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Harmonization Study Planning – Recruiting!

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.

Agenda to Finalize Harmonization Study

- Study design
- Samples
- Labs
- Reporting
- Analysis
- Logistics
- Timeline

Purpose of Harmonization Study

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

By including the NIBSC sample intended to establish the International Unit (IU), the values on the materials included in this study can be made traceable to the IU when it becomes available.

Teams: Samples, Labs, Reporting, Analysis Plan

Samples Team	• develop sample panel
Labs Team	• assemble & coordinate labs
Experiment Design & Analysis Team	• design experiment • compose analysis plan
Reporting Team	• draft reporting template • MIQE, digital MIQE

Samples Team Recruiting Update

letter prepared

Need 64 identical samples at a single high nominal concentrations that can be diluted by the testing laboratory,

16 negative controls diluted in the same VTM

Samples to include 3 suppliers each of…

Inactivated, cultured SARS-CoV-2 virus

Recombinant virus

Recombinant bacteriophage (‘armored’ RNA)

Unblinded, nominal values provided

When possible, use catalog products as they would be provided to a user

Manufacturers will send packaged materials to JIMB and JIMB will distribute to test laboratories

Labs Team Recruiting Update

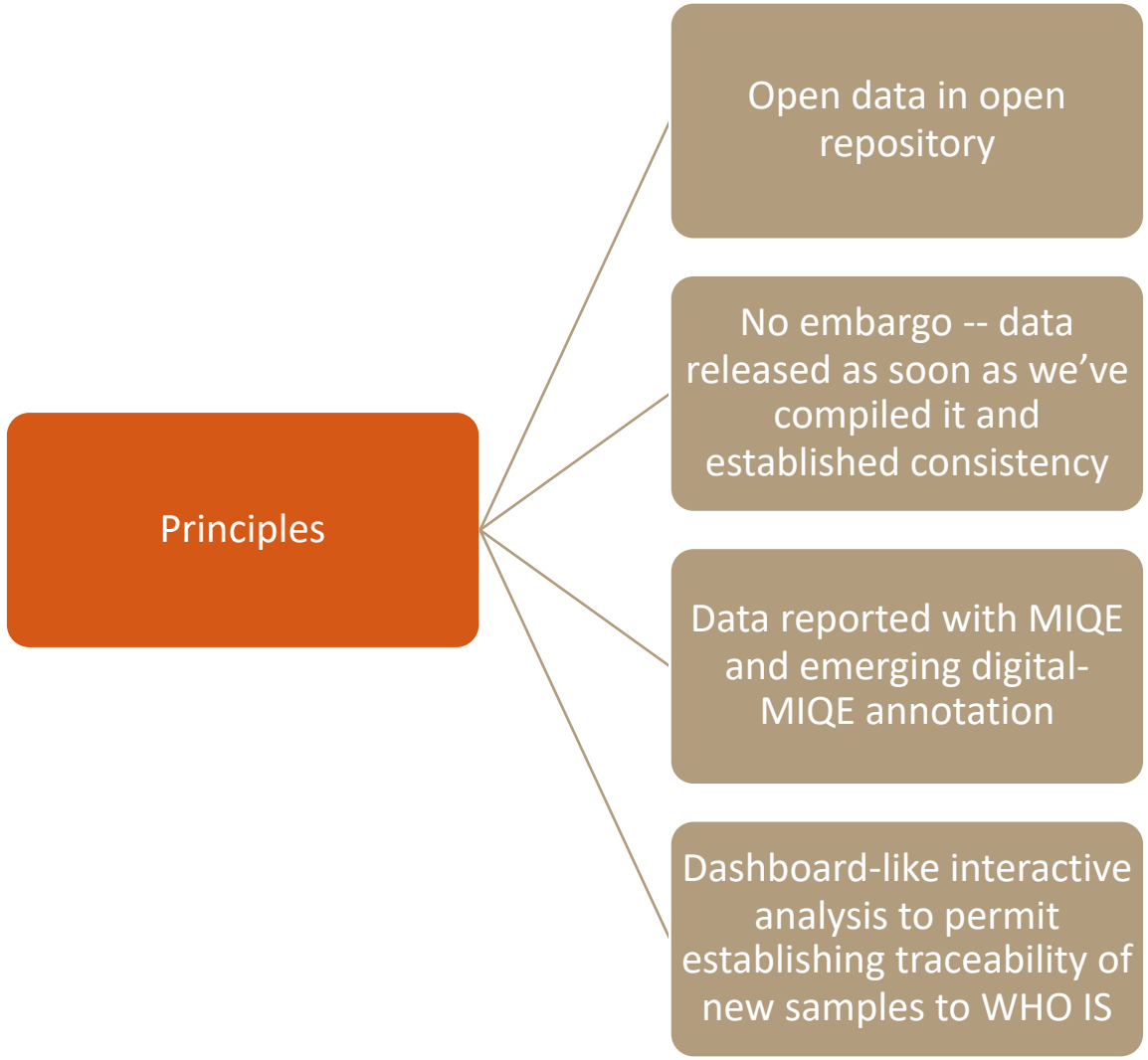
letter drafted

- Each lab will receive 4 tubes each of between 8 and 12 samples
  - full-process materials in VTM
  - “catalog” vialed material
  - all samples will be clearly labeled and unblinded
  - nominal abundance of viral RNA
  - “Certificate of Analysis” and “Instructions for Use”

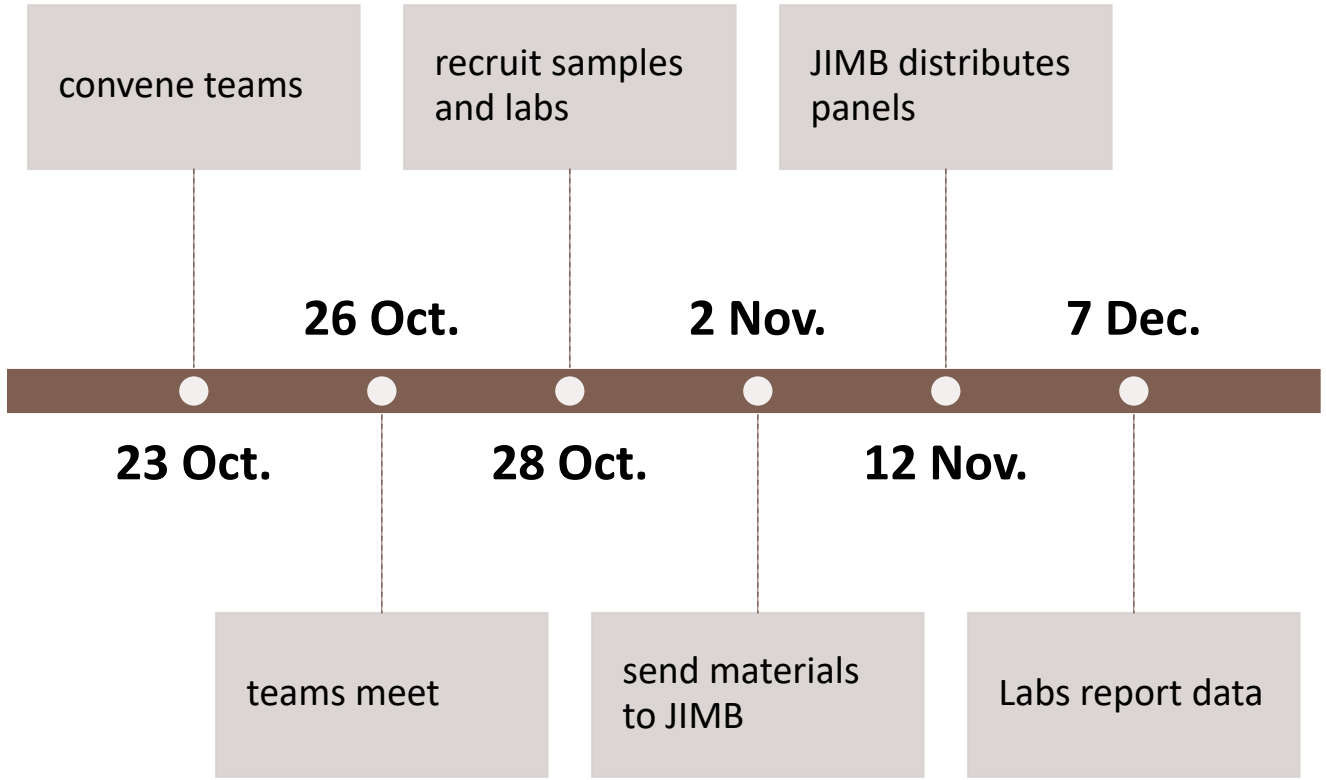
- Every lab will report results for each tube
  - results and a MIQE-compliant annotation & protocol in a provided form and questionnaire
- Recruiting
  - Test Developers
  - Clinical Labs
  - National Measurement Labs

Logistics -- David Catoe

Team formed for Design, Analysis, and Reporting



Timeline


convene teams
recruit samples and labs
JIMB distributes panels
26 Oct.
2 Nov.
7 Dec.
23 Oct.
28 Oct.
12 Nov.
teams meet
send materials to JIMB
Labs report data

Discussion

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

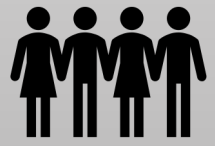
We can make the standards to make molecular testing robust, reliable, and quantitatively comparable.

‘Harmonization Kit” to establish comparability of a set of standards to put molecular testing results on a common scale

just a few labs, NMIs

“Benchmarking Kit” for turn-key evaluation of molecular testing platforms

test developers



“Validation Kit” for blinded validation with a dashboard to form a “smart-grid” for testing

routinely measured at testing labs