From: **Marc Salit -- Coronavirus Standards WG** msalit@stanford.edu
Subject: CSWG Mtg Summary 6 August 2021 - Roadmap Paper Framing and Recommendations
Date: August 10, 2021 at 12:48 PM
To: Marc Salit msalit@stanford.edu

Coronavirus Standards Working Group Meeting Summary

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.

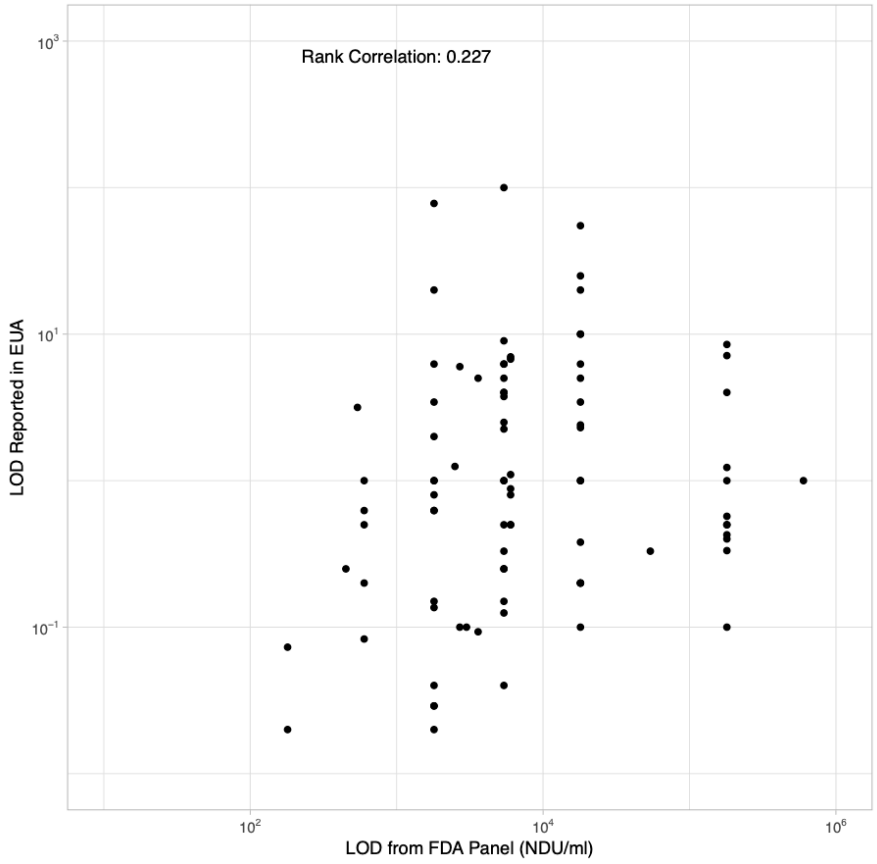
I include some of my notes & takeaways from Friday's meeting on such a charge below.

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 prioitizations
- 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!
Marc

Marc Salit, Ph.D.
Director, Joint Initiative for Metrology in Biology — http://jimb.stanford.edu
SLAC National Accelerator Laboratory
Adjunct Professor, Departments of Bioengineering and Pathology
Stanford University