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

What tests to do at what labs?  
What do we need for SOPs?  
Timeline
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Key bits for the SOP

- Sample rehydration
- Sample dilution
- Calibration curve
Timeline & Logistics

- **23 Oct**: Convene teams
- **26 Oct**: Teams meet
- **12-25 Nov**: Recruit samples and labs
- **17 Nov-18 Dec**: JIMB receiving materials
- **4 Jan**: JIMB distributes panels
- **8 Feb**: Labs report data
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