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Harmonization Study Plans: More delving...

Coronavirus Standards Working Group

What should a Coronavirus Standards Working Group do?



Assure development and availability of standards, controls, interlab testing, knowledge to support successful rollout & scaling of 2019-nCoV testing



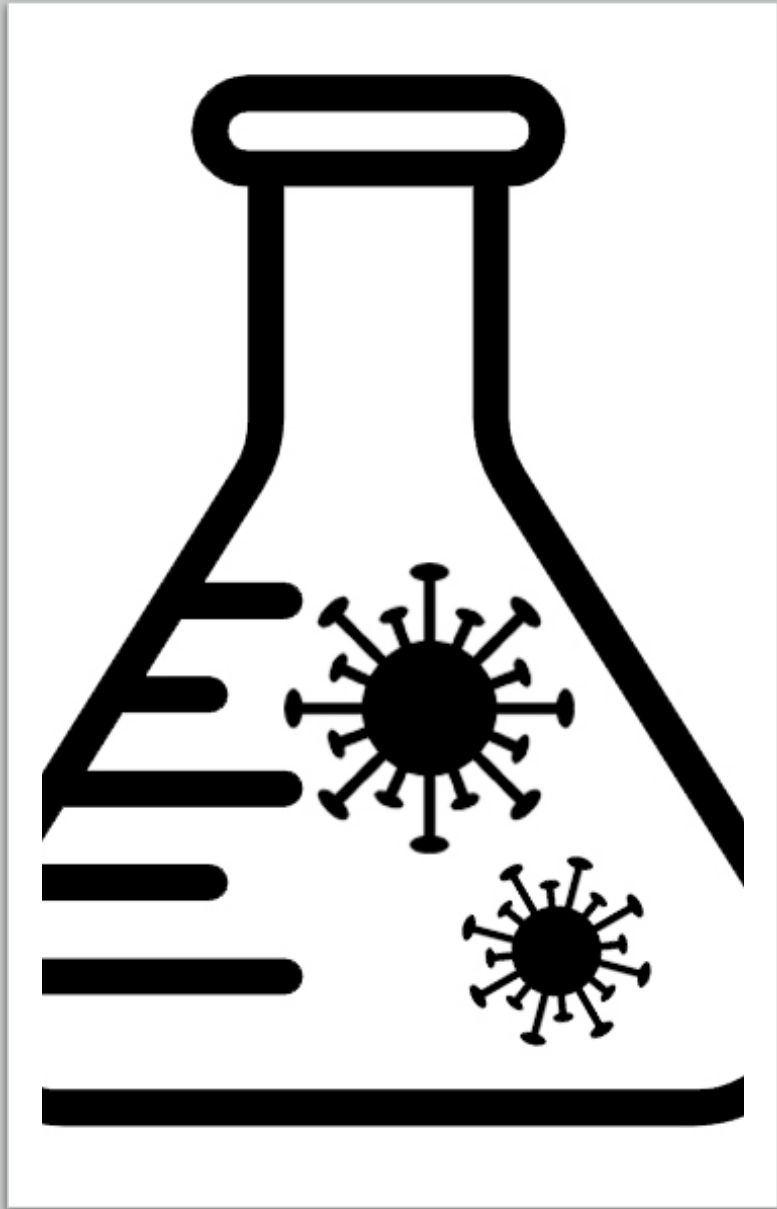
Identify and develop critical infrastructure to support...

- confidence in test results
- interoperability
- scale-up
- long-term capacity



Identify best practices that should be institutionalized

Learn what we need to so next time we have a global network in place ready to make standards.



Harmonization Study

What tests where? What do we need in an SOP?



What tests to do
at what labs?



What do we
need for SOPs?



Timeline

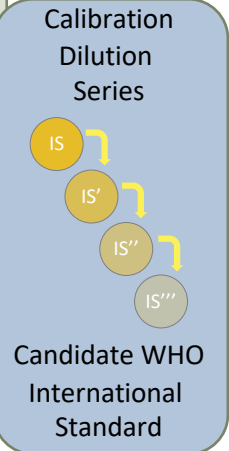
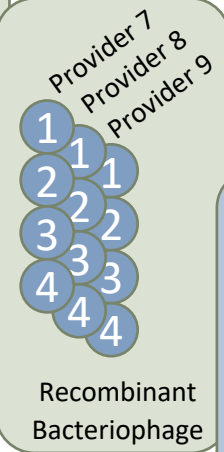
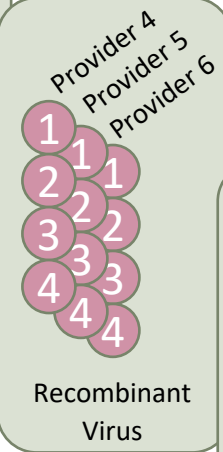
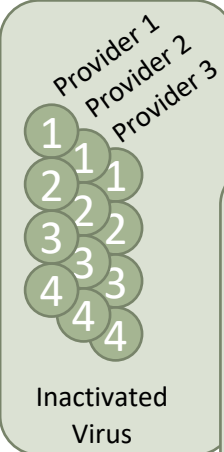
Purpose of Harmonization Study

The CSWG “Harmonization Study” will establish the equivalence of SARS-CoV-2 RNA target concentrations across a panel of materials and calibrate those results against the WHO International Standard (IS) reference sample.

By calibrating with the WHO International Standard (IS) the values on the materials included in this study can be assigned in the International Unit for SARS-CoV-2.



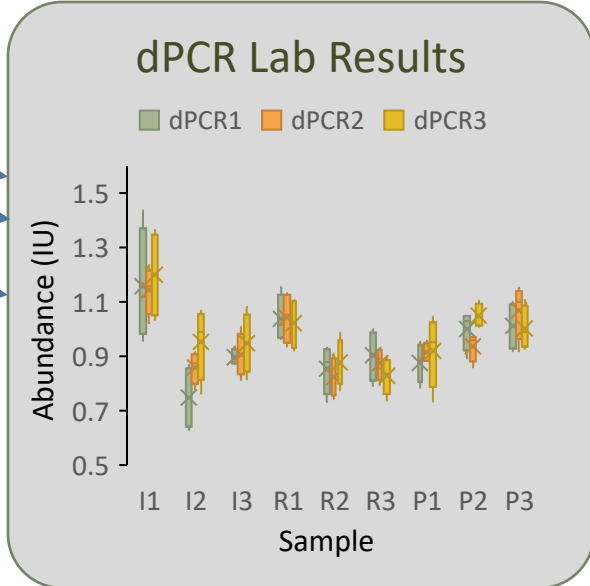
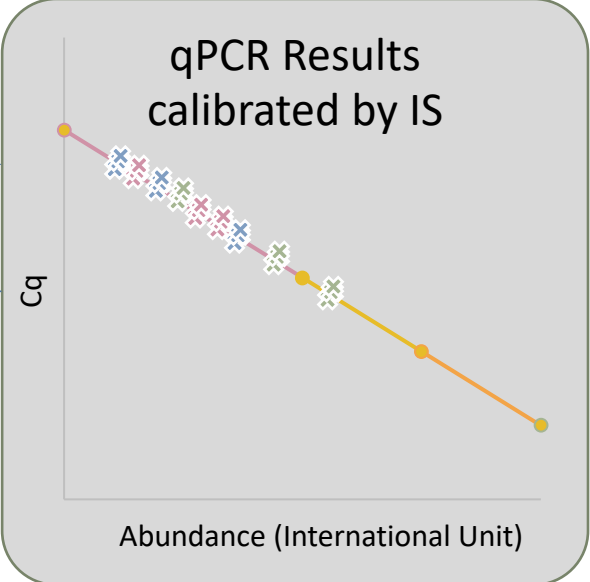
CSWG Harmonization Study Design



Standards and Controls Providers will contribute materials to be compared to candidate WHO International Standard (IS) with RT-qPCR and dPCR.



Labs will measure study materials calibrated with candidate IS. All results will be harmonized to the value of the IS.



What this study is not going to do



a comparison of tests



a comparison of labs

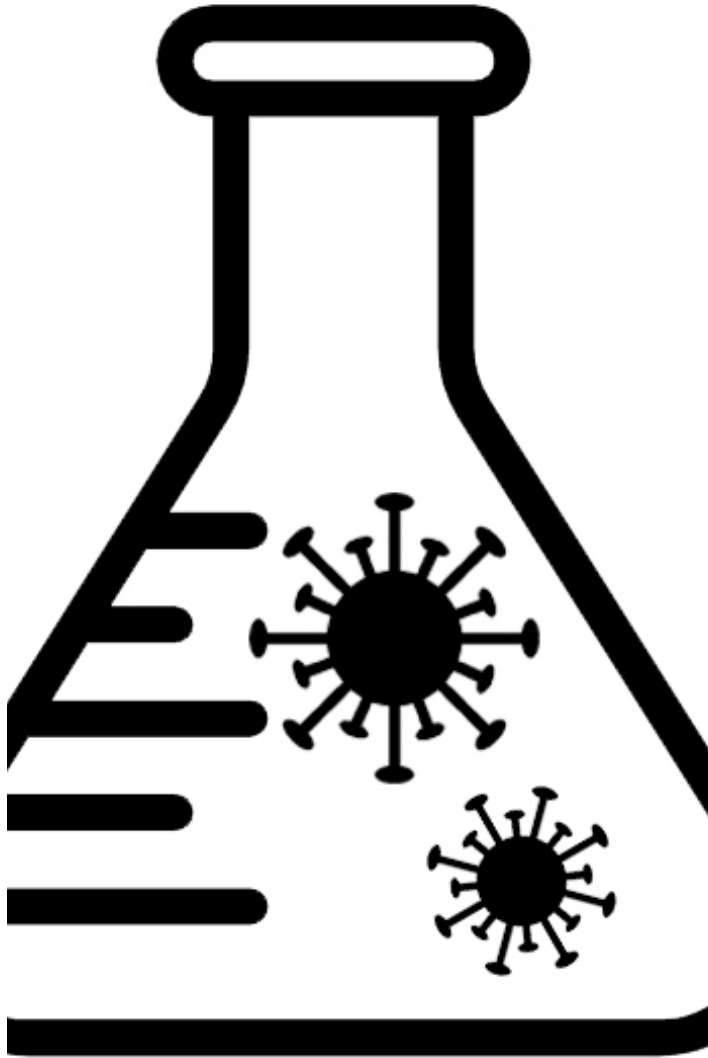


a survey of method performance (LOD, precision, repeatability)



an evaluation of commutability

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What do we need in an SOP?



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Timeline

Key bits for the SOP



Sample rehydration

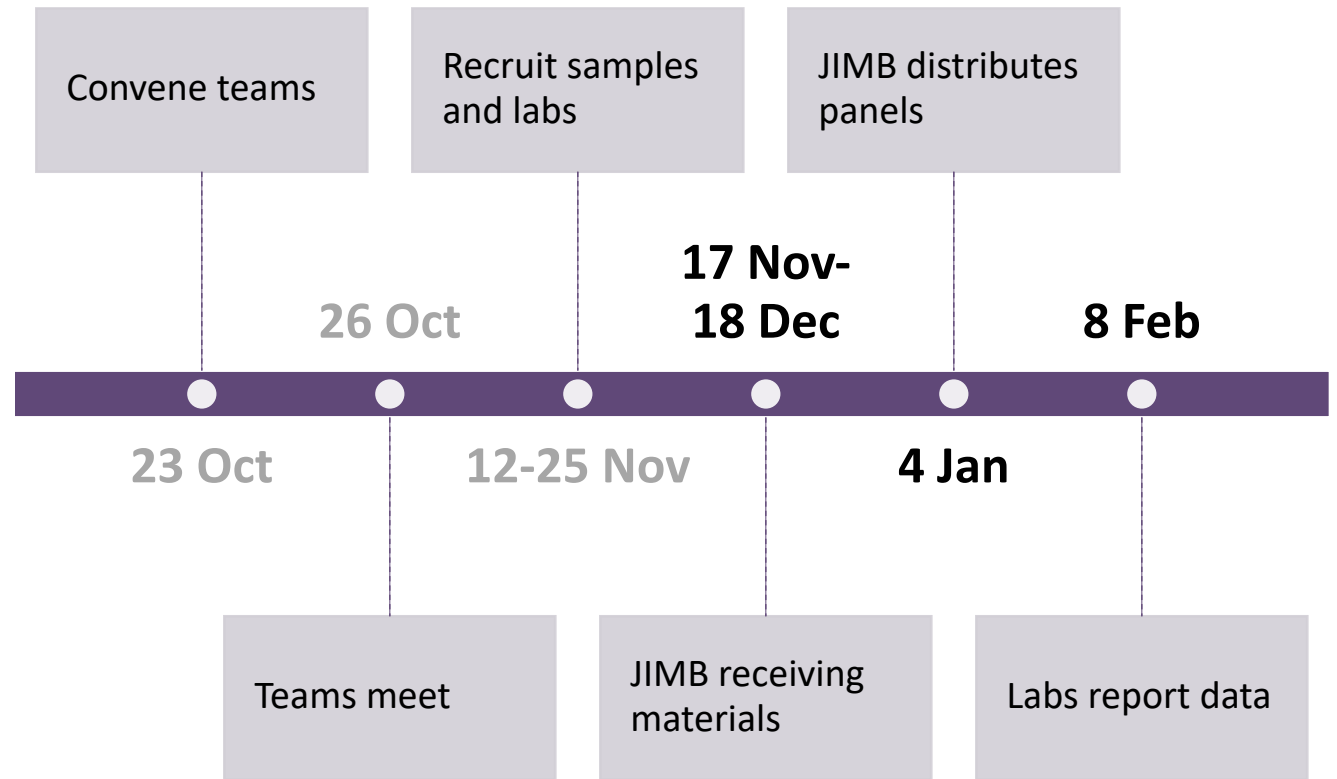


Sample dilution



Calibration curve

Timeline & Logistics



Reporting



Platform

JIMB to work with Curii



Protocol Information

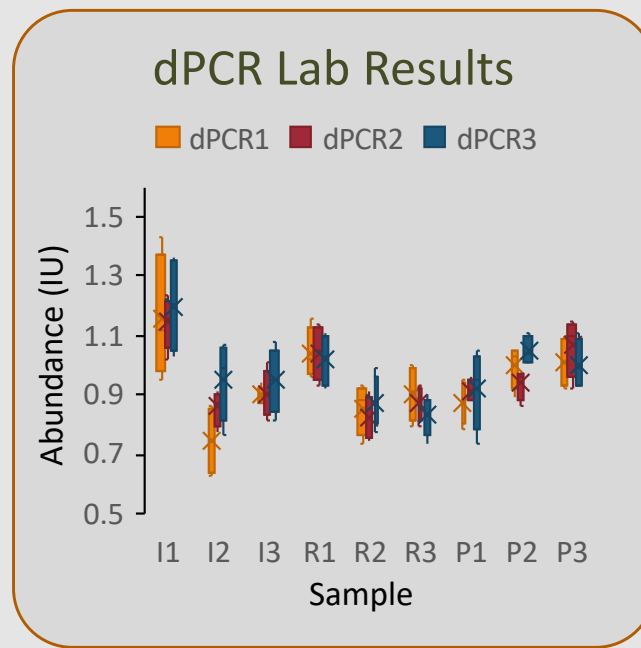
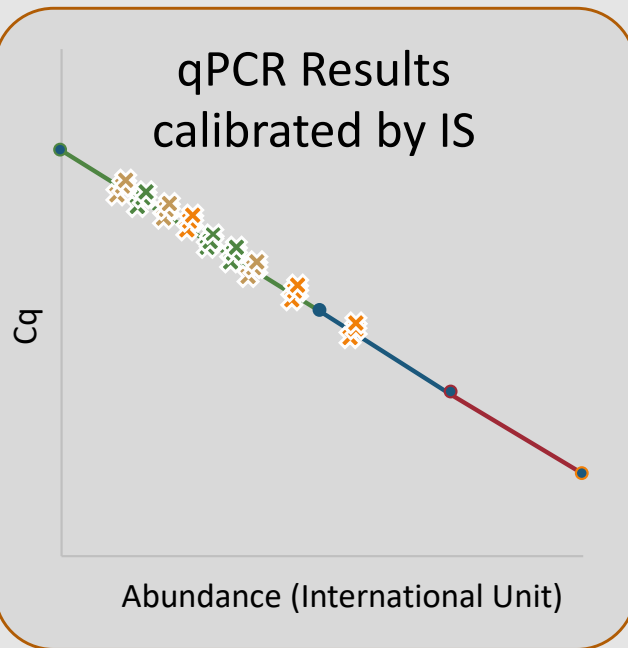
MIQE Table



Spreadsheet Report Form

see NIBSC tool

Analysis



- Focus on value assignment of 8 materials against the WHO IS
- Analysis and data evaluation inspired by experience with CCQM Comparisons
- Distribution analysis to harmonize results
 - establish measurement uncertainty from population of results



Discussion