

## Meeting Minutes for the VQA Advisory Board Conference Call

April 17, 2020

Taken by Miranda Carper, Duke VQA

### Attendees:

#### VQAAB Voting Members

- |                                                                  |                                                               |                                                            |
|------------------------------------------------------------------|---------------------------------------------------------------|------------------------------------------------------------|
| <input checked="" type="checkbox"/> Bill Meyer (Chair)           | <input checked="" type="checkbox"/> Robert Coombs (ACTG/HVTN) | <input checked="" type="checkbox"/> Nicole Tobin (IMPAACT) |
| <input checked="" type="checkbox"/> Joan Dragavon (ACTG/HVTN)    | <input checked="" type="checkbox"/> Urvi Parikh (MTN)         | <input checked="" type="checkbox"/> Jessica Fogel (HPTN)   |
| <input checked="" type="checkbox"/> Belinda Yen-Lieberman (ACTG) | <input type="checkbox"/> Grace Aldrovandi                     | <input checked="" type="checkbox"/> Marco Schito           |

#### VQAAB Non-Voting Members

- |                                                          |                                                                   |                                               |
|----------------------------------------------------------|-------------------------------------------------------------------|-----------------------------------------------|
| <input type="checkbox"/> Ron Bosch (SDAC)                | <input checked="" type="checkbox"/> Diane Costello (IMPAACT/ACTG) | <input type="checkbox"/> Meghal Patel (NICHD) |
| <input checked="" type="checkbox"/> Lori Merrill (NICHD) |                                                                   |                                               |

#### HANC

- Tyler Brown

#### NIAID/DAIDS

- |                                                    |                                         |
|----------------------------------------------------|-----------------------------------------|
| <input checked="" type="checkbox"/> Joe Fitzgibbon | <input type="checkbox"/> Keith Crawford |
|----------------------------------------------------|-----------------------------------------|

#### Virology Quality Assurance / Duke Human Vaccine Institute

- |                                                       |                                                   |                                                    |
|-------------------------------------------------------|---------------------------------------------------|----------------------------------------------------|
| <input checked="" type="checkbox"/> Thomas Denny (PI) | <input checked="" type="checkbox"/> Raul Louzao   | <input checked="" type="checkbox"/> Feng Gao       |
| <input checked="" type="checkbox"/> Andrea Pappas     | <input checked="" type="checkbox"/> Sal Scianna   | <input checked="" type="checkbox"/> Heidi Register |
| <input checked="" type="checkbox"/> Wes Rountree      | <input checked="" type="checkbox"/> Katelyn Xiang | <input type="checkbox"/> Marcella Sarzotti-Kelsoe  |
| <input checked="" type="checkbox"/> Kristen Skinner   | <input type="checkbox"/> Chris Todd               | <input checked="" type="checkbox"/> Miranda Carper |
| <input type="checkbox"/> Ambrosia Garcia              |                                                   |                                                    |

#### Virology Quality Assurance Sub-Contractor

- Mike Busch (Vitalant Research Institute)

### Action Items

- Notify the VQA participating labs about problems shipping controls
- Contact Frontier Science and see if labs will be able to submit clinical data without VQA controls

### Meeting Minutes

The agenda for the VQAAB call is as follows:

- Opening Remarks and Roll call
  - Thomas Denny welcomed the advisory board members on the call
  - Miranda Carper took roll call
    - There were 8 voting members on the call
- Question about minutes from February 21 VQAAB call
  - Bill Meyer asked if the face-to-face Advisory Board meeting will still continue and when will the board members be invited to the meeting?

- The meeting is tentative scheduled to take place the day before the EQAPOL Scientific Advisory Board meeting on September 9<sup>th</sup>, 2020. Duke will make a decision if the meeting should continue in May or June.
- A letter will be sent to invited VQAAB members
- Presentation: Considerations for Changing VQA PT Frequency
  - Presenter: Miranda Carper
  - During the February 21<sup>st</sup> VQAAB call, the Advisory Board suggested to change the frequency of the, Qualitative Nucleic Acid, and Drug resistant program.
  - VQA presented considerations and counter proposal for the VQAAB suggestion to change the PT frequencies during the February 21<sup>st</sup> VQAAB call.
    - VQAAB suggested to decrease the frequency of the HIV-1 Quantitative RNA from 6 times a year to 3 times a year
      - The VQA counter proposal: to decrease the PTs from 6 times a year to 4 times a year for the following reasons:
        - Labs will have more opportunities to be approved for testing or to be re-approved for testing
        - Cleaner grading scheme because labs are scored based on data submitted for the last four PTs
      - The VQAAB voted to decrease the PT frequency from 6 times a year to 4 times a year
    - VQAAB suggested to increase the frequency of both the HIV-1 Qualitative Nucleic Acid Testing (NAT) and the HIV-1 Drug Resistance Sequencing (GEN) PTs from 2 times a year to 3 times a year
      - The VQA counter proposal: to have both PTs remain at 2 times a year for the following reasons:
        - Increasing the PTs for both programs would add an combined cost of ~ \$80,000 US dollars to the budget due to shipping and QC costs
          - It will cost approximately 30,000 US dollars for shipping an additional Qualitative NAT PT panel. Unable to condense shipments to 1 time a year like the RNA program.
            - Fresh whole blood is shipped to labs.
          - It will cost approximately 41,000 US dollars for shipping an additional Drug Resistance PT panel and approximately 9,000 US dollars in internal QC costs
            - Does not include the cost and effort associated with analyzing the data. Or the impact of testing an additional PT on the budget of small underfunded laboratories.
        - The VQAAB voted to keep the frequency of the HIV-1 Qualitative NAT and HIV-1 Drug Resistance Sequencing PT at 2 times a year
- Discussion of logistical Issues shipping controls to international labs
  - Due to country lockdowns, increased import restrictions, and decrease in flights carrying shipments; the VQA is having difficulties in shipping controls or PTs.

- Two shipments went out recently, however the packages are sitting in World Courier facilities until restrictions lift.
- Some labs are low on controls and may run out due to the shipping issues
  - VQAAB suggested that labs may have to submit data without the VQA controls
  - Will need to develop a long-term plan if shipping problems continue for an extended period of time.
- Discussion of Data
  - HIV-1 Quantitative RNA data RNA2020\_02
    - Three labs received a score of PC and one lab a score of P.
    - Two labs received a Potential Issue Alert (PIA) for accuracy and standard deviation issues.
      - Labs received a passing score, labs were given the opportunity to replace their data to prevent receiving a score of PC or P later.
      - There was one change of status
        - Approved to provisionally approved
  - HIV-1 Qualitative Nucleic Acid Testing data DNA2020\_03
    - All labs received a score of C
  - HIV-1 Drug Resistance Sequencing data GEN2019\_11
    - Two labs received a score of PC for RT/PR gene regions
      - 1 lab had missing data
      - 1 lab had a insertion/deletion
- Questions and closing remarks
  - Will Frontier Science need to be contacted to ensure labs are still able to submit clinical data even if they run out of VQA controls?
    - Yes, Frontier science will need to be contacted to see if they will need to make coding changes.
  - Are their problems shipping to domestic sites
    - FedEx is still able to ship at this time
    - COVID-19 samples are packaged and shipped as a category B.