

**From:** Marc Salit -- Coronavirus Standards WG msalit@stanford.edu  
**Subject:** CSWG Mtg Summary 23 October -- Harmonization Study Plan  
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# Coronavirus Standards Working Group Meeting Summary

Dear Colleagues –

Thanks to you all for the robust scientific conversation this morning as we finalize the plans for the Harmonization Study. We had great progress and salient conclusions.

Our slides from this morning are [attached here](#). Our meeting was recorded, and the recording can be viewed at this [link](#).

Critical to our progress is this definition:

- The CSWG “Harmonization Study” will compare a panel of SARS-CoV-2 controls and calibration materials to put them on the same abundance scale.

It was suggested that we qualify the term 'abundance scale' with a modifier to indicate that the scale is relative, and there was lots of discussion of what unit is appropriate for the scale. The best observation is that the study can proceed without considering or resolving these matters.

Also critical to our progress was the assertion of “**What this study is NOT.**” It is *not* a comparison of tests, or of labs, or a survey of test or method performance for LOD, precision, repeatability; it is not a study of commutability.

We formed teams to develop and operate the study. One to recruit the samples for the panel, another to recruit the labs, and another for the experiment design, reporting, and analysis. [Russell Garlick](#) is leading the sample recruitment team in partnership with [Hui Wang](#), [John Sninsky](#) is leading the lab recruitment team with [Sebastien Fuchs](#), and [Jim Huggett](#) and [Sasha Zaranek](#) are leading the design/analysis/reporting team.

Please watch for follow-on emails to convene working teams and recruit and operate the study. I will try to re-animate the Slack to facilitate this!

A very rough draft scope of the study is here, absolutely subject to refinement.

#### Materials:

- between 6-12 materials, all suitable to be extracted
- inactivated virus, recombinant virus, 'packaged' virus
  - NIBSC candidate IS materials to be included
- 4 nominally identical samples of each material to each participating lab
  - at high level suitable for dilution to the range that suits the participating laboratory measurement process

#### Labs:

- Targeting about 9-12 labs
  - around 3 NMIs, 3 Test Developers, 3 Clinical Labs

#### Reporting:

- Each participating lab reports back quadruplicate results (leaves room for a failed sample while still providing 3 results)

#### Analysis:

- Develop an open repository for results and reports
- Develop a dashboard that summarize the data analysis
- analysis yields BOTH relative and absolute measures of copies/mL for each sample in the panel, with estimate of uncertainty.

#### Timeline:

- 23 Oct
  - convene teams
- 26 Oct
  - teams meet
- 28 Oct
  - recruit samples and labs
- 2 Nov
  - send materials to JIMB
- 12 Nov

- 12 NOV
  - JIMB distributes panels
- 18 Dec
  - Labs report results

Cheers and best regards!

Marc

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