# APPLIED BIOMARKER ANALYSIS

*Join us for the Second Annual Applied Biomarker Analysis Webinar*

## OCTOBER 29, 2020

Sponsored by: PPD®

*Biomarkers Derived from Correlates of Protection in Vaccine Studies*

**Nicole Frahm, PhD**

Exploratory Biomarker Leader, Bill & Melinda Gates Medical Research Institute

*Clinical Biomarkers for Immune Health in 3D Genomics: From Auto-Immunity to Immuno-Oncology and COVID Severity*

**Alexandre Akoulitchev, PhD**

Director, Oxford BioDynamics

*Clinical Flow Assay: Development, Validation, and Implementation Challenges Across Several High Priority Assets*

**Erin Stevens, PhD**

Associate Research Fellow, Pfizer

*Molecular Quantification in Biomarker and Biodistribution Studies: Selecting qPCR vs ddPCR*

**Timothy Lochmann, PhD**

Research Scientist, PPD

*A CMV IgG Point-of-care Test to Aid Rapid Patient Screening in Vaccine Clinical Studies*

**Xuemei Zhao, PhD**, Senior Principal Scientist, Merck

For more information, please visit: WWW.BOSTONSOCIETY.ORG/ABA/

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## ORGANIZERS' WELCOME

**Welcome to the 2020 Applied Biomarker Analysis Meeting.**

Our organizers have gathered an excellent group of speakers for the second annual ABA meeting. The program is arranged to incorporate extensive audience participation and discussion. We encourage attendees to take full advantage of the opportunity to engage in discussion in order to receive the maximum benefit from the ABA experience.

Thank you for your participation.

## ORGANIZING COMMITTEE

### Presiding Chairs

**Chairs:** Dieter Drexler, Bristol-Myers Squibb
Patrick Bennet, PPD Laboratories

### Committee Members

Omar Laterza, Merck
John Moriarity, BioAgilytix
Hendrick Neubert, Pfizer
Paul Rhyne, Bill & Melinda Gates Medical Research Institute
Robyn Rourick, Genentech
Christina Satterwhite, Charles River
Wei Dong, Takeda
Steven Piccoli, Sun Pharmaceutical Advanced Research Center



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# ABA 2020 WEBINAR AGENDA

## THURSDAY, OCTOBER 29

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|---|---|
| 11:00 - 11:10 | **Conference Opening**<br>Patrick Bennet, PPD Laboratories & Dieter Drexler, Bristol-Myers Squibb |
| 11:10 - 11:50 | *Clinical Biomarkers for Immune Health in 3D Genomics: From Auto-Immunity to Immune-Oncology and COVID Severity*<br>Alexandre Akoulitchev, Oxford BioDynamics |
| 11:50 - 12:00 | **Q & A** |
| 12:00 - 12:05 | Speaker Introduction<br>Omar Laterza, Merck |
| 12:05 - 12:45 | *A CMV IgG Point-of-Care Test to Aid Rapid Patient Screening in Vaccine Clinical Studies*<br>Xuemei Zhao, Merck |
| 12:45 - 12:55 | **Q & A** |
| 12:55 - 1:55 | **Break** |
| 1:55 - 2:00 | Speaker Introduction<br>Robyn Rourick, Genentech |
| 2:00 - 2:30 | **Vendor Presentation**<br>*Molecular Quantification in Biomarker and Biodistribution Studies: Selecting qPCR vs ddPCR*<br>Timothy Lochmann, PPD |
| 2:30 - 2:35 | **Q & A** |
| 2:35 - 2:40 | Speaker Introduction<br>Hendrick Neubert, Pfizer |
| 2:40 - 3:20 | *Clinical Flow Assay Development, Validation, and Implementation Challenges Across Several Very High Priority Assets*<br>Erin Stevens, Pfizer |
| 3:20 - 3:30 | **Q & A** |
| 3:30 - 3:35 | Speaker Introduction<br>Paul Rhyne, Bill & Melinda Gates MRI |
| 3:35 - 4:15 | *Biomarkers Derived from Correlates of Protection in Vaccine Studies*<br>Nicole Frahm, Bill & Melinda Gates MRI |
| 4:15 - 4:25 | **Q & A** |
| 4:25 - 4:30 | **Closing Remarks** |



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# ABSTRACTS

### *Biomarkers Derived from Correlates of Protection in Vaccine Studies*

**Nicole Frahm, Bill & Melinda Gates MRI**

Vaccines in global health are developed to prevent infection and subsequent disease, based on the notion that vaccine-induced immunity can mimic protective immune responses that develop following infection. Yet for many diseases with significant morbidity and mortality, including tuberculosis (TB), malaria and HIV, protective immune mechanisms are poorly understood. Identifying correlates of protection (CoP) mediated by infection or vaccination has the potential to accelerate future vaccine development since validated biomarkers based on CoP can serve as surrogate endpoints in smaller proof-of-concept trials, rather than constraining trials to rely on clinical endpoints in large phase 3 studies to evaluate vaccine efficacy.

This presentation will use the currently ongoing TB Immune Correlates Program as an example for the process of identifying CoP with the intent of validating biomarkers as surrogate endpoints in future TB vaccine studies. While focusing on a single disease, this process can easily be adapted to other vaccine studies as well as drug trials, providing the basis for the development of biomarker strategies regardless of the underlying application.

# BIOGRAPHIES

**Alexandre Akoulitchev, PhD,** Oxford Biodynamics

Dr. Akoulitchev read mathematics, physics, chemistry, biochemistry and biophysics at Moscow Institute of Physics and Technology. In 1989 he was selected by the George Soros Foundation for the Oxford Scholarship, associated with St. Antony's College. He obtained his PhD in cell biology from University College, London (with the research based at the Imperial Cancer Research Fund). He spent six years at the Robert Wood Johnson Medical School-UMDNJ, NJ, as a research assistant funded by the Howard Hughes Medical Institute. Upon his return to England, he established his research laboratory at the Sir William Dunn School of Pathology, University of Oxford. He was a University Academic Fellow (Research Council UK) and a Senior Fellow of Exeter College, sponsored by Cancer Research UK, the Wellcome Trust, The Medical Research Council and Monsanto Foundation. Alexandre is a Fellow of the Royal Society of Medicine and Chief Scientific Officer of Oxford Biodynamics Plc.

**Nicole Frahm, PhD,** Bill & Melinda Gates Medical Research Institute

Dr. Frahm is the Exploratory Biomarker Leader at the Bill & Melinda Gates Medical Research Institute and holds an affiliate Associate Professor appointment at the Fred Hutchinson Cancer Research Center. She received her PhD in Immunology at the University of Hamburg, Germany, and completed her post-graduate work with a joint appointment at Massachusetts General Hospital and Harvard Medical School in Boston, Massachusetts. During her career, Dr. Frahm studied the influence of HIV sequence diversity on its recognition by cytotoxic T lymphocytes, as well as the factors governing the recognition of sequence variants both in HIV-infected subjects and in vaccine trial participants. In her role as the Exploratory Biomarker Leader, she oversees the evaluation, prioritization and implementation of cutting-edge biomarker technologies, with a particular focus on systems biology tools, across small molecule, biologics, vaccine and diagnostics programs across the portfolio of the Gates MRI. Dr. Frahm has published 106 peer-reviewed manuscripts.

**Timothy Lochmann, PhD,** PPD

Dr. Lochmann is a Research Scientist in the Molecular Genomics group of PPD in Richmond, Virginia. Tim received his Ph.D. in 2011 at The Pennsylvania State University's College of Medicine in Hershey, Pennsylvania, where he studied retroviral RNA packaging through mutational analysis. His postdoctoral experiences at Virginia Commonwealth University include epigenetic regulation of genes in neurodegenerative diseases. These studies were followed by several projects using large-scale, small-molecule drug screens coupled with genomic, epigenomic, RNA expression, and metabolomic data to identify potential biomarkers for the effective treatment of cancers such as neuroblastoma and lung cancer. His postdoctoral work resulted in nine publications, in journals including PNAS, Clinical Cancer Research, Science Translational Medicine, and Cancer Cell. Tim joined PPD in early 2019, and has since been involved in numerous developments, qualifications, and validations, including six projects utilizing qPCR, ddPCR or both technologies to help answer novel therapeutic questions for pharmaceutical sponsors.

**Xuemei Zhao, PhD,** Merck

Dr. Zhao is currently a Senior Principal Scientist in the Translational Molecular Biomarkers Department at Merck & Co., Inc. in Kenilworth, NJ. She received her Ph.D. in Chemistry from Columbia University and performed her postdoctoral research at Cold Spring Harbor Laboratory. Afterwards, Xuemei joined the Proteomics Department in Molecular Profiling at Merck in 2004. She led the biochemistry group focusing on sample preparation for LC-MS based proteomics profiling for biomarker discovery and new target identification. In 2012, Xuemei transitioned to clinical biomarker development. Currently, she leads the immunoassay group to develop, validate, and deploy immunoassay-based biomarkers in all phases of clinical development and all therapeutic areas at Merck & Co., Inc.

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## Thank you to all of our Organizers, Speakers, Sponsors and Delegates!

Without your dedication, support and participation ABA 2020 would not be possible. We greatly value your comments regarding ABA 2020 as well as thoughts or suggestions for improving future conferences.

Please take the time to fill out our survey when we send it to you next week.

Sincerely,

The Boston Society