How a global forum of scientists working on immune assays supported the development of SARS-CoV-2 medical countermeasures

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To develop and standardize **assays** to support vaccine development

**349** experts from **26** countries and **>100** entities were convened since Jan 2020

Live deliberations on **assay design and performance**
Researchers collaborating on **protocols** and access to reagents and proteins
Researchers collaborating on developing international and secondary **serology standards**

**Improved interpretability** of immune responses and harmonization of results
**Enhanced access** to assays, proteins and reagents
Communicating information to research community

• Meeting reports posted on WHO R&D Blueprint website
• Special meetings of the expert group held with Vaccine Developers
• Reports from the group made at WHO R&D forums and public consultations
• Training sessions held for use of the WHO International Standard
Achievements

• Viruses and other key reagents available
• Optimal conditions for culturing SARS-COV-2
• Binding assays – multiple antigens and formats (e.g. ELISA and multiplex)
• Neutralization assays – wtVNA, psVNA, sVNA
• Neutralization assays for Variants of Concern and Variants of interest
• Role of Fc-mediated effector functions
• Assessment of T cell responses
• Duration of immunity assessed
• Cross reactivity with other coronaviruses assessed
• 1\textsuperscript{st} WHO International Standard established
• Secondary standards made available and new International Standard in development
Over 2400 units 20/136 were shipped to 581 individual customers

Stocks of 20/136 depleted in August 2021

Kit manufacturers have adopted the WHO IS units (ELISA, sNeut)

Secondary standards calibrated in IU:
NIBSC 21/234 and US Serology standard
- 2nd WHO International Standard candidates were evaluated and will be presented to the WHO ECBS
- Currently available working standard 21/338
Assessing effects of Variants of Concern

• Rapid assessment and sharing of data on the effects of variants of concern (VOC) and variants of interest (VOI) on immunity
• Contribution to multiple consultations regarding variants
• Omicron – sharing of planned studies and publicly posted study tracker
Lessons learned

• Rapid sharing of results to advance the field
• Reporting widely to research community and vaccine developers

• Challenges
  • Viruses and reagents
    • Distribution of viruses
    • Panels of sera
    • Proteins – Full Spike

• Standards
  • Usage
International Standard

- International Standard - plasma with high titer anti-SARS-CoV-2 antibody collected early in the pandemic (prior to May 2020): pool from 11 donors
- Collaborative study to generate data - 50 laboratories from 14 countries with the standard and a common panel
- WHO IS established by WHO ECBS on 10th December 2020
- Available in NIBSC catalogue on 18th December 2020
- Assigned unitage – 1000 IU/mL