Clinical Trials

- Opportunity to design and prioritize well-powered RCTs through ACTIV master protocols was crucial for rapid progress
  - Reward system in many AHCs at odds with the need to conduct larger, harmonized CT across networks to ensure adequate power
    - How to ensure appropriate "academic credit" for all involved and not just the PI?
- COVID highlighted the critical need for emphasizing diversity in trial enrollment
  - Moderna vaccine trial provided important lessons
  - But also made it clear that that this capability is uneven across networks

Peer Review

- Virtual meetings are working
  - Review discussion, engaged, management, score distribution are all similar to in person meetings
  - CSR currently sees no change in reviewer diversity, but perhaps moving forward this will change
  - Recruiting members is easier
- Security matters - centralized access control/monitoring; password requirement; waiting room enabled to vet access; disabled recording/screen sharing/livestreaming/chats
- Significant cost savings
- Need a focused data-driven survey approach to supplement the current information that has been gathered

General Operations

- During a surge in demand it is critical to have a process to prioritize and manage access to limited resources
  - Project managers proved invaluable in many cases
  - The trans-NIH group, The Coronavirus Response Team, proved essential to coordinating logistical issues related to NIH Staff, space, and other logistical issues
- Communication, both internal and external, proved essential
  - Consistent, timely, tuned to the specific audiences
  - Various information portals helped inform both internal and external stakeholders

immediate challenges

Many Scientific Questions

- Vaccine hesitancy

- Additional testing paradigms
  - "At home" testing
  - Novel surveillance technologies

- Unanswered research questions – acute, short term and long-term impact of COVID-19 in different populations

- Pandemic revealed the extreme divide in health disparities – how best to redress?

Restarting Biomedical Research

- Not all research organizations and/or grantees are able to adapt to the pandemic

- Balancing funding decisions for COVID-19 needs versus overall IC mission
  - Human studies with primary data collection, the pandemic paused or stopped in-person recruitment, informed consent, interventions, and data collection.

- How best can NIH protect investments to especially at-risk groups (e.g. trainees, clinical trials, ESIs)

Peer Review

- Hybrid models should be considered
    - Alternating in-person and virtual
    - Meeting with both in-person and virtual
- Concerns and unanswered questions
    - Lost networking, especially those earlier in their career
    - Are some reviews better in-person vs virtual?
    - What is the best time format (standard full day or protracted half day – Zoom fatigue and time zone considerations)?
    - Environment, internet, and other infrastructure needs for NIH review staff, NIH program staff, and reviewers

Operational Considerations

- Evolving from a crisis response to a chronic state

- Consider need for reconfiguration of physical workspace

- Planning for the next crises
    - Emergency management center?
    - Retrospective analysis underway to inform strategic planning for next event

- Deficits due to lack of demand for fee-for-service operations

discussion