From: **Marc Salit -- Coronavirus Standards WG** msalit@stanford.edu
Subject: CSWG Mtg Summary 12 Feb 2021: Serological Standards Harmonization Study Proposal
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Coronavirus Standards Working Group Meeting Summary: Harmonizing Serological Standards

Dear Colleagues —

Thanks for our meeting this morning Friday 12 February — May Chu and Jon Windsor of CU Anschutz School of Public Health presented a candidate harmonization study for serological standards, and led a discussion on possible study purpose, design, and principles.

I briefly reported a delay in our timeline for the viral RNA Harmonization Study -- RNA panels will ship to labs on 8 March 2021.

The proposed **Serolgical Harmonization Study** is familiar, inspired by our viral RNA study:

- calibrate a variety of widely available serological standards to the WHO International Standard so all can be expressed in the International Unit
- enable equitable, global access to harmonized SARS-CoV-2 serology reference materials

The slides from this morning are here and are posted on the website, and the link to the meeting recording is here, with a transcript.

Jon proposed forming teams for 1) Materials recruitment, 2) Labs recruitment, 3) Data reporting, 4) Analysis. **Please reply to this note if you're interested to participate in any role.** The list below describes some of the team objectives.

Critical first work in the teams will be to come to consensus on the principles for selecting materials, labs, and assay methods -- these principles are needed in advance of recruiting. I list some suggestions for participation and some discussion notes from this morning's meeting:

- strong interest to include vaccine developers as participating labs
- consider panel antigenicity changes with emerging variants
    - anecdotally there is a several-fold difference with the B.1.351 or 501.V2 variant that emerged in South Africa
- would qualitative test results be useful in this study?
    - how would we use them?
- the role of 'neutralization' assays in the study -- both LDT and potential proxy assays like the GenScript EUA assay
- establish principles to develop logistics -- single lab to manage (CU?) or multiple points to distribute?
- pooled samples versus unpooled samples from recovered individuals?
    - how to treat these differently?

Next week we'll hear a summary from our colleagues at INSTAND (Heinz, Peter and Martin) who will present a summary of their experience of operating 3 serology EQAs.

Our meeting next Friday 19 February will happen at the usual time (0800 PST) and zoom coordinates, watch for the invite!

Cheers!
Marc

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