Coronavirus Standards Working Group Meeting Summary: Harmonization Design Review

Dear Colleagues —

Thanks for the great engagement this morning — we had a pseudo-directed design review of the CSWG Harmonization Study, and came to a study design that will create a harmonized RT-qPCR scale relative to the candidate WHO IS material.

Along with the study panel we assemble, we will distribute the lyophilized candidate IS and each RT-qPCR lab will rehydrate and prepare a dilution series of that material in their "local" buffer solution, which will be measured along with the panel. All will be done in quadruplicate. Results of these measurements will be reported in Cq and centrally analyzed.

The candidate WHO IS material will act as a calibrant for the full panel of CSWG study materials, and results will establish values for the study materials traceable to the value of the candidate WHO IS.

The Sample and Lab teams will revise their recruitment letters to reflect the design refinements.

We will have subgroup meetings of the Samples, Lab, and Design/Reporting/Analysis teams next week.

Logistics remain to be established and a protocol will be developed to provide guidance for the RT-qPCR measurements. A separate protocol will be developed to provide guidance for the digital PCR measurements, which will of course also report results that can be compared to the nominal value of the candidate WHO IS.

I [link here](#) the slide deck I prepared for today's 30 October CSWG meeting, but the order in which the slides were displayed was not linear, and not all slides were displayed. The meeting recording, which is [linked here](#), is the authoritative record.

Best regards to all!
Marc

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