

22 January 2021

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Harmonization Study Experiment Design and SOP

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



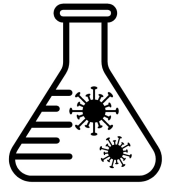
Identify and develop critical infrastructure to support...

- 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: SOP, Reporting, Timeline



SOP



Reporting



Timeline

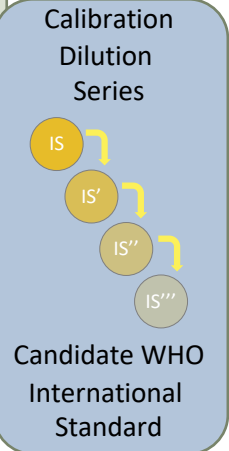
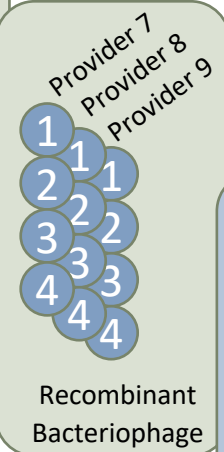
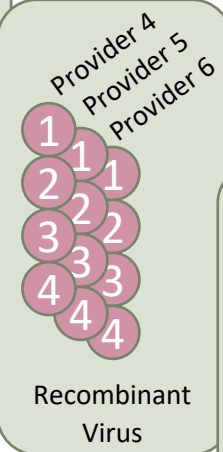
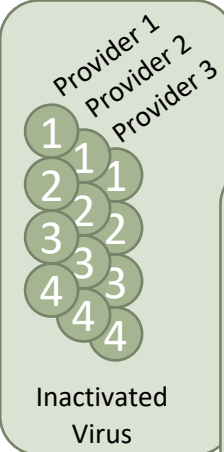
Purpose of Harmonization Study

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.

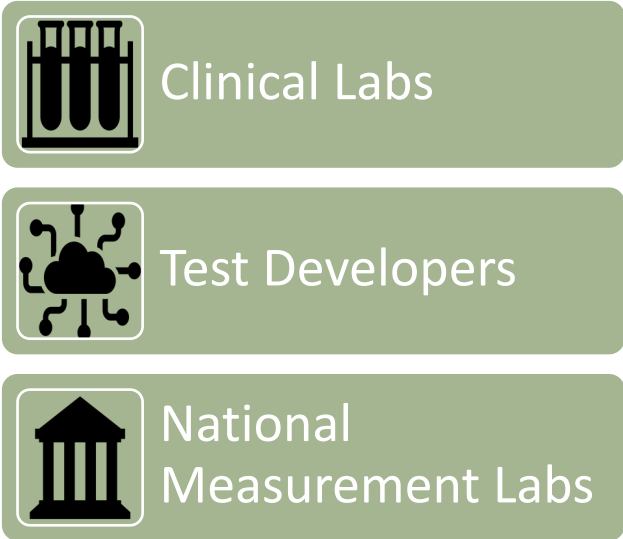
By calibrating with the WHO International Standard (IS) the values on the materials included in this study can be assigned in the International Unit for SARS-CoV-2.



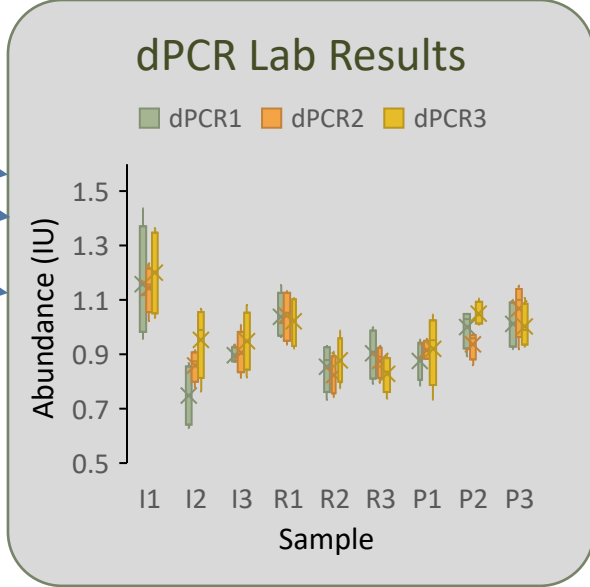
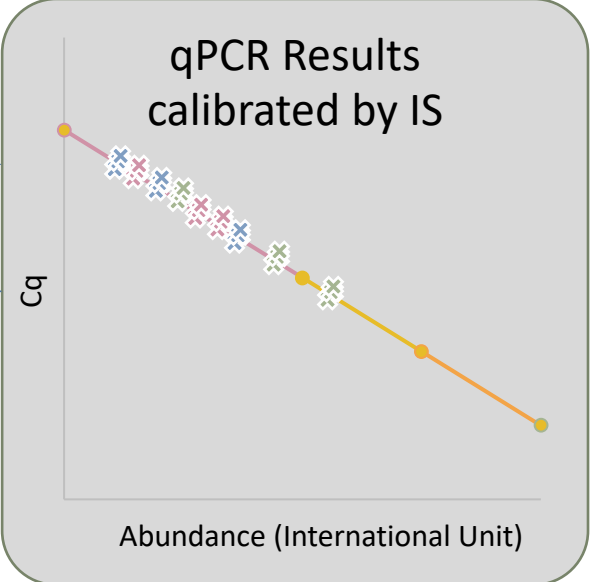
CSWG Harmonization Study Design



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

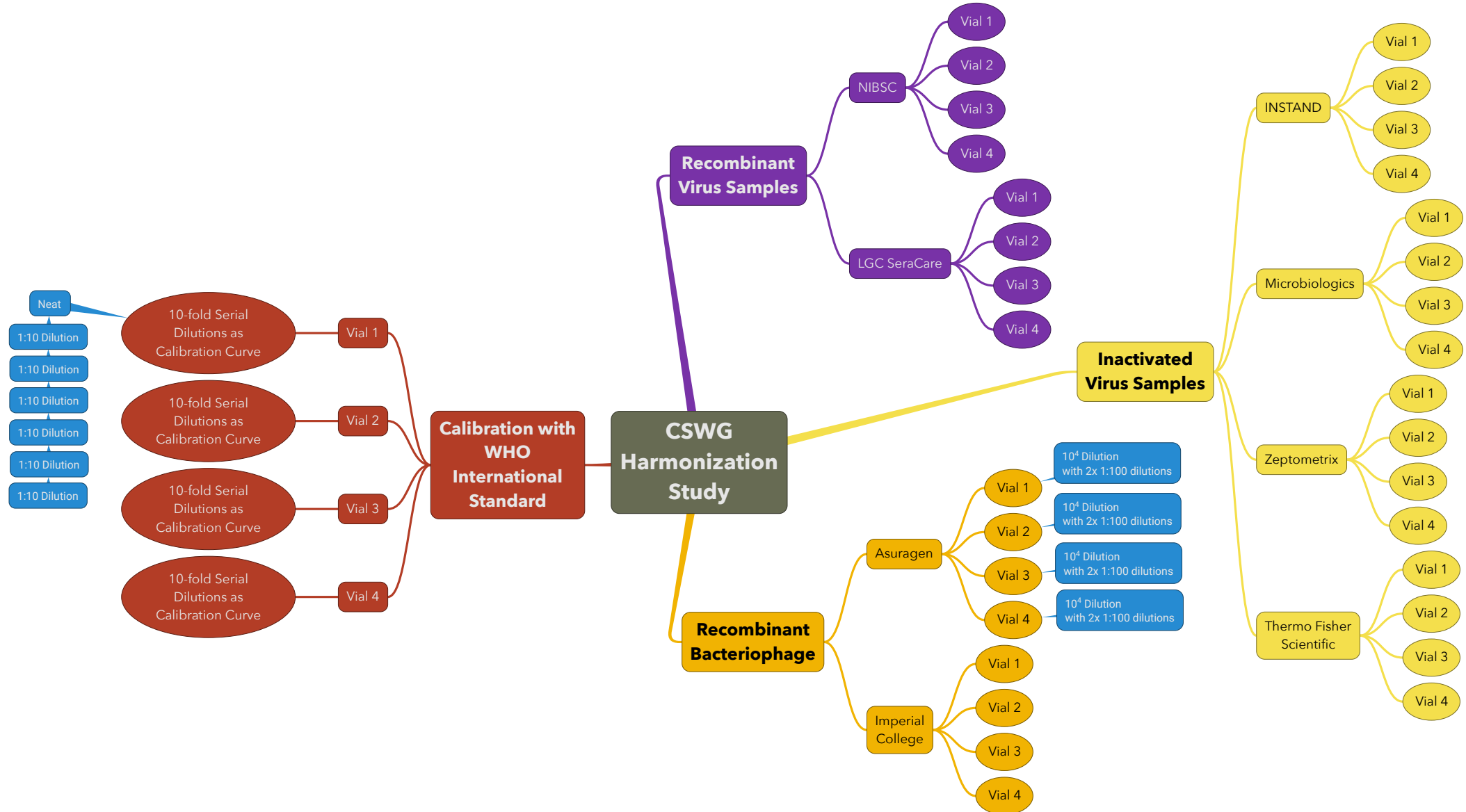


a survey of method performance (LOD, precision, repeatability)



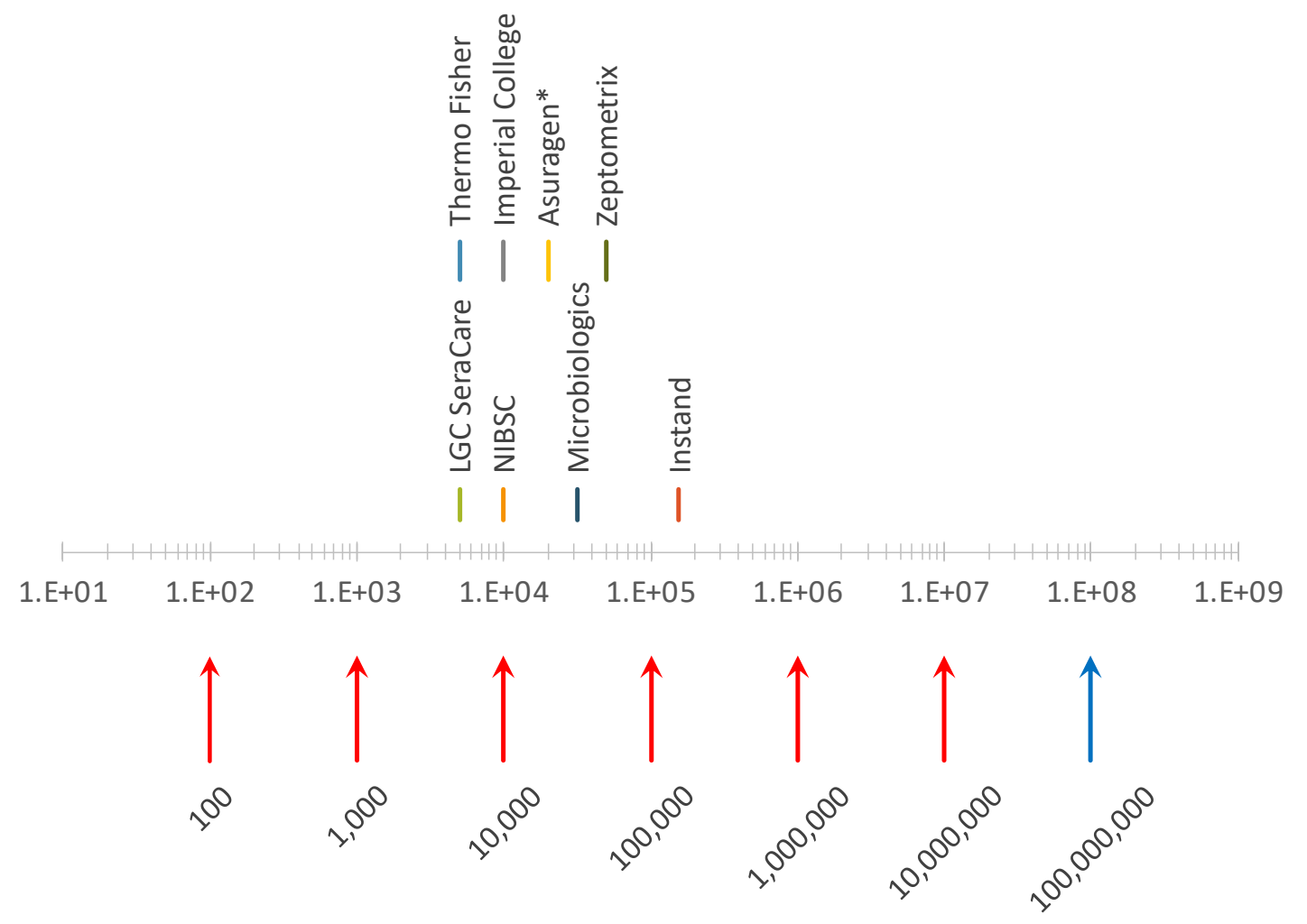
an evaluation of commutability

Calibration and Sample Panel Experiment Design



Calibration and Sample Levels

(copies/mL)



Let's look at the Google Doc



Metadata Entry Form

- Lab Information
- Sample Receipt and Handling
- Sample Handling/Preparation
- Assay Description & Experiment Design
- Results



CSWG Harmonization Study Metadata Form

This form will be filled out by each lab to provide metadata that will be used in data analysis.

- * send each lab a tinyurl with their specific form link, filled in with the lab name so they can have a persistent place to edit their entries – give them a QR code to this link in the box!
- * send an instruction sheet for using the form (i.e. must submit to keep the changes??)
- * develop reporting spreadsheet template
- * prepare and develop specific links to these files?
- * can we make it easy to submit the partially filled forms? (submit button for each section?)

The name and photo associated with your Google account will be recorded when you upload files and submit this form. Not msalit@stanford.edu? [Switch account](#)

Name of participating lab? (will require)

Your answer

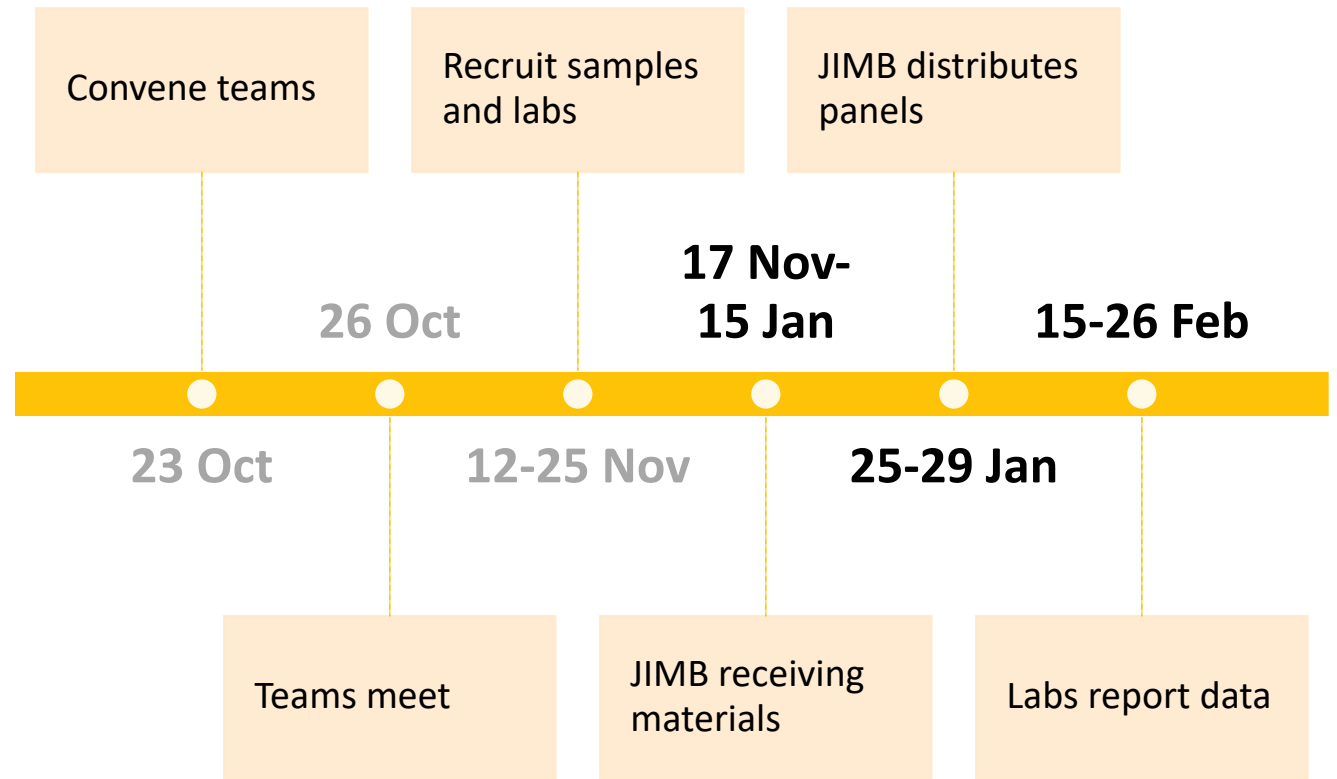
Please list the best way to contact the person or people filling out this form. (will require)

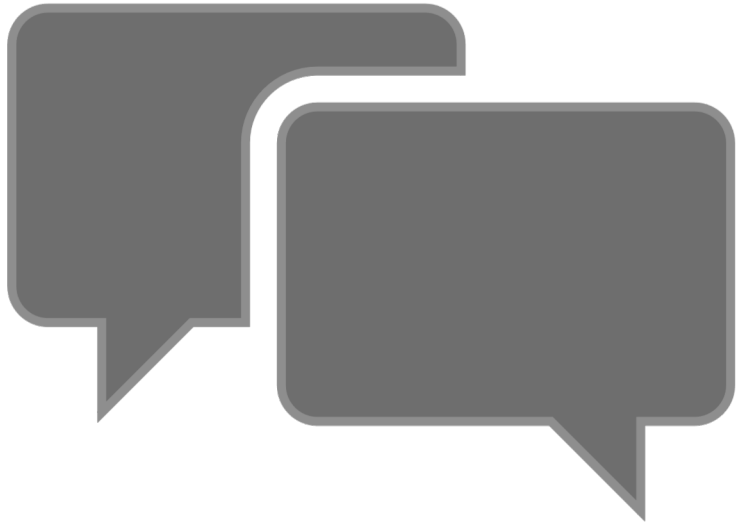
Data Entry Form

Sample code	Sample name	Replicate_1	Replicate_2	Replicate_3	Replicate_4
ISN	WHO-IS_neat				
IS1	WHO-IS_dilution_1				
IS2	WHO-IS_dilution_2				
IS3	WHO-IS_dilution_3				
IS4	WHO-IS_dilution_4				
IS5	WHO-IS_dilution_5				
IS6	WHO-IS_dilution_6				
I1	Instand				
I2	Microbiologics				
I3	Thermo Fisher				
I4	Zeptomatrix				
R1	LGC SeraCare				
R2	NIBSC				
P1	Asuragen				
P2	Imperial College				
NTC	Nontemplate_control				

- Values to report will depend on method
 - qPCR
 - dPCR
- All data to be reported as close to 'raw' and unprocessed as possible
 - expectation is to do a single run and report all data
 - 4 replicate vials make the experiment resilient to mishaps
- Tabs for each target, and annotation of any batching

Timeline & Logistics





Discussion

