From: **Marc Salit -- Coronavirus Standards WG** msalit@stanford.edu
Subject: CSWG Mtg Summary 26 Feb 2021: Serological Harmonization Study Landscape
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Coronavirus Standards Working Group Meeting Summary

Dear Colleagues —

Thanks for our meeting this morning Friday 26 February — May Chu and Jon Windsor of CU Anschutz School of Public Health presented more details and led discussion about a harmonization study for serological reference materials. Discussion focused on priority study objectives and implications for design. We had a more thorough conversation about the materials and tests that would suit the study, and agreed to have more follow-up in smaller meetings next week (watch for details).

Our meeting recording is here, and the slide deck is here. Our website will be updated to include the slides and this meeting summary.

I'm grateful for everyone's engagement and for so many who are interested to participate by bringing materials to the study or measuring the panel we assemble (or both!). There was good discussion of the variety of materials and assays, and it came clear that we need a way to decide what is in scope (for both materials and assays), and to prioritize both the objectives and the inclusion criteria.

I came away with observations enumerated below about the study, and propose we focus on developing consensus around them:

This proposed study objective includes the intention ***to enable equitable, global access to harmonized SARS-CoV-2 serology reference materials***. That will shape the scope and design of the study.

I think we have really appropriate targets for the most important "customers" of our harmonized reference materials:

1. Tests that offer measures that are correlates of protection (vaccine

1 - Tests that offer measures that are correlates of protection (vaccine performance)
2 - Tests deployed for serosurveillance in low resource settings.

This leads to some criteria for materials (in addition to the WHO IS):

- should be widely available
- should be reactive in measurements of correlates of protection
- should be reactive in measurements for serosurveillance
- should be representative of circulating variants
- could include serum samples from vaccinated individuals

And a set of questions to answer to develop the criteria for what assays to include in the harmonization study:

- Qualitative v. Quantitative?
- commercially available tests?
- LDTs?
- BSL-1?
- Vaccine Performance Assays?
- Field assays suitable for serosurveillance ?

Cheers!
Marc

P.S. -- I briefly confirmed that our timeline for shipping the sample panels for our viral RNA Harmonization Study is 8 March 2021.

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