

Minutes for NIAID/Duke VQA Conference Call

31 October 2019

Taken by Miranda Carper, Duke VQA

Attendees:

VQAAB:	Ron Bosch, Bob Coombs, Diane Costello, Joan Dragavon, Jessica Fogel, Lori Merrill, Bill Meyer, Linda Robbins, Nicole Tobin, Belinda Yen-Lieberman
HANC:	Tyler Brown
NIAID:	Keith Crawford
Frontier Science	Heather Sprenger
Duke Members:	Tom Denny, Raul Louzao, Wes Rountree, Katelyn Xiang, Heidi Register, Miranda Carper, Andrea Pappas, Sal Scianna; Marcella Sarzotti Kelsoe

Agenda:

- 15-20min presentation on the Duke VQA team
 - Presented by Tom Denny
- Review of DNA Summary Reports (6)
 - Presented by Miranda Carper
- Review of RNA 36-4 Summary Report (1)
 - Presented by Wes Rountree
- Questions and Closing Remarks

Minutes:

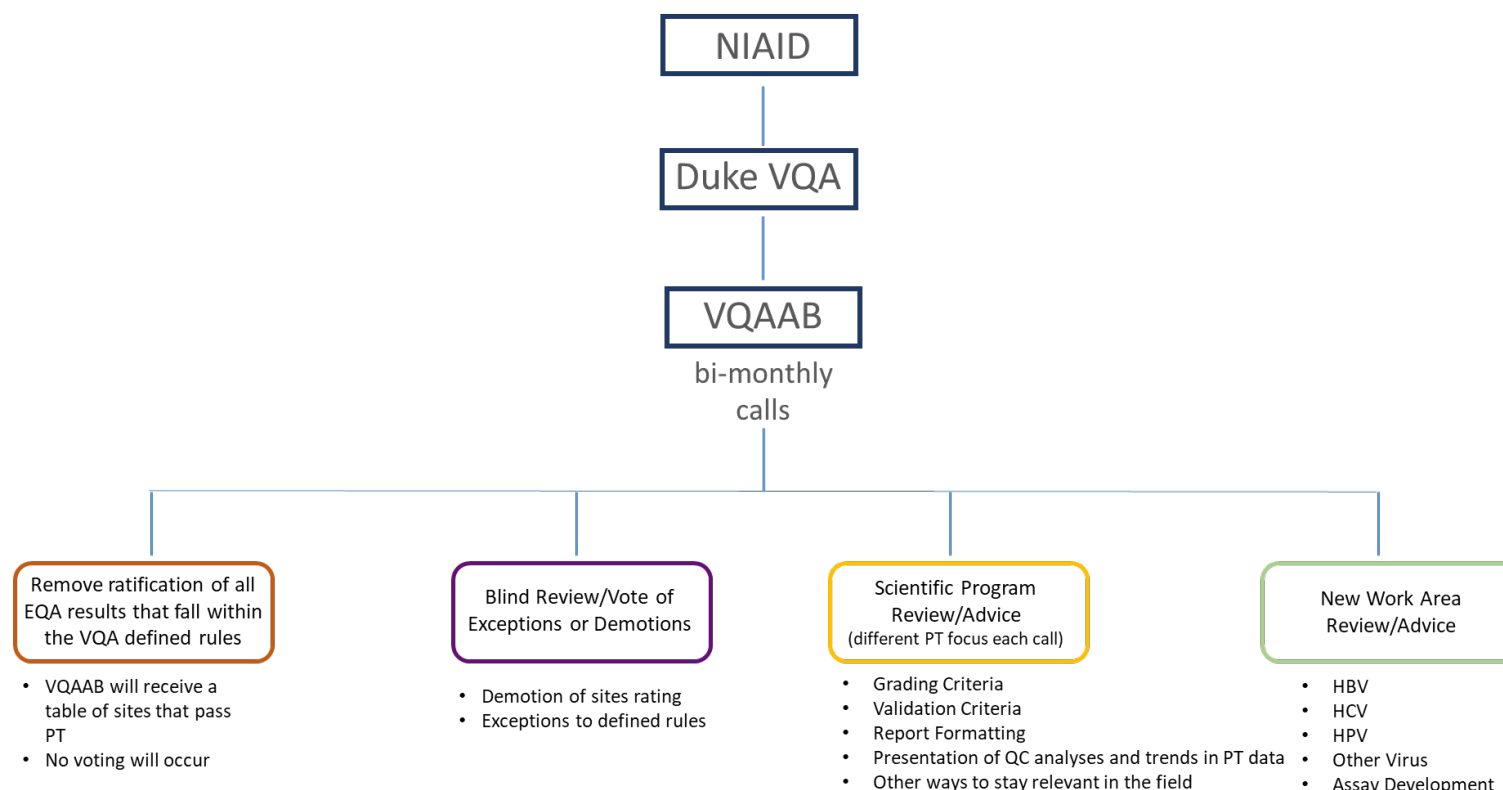
- Tom Denny gave a presentation on the Duke VQA team and proposed restructuring the function of the VQA Advisory Board. Highlights of presentation include:
 - Description of Duke Human Vaccine Institute (DHVI)
 - Denny Portfolio
 - Immunology Virology Quality Assessment Center
 - External Quality Assurance Program Oversight Laboratory (EQAPOL)
 - Part of Denny Portfolio since 2010
 - Supports HIV/AIDS research and vaccine trials.
 - Viral Diversity and Viral Repository
 - Collaborate with Mike Busch
 - Can be used to make panels for VQA Proficiency Testing.
 - Immune Quality Assessment (IQA)
 - Part of Denny Portfolio since 1999
 - Tests sites' ability to 1) freeze human cells from blood and 2) determine CD4 counts in fresh human blood via Flow Cytometry
 - Non-Human Primate Core Virology Laboratory (NHPCVL)

- Supports clinical trials for HIV vaccine development
- Virology Quality Assurance (VQA)
 - Awarded June 21, 2019
- Organization Chart of Duke VQA Team
- Introduction of VQA Co-Investigators
 - Feng Gao, MD
 - John Bartlett, MD
 - Susanna Naggie, MD
 - Micah Luftig, PhD
 - Marcella Sarzotti-Kelsoe, PhD
 - Mike Busch, MD, PhD
- Introduced the Proposed changes to the VQA Advisory Board (see **Appendix I**)
- Concluding remarks and contact information
- Tom Denny let the VQAAB board know they can contact him with any questions and that he is available for further discussion via phone call or email. Duke also welcomes any of the current VQA Advisory Board members to remain on the board.
 - 2 to 3 additional board members chosen by Tom Denny will be added in a couple of months.
 - Duke and VQAAB agreed that if any VQAAB member wishes to step down as a board member to email Tom Denny directly. If Tom does not hear from you, he will assume the board member will want to remain on the Advisory Board.
- Tom opened the call to Questions and Comments
 - VQAAB inquired if there were any problems with the transition
 - Duke Response: The only complication was the inability to transfer materials to Duke VQA due to wording in IRB. Duke VQA has had to produce more products than originally anticipated. Everything is on track at this time for future send-outs
 - VQAAB agreed with the new restructuring plan
 - In response to inquiries about changes to be made, Duke reported that all VQAAB meeting minutes and reports will continue to be posted on the HANC website. Also, that the statistical analysis of data for each program will remain consistent. In the new year the Duke VQA will make available a new platform for sites to submit data but the analysis will still remain the same.
 - The VQAAB will continue to be responsible for sending the letters to sites when they have a change of status.
 - VQAAB inquired if there would be an opportunity to have a face to face meeting like the Science Advisory Board of EQAPOL
 - Tom's responded he would love to have a meeting for 1 to 2 days to discuss the program and how to approve in the future. But we would have to get approval from NIAID.
- Discussion of Reports
 - DNA reports
 - All labs passed
 - No labs had a change in status

- RNA
 - One lab did not pass due high standard deviations from previous data.
 - Data suggests there are technical issues involved such as maintenance of the instrument.
 - Duke VQA will contact lab and ask about maintenance of the instruments

Next Meeting will be held on Thursday, December 19, 2019

Proposed Changes to the function of the VQA Advisory Board



Proposed changes to the function of the VQA Advisory Board (VQAAB). Duke VQA proposes the monthly VQAAB calls decrease to bi-monthly. Each call will have the above proposed format. The VQAAB will receive a table containing the list of sites that passed previous PTs following the defined VQA rules. No voting will occur with these types of reports. However, Duke VQA in a blinded manner, will bring to the attention of the VQAAB any exceptions or demotions for review either during the bi-monthly calls or via email as needed. Each call will also contain a short presentation highlighting a PT program (rotate between Quantitative RNA, Qualitative DNA, and Drug Resistance Mutation Sequencing PT programs) to foster scientific review and advice on PT programs. Discussion points may include presentation of QC data, tracked trends of PT data, ISO/GCLP certification, internal audits, validation criteria, changes to grading criteria, other ways to stay relevant in the field, and changes to report formats. Lastly, Duke VQA will seek review and advice for new work areas such as alternate viral work (validations) or assay development.