

Spotlight on Sponsor: Q&A with IAVI

IAVI is a not-for-profit organization focused on the development of vaccines and antibodies for HIV, tuberculosis, influenza, emerging infectious diseases, namely Lassa fever, Marburg, SARS COVID-19, and neglected diseases such as snakebite envenoming. IAVI's goal is to translate scientific discoveries into affordable and globally accessible public health solutions. With their headquarters in New York City, New York (US), IAVI brings 25 years of breakthrough vaccine research expertise via a team of in-house researchers, operating internationally in the US, UK, and India.

IAVI audited NeoGenomics in 2015 and since then has contracted the services of NeoGenomics for several projects, spanning the use of qPCR and RT-qPCR across assay transfer, validation and optimization needs. The Design and Development Lab within IAVI has worked with NeoGenomics to conduct preclinical and clinical studies, which included bio-distribution, exploring viral load in different human tissues, and confirming virus shedding.

NeoGenomics is delighted to host this Q&A with two of the scientific team members from IAVI's team, Eddy Sayeed, Executive Director, Process Development & Vaccine Manufacturing/Vaccine Development, and John Coleman, Principal Research Scientist.



Q: How did the IAVI team find out about NeoGenomics prior to the audit?

A: NeoGenomics was referred to IAVI by another Contract Research Organization (CRO) that IAVI had previously contracted to test viral vectored vaccine clinical samples for virus shedding. The business model of that CRO evolved, and hence they recommended NeoGenomics to support IAVI for future studies.



Q: What were the drivers underlying the decision to contract with us?

A: As part of the vendor selection process, IAVI performed a Technical and Quality Systems Audit of NeoGenomics. During the audit, it was apparent that NeoGenomics had the platforms, technical knowledge, and the ability to validate, qualify, and optimize qPCR and RT-qPCR assays and dedicated teams to support vaccine programs. They also had solid project management and scientific consultant capabilities. NeoGenomics is CLIA (Clinical Laboratory Improvement Amendments) certified and had the Quality Systems to support molecular testing of clinical samples.



Q: Describe your interactions with the project and scientific team at the Houston labs

A: The interactions with the team at the Houston lab have been very collaborative and collegial. After introductions and brief presentations from both the IAVI and NeoGenomics teams, we had the opportunity to tour the labs. Our QA team member was able to assess the competency of the NeoGenomics' team and their ability to conduct the scope of the work. The IAVI Team felt comfortable that the team at the Houston labs were perfectly capable of undertaking these studies to the highest standard as required by the FDA.



Spotlight on Sponsor: Q&A with IAVI



Q: What were the key strengths and highlights of the team responsible for the delivery of your data and results?

A: The NeoGenomics team has the technical expertise to develop and qualify novel multiplexing assays to support preclinical and clinical testing of samples from clinical studies to the highest standards. The Technical Team at NeoGenomics has been very collaborative and interactive with the IAVI Team and paid close attention to the Client's requirements. The assay development/qualification of assays was completed in a timely manner and delivered results to meet aggressive timelines. The quality of testing reports has been of the highest standards.



Q: Are you planning future work with NeoGenomics? If so, please explain

A: IAVI has a strong portfolio of using viral vaccines as a platform for developing vaccines against HIV and emerging diseases. Currently, the team at Houston is completing a preclinical bio-distribution study using RT-qPCR on one of IAVI's vaccine candidates and we've already selected them to conduct the Clinical part of testing these samples. These assays will be used across the entire portfolio of vaccines being developed at IAVI. IAVI will continue collaborating with NeoGenomics for these activities.



Q: From the work performed by Neo, how does this help to support the IAVI mission?

A: As mentioned above, IAVI is focused on developing vaccines that are globally required and easily accessible, so having an experienced and well-respected CRO that can conduct and complete preclinical and Clinical studies competently helps to facilitate vaccines to licensure.



Q: Would you consider pointing other groups towards NeoGenomics, given your own experiences?

A: NeoGenomics has the expertise and capabilities to develop, qualify, and fully validate assays to specific client needs. NeoGenomics has the ability to undertake Molecular testing, namely NGS, qPCR, RT-PCR, sequencing as well as ELISA and multiplexing. Based on requests from other external groups, IAVI has recommended these groups' services for testing clinical samples.

12701 Commonwealth Dr., Suite 9
Fort Myers, FL 33913 United States
Phone: 866.776.5907
Fax: 239.690.4237

31 Columbia
Aliso Viejo, CA 92656 United States
Phone: 800.720.4363
Fax: 949.425.5865

7256 S. Sam Houston Pkwy W., Suite 300
Houston, TX 77085 United States
Phone: 800.720.4363 / 713.528.4363
Fax: 713.668.3565

NeoGenomics Laboratories, Inc.
4570 Executive Drive., Suite 250
San Diego, CA 92121
Phone: 949.445.7300 x5056

NeoGenomics Europe, S.A.
A-One Business Center
Bâtiment A5, 2nd Floor
Z.A. La Pièce/Route de l'Etraz 1
1180 Rolle, Switzerland
Phone: +41.21.721.06.00
Fax: +41.(0)21.826.00.73

NeoGenomics Singapore Pte. Ltd.
61 Science Park Road, #02-11
Singapore 117525
Phone: +65.69115202

Suzhou NeoGenomics
Pharmaceutical Research Co., Ltd
Building 6, Block 19, Yong'an Road
Huguan Industrial Park,
Suzhou New District, China

