APPLIED BIOMARKER ANALYSIS

WEBINAR

MAY 24-25, 2021

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APPLIED BIOMARKER ANALYSIS

ORGANIZERS' WELCOME

Welcome to the 2021 Applied Biomarker Analysis Meeting.

Our organizers have gathered an excellent group of speakers for the third 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

The Boston Society

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ABA 2021 WEBINAR AGENDA

MONDAY, MAY 24

11:00 - 11:10	**Conference Opening** Patrick Bennet, PPD Laboratories & Dieter Drexler, Bristol-Myers Squibb
11:10 - 11:40	*Developing Assays and Standards to Support Shigella Vaccine Development* Calman MacLennan, Bill & Melinda Gates Foundation
11:40 - 11:50	**Q & A**
11:50 - 11:55	Speaker Introduction Patrick Bennet, PPD
11:55 - 12:25	*Using Remote Sampling to Analyze Biomarkers: Benefits and Challenges* James Rudge, Neoteryx, UK
12:25 - 12:35	**Q & A**
12:35 - 1:20	**Break**
1:20 - 1:25	Speaker Introduction Patrick Bennet, PPD
1:25 - 1:55	**Vendor Presentation** *Decentralized Clinical Trials - The Bigger Picture* Francis Jones, PPD
1:55 - 2:00	**Q & A**
2:00 - 2:05	Speaker Introduction Paul Rhyne, Bill & Melinda Gates MRI
2:05 - 2:35	*The Impact of Decentralized Clinical Trials on Laboratory Testing:* *Self-collection of Blood Samples and at Home Point of Care Testing in Clinical Trials* Chuck Drucker, Q^2 Solutions
2:35 - 2:45	**Q & A**
2:45 - 3:05	**Panel Discussion - All speakers**

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TUESDAY, MAY 25

11:00 - 11:05	**Conference Opening** Robyn Rourick, Genentech
11:05 - 11:35	*Current Practice and Perspective for Biomarker Analysis in China* Kelly Dong, UP Pharma, Shanghai
11:35 - 11:45	**Q & A**
11:45 - 11:50	Speaker Introduction Patrick Bennet, PPD
11:50 - 12:20	*Driving Biomarker Research in China* Zhanmin Li, Teddy Lab
12:20 - 12:30	**Q & A**
12:30 - 12:35	Speaker Introduction Robyn Rourick, Genentech
12:35 - 1:05	*COVID-19 Rapid Response Biomarker Implementation* Erica Troksa, Covance
1:05 - 1:15	**Q & A**
1:15 - 1:45	**Break**
1:45 - 1:50	Speaker Introduction Paul Rhyne, Bill and Melinda Gates MRI
1:50 - 2:20	*MEEDAT- A Multiplex ELISA of Biomarkers for Environmental Enteric Dysfunction* Robert Choy, PATH
2:20 - 2:30	**Q & A**
2:30 - 3:00	**Vendor Presentation** *Translating Pharmacodynamic Immune Biomarkers to the Clinic* Christopher Kirkham, Charles River
3:00 - 3:05	**Q & A**
3:05 - 3:10	Speaker Introduction Steven Piccoli, Sun Pharmaceutical
3:10 - 3:40	*AI Approach for Identifying Drug Sensitivity Biomarkers Across Diverse Data Types for Patient Selection* Coryandar Gilvary, OneThree Biotech
3:40 - 3:50	**Q & A**
3:50 - 3:55	**Closing Remarks**

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ABSTRACTS

Developing Assays and Standards to Support Shigella Vaccine Development
Calman MacLennan, Bill & Melinda Gates Foundation

Shigella is the main cause of diarrheal deaths globally next to rotavirus. Despite the demonstration of efficacy against shigellosis with an S. sonneiO-antigen/rEPA conjugate vaccine developed by the NIH 24 years ago, no vaccine to date has been licensed for widespread use. However, several vaccines are currently in clinical development predicated on the findings with the NIH conjugate vaccine that support serum IgG to O-antigen as a correlate of protection. As a result, much attention has been given to the measurement of these antibodies by ELISA and functional activity using SBA. This talk will focus on efforts to harmonise these assays across enteric diseases laboratories and develop a first international standard serum for *Shigella*.

Using Remote Blood Sampling to Analyze Biomarkers - Benefits and Challenges
James Rudge, Neoteryx, UK

The SARS-CoV-2 pandemic brought into sharp relief the need for remote sampling where populations were asked to remain at home in an attempt to control the spread of the virus. No longer was it safe for people to attend clinics or participate at clinical trial centres. Prior to the pandemic, there had been increased interest in remote sampling to help monitor health conditions. For example, it had become commonplace for diabetics to measure their blood glucose levels at home using point-of-care glucometers from capillary blood samples. However, the point-of-care sampling approach to monitor other biomarkers has been less popular leading to a continued reliance on people attending phlebotomy clinics.

An area where remote analysis of biomarkers from capillary blood sampling has been a huge success, is in the use of dried blood spot (DBS) cards for neonatal screening. Nevertheless, increased needs for improved reliability and quantitation has led to the development of technologies such as VAMS®. VAMS uses a volumetric absorptive approach to microsampling to collect a quantitative, fixed volume of capillary blood. Like DBS, VAMS samples can be mailed to the lab for analysis without the need for a cold chain.

This presentation will focus on what classes of biomarkers have been successfully developed from volumetrically collected dried blood samples and approaches to transitioning other popular biomarkers onto the VAMS platform.

The Impact of Decentralized Clinical Trials on Laboratory Testing

Self-collection of blood samples and at home point of care testing in clinical trials

Chuck Drucker, Q² Solutions

The hype is over. Decentralized clinical trials are here to stay. But how does the decentralized approach impact laboratory testing processes today and in the future? Today, home specimen collection visits by nurses or phlebotomists have become relatively common. Most large CROs have either acquired or built home nursing capabilities. But what's next? Will self-collection of blood samples and at home point of care testing become a reality? Even if the technologies continue to rapidly evolve and device regulatory hurdles are achieved, are we as an industry ready to tackle the operational and patient burden challenges of such approaches?

Current Status and Future Perspectives of Biomarker Analysis in China

Kelly Dong, UP Pharma, Shanghai

Driven by the rapid growth of economy and the increasing demand of unmet medical needs, pharmaceutical industry and medical research have become one of the most fast developing sectors in China in the past two decades. Vast amount of resource have been invested into the area which enable the industry to evolve from generic to innovative and "me better". Reflecting the increasing effort in innovative therapeutics and precision medicine, biomarker analysis has become the integral part in the medical research and clinical development. This presentation will provide an overview on current practice, landscape of local service providers, the challenges encountered and future perspectives for biomarker analysis in China.

COVID-19 Rapid Response Biomarker Implementation

Erica Troksa, Covance

Within the vast experience and expertise of Covance Biomarker capabilities, the teams within Covance had to leverage new and old strategies to implement a rapid response to biomarker needs in support of COVID -19. In this discussion, we will highlight the strategy to resource and develop extended biomarker offerings to support the COVID-19 needs across exploratory and CAP/CLIA departments within Covance. In addition to identifying the approach to bring forth new biomarker strategies amidst the pandemic crisis, we will also demonstrate how the applications of these biomarkers were utilized across multi-disciplinary therapeutic studies, including COVID-19 vaccine trials.

MEEDAT, a Multiplex ELISA of Biomarkers for Environmental Enteric Dysfunction

Robert Choy, PATH

Environmental enteric dysfunction (EED) is an intestinal disorder common among children in low-resource settings. EED is characterized by blunting of intestinal villi, growth stunting, malnutrition, reduced oral vaccine efficacy, and cognitive developmental deficits. Definitive diagnosis of EED requires an intestinal biopsy, a procedure that is not routinely feasible in geographies where EED is prevalent. We therefore sought to develop a panel of biomarkers suitable for evaluating EED in low-resource settings. PATH previously developed a 7-plex ELISA for testing micronutrient deficiency using alpha-1-acid glycoprotein, C-reactive protein, ferritin, soluble transferrin receptor, thyroglobulin, retinal binding protein 4, and histidine-rich protein 2. We added four additional biomarkers for intestinal damage and repair and growth stunting (intestinal fatty acid-binding protein, soluble CD14, insulin-like growth factor 1, and fibroblast growth factor 21) to yield the micronutrient and EED assessment tool (MEEDAT). The performance of this panel of 11 biomarkers has been verified with a set 300 serum samples collected in a rotavirus vaccine study in Malian infants. This analysis identified correlations between MEEDAT biomarkers, anthropometry, and vaccine immunogenicity that will be further explored in upcoming studies. We will also consider how MEEDAT biomarkers may serve as a novel approach to evaluate enteric vaccine efficacy.

Translating Pharmacodynamic Immune Biomarkers to the Clinic

Christopher Kirkham, Elisa Masat, Clare Hetheridge, Charlotte Hayden, Mikaela Hughes, Russell Garland, S. Rhiannon Jenkinson

Primary and secondary endpoints in first-in-human clinical trials are traditionally concerned with safety. Expanding the remit of these studies to include exploratory biomarkers from an early stage provides key information on efficacy and mode of action of the therapeutic in humans. This strategy can assist in go/no-go decisions, thus greatly increasing the likelihood of success in progressing a therapeutic through to the clinic. We routinely employ biomarkers to monitor immune responses and their modulation by novel therapeutics. Phase I safety trials are typically run in healthy donors where the immune system is in a quiescent state, therefore determining whether a therapeutic is on target often requires an appropriate ex vivo stimulation. Here, we show modulation of LPS-stimulated immune responses as an example of translation of a biomarker assay through the stages of drug discovery. We discuss strategies to identify biomarkers in human whole blood assays using NanoString molecular profiling, how this can be focused into a panel of cytokine analytes at the protein level using Luminex multiplexing, and how this can then be used in murine PD models to gain in vivo data. Finally, we discuss how the selected biomarkers can be translated and validated to Good Clinical Laboratory Practice (GCLP) standards, where the performance of key assay parameters is determined to ensure reliable clinical data. This strategy is an example of how analysing PD biomarkers in a translational manner provides early indications as to whether a therapeutic modulates its expected target in humans.

BIOGRAPHIES

Robert Choy, PhD, PATH

Robert Choy is Director, Research and Development in PATH's Center for Vaccine Introduction and Access, Enteric and Diarrheal Diseases. He also serves as the leader for PATH's Drug Innovation and Access Initiative team and Coronavirus Vaccine Initiative Opportunities subteam. In addition to MEEDAT, he currently leads projects developing vaccines for rotavirus and therapeutics for cholera and cryptosporidiosis. Robert received his PhD in Molecular and Cellular Biology from the University of Washington.

Kelly Dong, PhD, United-Power Pharma Tech Co.

Kelly obtained her Ph.D. degree from McGill University, Canada. She has more than 25 years of multinational industry experience working for pharmaceutical companies and CROs in Canada, the UK, and China. Her scientific expertise encompasses drug discovery DMPK and regulated bioanalysis for preclinical and clinical development. After 20-year overseas experience in North Amercia and Europe, Kelly joined GlaxoSmithKline R&D China in August 2009. She was the Director of DMPK for CNS drug discovery and Head of Bioanalysis, Immunogenicity and Biomarker in China, overseeing over 50 preclinical and clinical studies across different therapeutic areas. Kelly joined United-Power Pharma as the Chief Executive Officer since February 2018. She is also a Research Fellow at the National Engineering Research Center of Protein Drugs. Kelly is one of the founders and a steering committee member of China Bioanalysis Forum (CBF). She is also an active contributor to the scientific community, with more than 60 scientific publications and invited lectures.

Chuck Drucker, PhD, Q^2 Solutions

Chuck Drucker is Head of Decentralized Trial Solutions at Q^2 Solutions, the laboratory division of IQIVA, where he leads a team accountable for developing solutions and supporting clinical trials related to home healthcare, patient self-collection of specimens, point of care testing, direct to patient solutions, and referral laboratory services. Previously he led Alliance Management and Marketing at Q^2 Solutions. In addition, he is the founder of Sales and Marketing Professionals in Science (SAMPS). Prior to Q^2 Solutions, Mr. Drucker held positions at Covance, AAI Pharma, and Amersham Biosciences (now Cytiva). He has an MBA and a bachelor's degree from Rutgers University.

Coryandar (Cory) Gilvary, PhD, OneThree Biotech

Coryandar (Cory) Gilvary's research has primarily focused on developing new machine learning techniques for increasing the efficiency and innovation of drug development and discovery. She takes the unique approach of combining distinct types of noisy, high-throughput data to maximize algorithmic performance, while also building interpretable models that allow for a deeper mechanistic insight to the mode of action of therapeutics. She has leveraged cutting edge AI concepts across diverse disease areas including, but not limited to, oncology, diabetes and Parksinson's disease. Outside of her biological research, she spent time developing cutting edge machine learning models at one of the world's leading quantitative hedge funds.

Much of Cory's early research work formed the core OneThree platform, which is currently being expanded upon. Currently, she leads OneThree's the data science and computational biology efforts both internally and with OneThree's partners. At the beginning of 2020, she spearheaded OneThree's internal efforts to provide free toxicity screening to any researchers working on treatment for COVID-19.

Francis Jones, PhD, PPD

- Senior Director in the PPD Digital team focusing on Decentralised Clinical Trial Strategy and Innovation.
- More than 20 years' drug development experience working for both Pharma and CRO
- Current role focuses on clinical trial strategy development - writing proposals, reviewing trial protocols and helping clients design optimised DCT solutions.
- Extensive experience project managing global clinical trials across a range of therapeutic areas.
- Has a pharmacology PhD from Cardiff Medical School, UK
- Location: West Sussex, UK

Christopher Kirkham, PhD, Charles River Laboratories

Chris is a Manager within the Bioanalytical Services group at Charles River Laboratories. He is based at the Portishead site in the UK, which specialises in immunology and infection. Chris leads a team focused on immune modulation in both pre-clinical and early phase clinical phases of drug discovery programmes, with a particular focus on pharmacodynamic (response) biomarkers. The team has supported studies for multiple clients within these fields. Chris was awarded his PhD in 2014 by the University of Leeds, UK.

Zhanmin Lin, PhD, Teddy Lab

Dr. Lin has experience spanning over 15 years in molecular biology and virology. Now he serves as EMEA project manager at Teddy Lab, based in Amsterdam, leading the global clinical trials on COVID vaccine development. Prior to that, Dr. Lin had studied in the field of Neuroscience for Msc and PhD at Erasmus Medical Center in The Netherlands. He received his BSc degree in China Pharmaceutical University.

Calman A. MacLennan, MD, Bill and Melinda Gates Foundation

Cal MacLennan is Senior Program Officer for Bacterial Vaccines in the Enteric and Diarrheal Diseases team at the Bill and Melinda Gates Foundation, responsible for the Shigella and Salmonella vaccine product development portfolios. Following his medical degree and DPhil from Oxford, and during specialist training in clinical immunology, he spent time in Malawi and Kenya investigating immunity to invasive Salmonella disease. From 2010, Dr MacLennan was Head of the Exploratory Programme at the Novartis Vaccines Institute for Global Health, Italy, developing vaccines against Salmonella, Shigella and meningococcus. He returned to Oxford, in 2015 to the Jenner Institute, before moving to the Gates Foundation in 2017. His ongoing work at the Jenner Institute focuses on gonorrhoea vaccine development. He is an honorary consultant immunologist, Professor of Vaccine Immunology and Director of the MRC/GCRF BactiVac Bacterial Vaccinology Network.

James Rudge, PhD, Neoteryx

James Rudge, PhD, has served as Technical Director of Neoteryx since January of 2015. Dr. Rudge is a co-inventor of the Mitra® device and the patented VAMS® technology, which he co-created to enable a volumetric absorptive approach to microsampling. Dr. Rudge has co-authored 11 papers on VAMS with global collaborators, and he has authored a new book chapter on patient-centric sampling to be published in 2021. Dr. Rudge has given many podium presentations on volumetric absorptive microsampling over the years and was the plenary speaker at the 2021 CPSA (Clinical & Pharmaceutical Solutions through Analysis) EU virtual conference. Dr. Rudge is involved with a number of research collaborations with global institutions, and is part of a large European research consortium addressing unmet needs in inflammatory disease.

Prior to joining Neoteryx, Dr. Rudge worked for Phenomenex for 14 years. During his years at Phenomenex, Dr. Rudge

held a number of roles including Key Account Manager, Field Service Specialist and European Business Development manager for Clinical. These roles allowed him to collaborate with customers on a wide range of projects, and he regularly worked in customer laboratories (globally) developing novel sample preparation and LC-MS/MS methods.

Dr. Rudge received a BSc. with honors (Hons) IIi in Biochemistry and a PhD in Organic Chemistry from the University Wales, Swansea. His doctoral work was focused on novel chemiluminescent probes for immunoassays.

Erica Troksa, PhD, Covance

Erica Troksa received her Doctorate in Pharmacology from the University of Illinois at Chicago in 2011. After gaining assay development experience for a commercial Biotech company, she transitioned into a scientific role in Covance Translational Biomarker solutions team in 2013. In this role, Dr. Troksa expanded her expertise in de novo development of novel biomarkers and complex validation for multiplex immunoassay offering. She translated this experience into support of the wider TBS team and onto additional groups throughout Covance, and external partners, to help support pre-clinical and clinical biomarker development across ligand binding assays, flow cytometry, and cell based assays. As of 2020, Dr. Troksa added the Global Immunology team in Covance Central Laboratory Services Indianapolis facility to her list of responsibilities. Dr. Troksa leads the TBS and CLS Immunology teams in scientific innovation, operational excellence, and strategic planning across the exploratory and CAP/CLIA biomarker portfolio.

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Without your dedication, support and participation ABA 2021 would not be possible. We greatly value your comments regarding ABA 2021 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