Dear Colleagues —

As always, it was great to work together on Friday morning -- the slides are linked here, and the recording and transcript is linked here.

Roadmap Manuscript -- Framing, Consultations, Recommendations
Thanks for the thoughtful and productive engagement on the Roadmap paper this morning. This was a great follow-on to the consultations Tim and I had last week. Further consultations are underway this week, some inspired by Friday’s meeting. Tim and I took lots of notes, and are integrating a CSWG-wide perspective. We will share a revised manuscript late this week.

Friday’s call showed significant support for recommending some sort of a standing “Pathogen Standards Working Group.” Our collective experience in the ~500 days we’ve been working together makes a case that there are gaps in attending to standards infrastructure in the diagnostics ecosystem. Our consultations and our meeting on Friday is assembling a description of those, and as part of our Roadmap paper we’ll continue to compose them into a “charge” for a Standards Working Group.

I believe that we’re filling gaps. Those gaps will be best filled if we develop a crisp remit for institutional action, either by an existing pandemic preparedness/response body, or alternatives.

I include some of my notes & takeaways from Friday’s meeting on such a charge below.

WG Meeting discussion points -- Role, Remit, and Considerations for a Pathogen Standards Working Group:

- Can we argue that a standing working group is better prepared to rapidly respond
Can we argue that a standing working group is better prepared to rapidly respond to an emergent pandemic?

- Could a standards working group advocate for policy to prioritize standards development and dissemination?
  - for instance, making plasma packs available immediately to develop standards for serology, even as plasma packs are being used as therapeutics
  - From WHO: see *Cross-cutting research priorities here:* "An enabling priority on access to information, reagents, tools, protocols and standards without which none of the above [understanding transmission, immunity; assay development, best practices & protocols] can proceed efficiently."

- Could a coordination body coordinate & establish access to widely-available reference materials in advance of a WHO International Standard?
  - could those then be calibrated to the WHO IU when available?

- Consider WHO Research Roadmap for guidance and coordination charge
  - include other pathogens in worklist
    - see *WHO prioritizations*

- Globalize -- include low- and middle-income nations
  - Include the Global South
  - CSWG membership is largely US-based, can we engage regulatory systems other than FDA?
  - WHO’s mission of “Health for All”

- Democratize standards
  - while maintaining fit-for-purpose quality

- Include regulators and public health agencies in working group activity
  - coordination will raise confidence in regulation and public health policy
  - would coordination have made results from FDA Reference Panel better?

- Can we demonstrate utility of harmonized standards?
  - use NIBSC collaborative study results?
  - show INSTAND EQA results, and emphasize variation of Cq measurement results
  - show disappointing correlation between FDA Reference Panel LODs and EQA LOD claims (see below graph in this email)
  - show limitations of conclusions of *recent MMWR report* using Cq data alone (*Figure 2*).
    - Authors do a good job of calling out limitations, including the limitations of reporting signal only from any diagnostic PCR test designed to be thresholded to yield a qualitative positive/negative result.
  - can we develop advocacy for the utility of quantitative, calibrated, diagnostics to better respond to a pandemic
Correlation of FDA Reference Panel LOD results from 7 Dec 2021 with LODs reported in EUAs
(unpublished graph showed in meeting)

Cheers and stay safe!
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