Opening Remarks (8:00 – 8:30am)

Peter Marks, MD, Ph.D.
Director
Center for Biologics Evaluation and Research

Integration of MIDD in drug development and regulatory decision-making - Overview of efforts under PDUFA VI

Rajanikanth Madabushi, Ph.D.
PoC for MIDD paired meeting Pilot program
Center for Drug Evaluation and Research

8:30am – 10:30am

Session 1: Methodological advances in immunogenicity assessment

1. Aleksander Popel, Ph.D, Johns Hopkins University
   • Quantitative Systems Pharmacology: Applications to Immuno-Oncology

2. Xiaoying Chen, Ph.D, Pfizer
   • A Systems Pharmacology Modeling Approach to Immunogenicity Prediction

3. Lora Hamuro, Ph.D, Bristol-Myers Squibb
   • Quantitative Assessment of the Immunogenicity Impact on Safety and Efficacy for a Nivolumab & Ipilimumab Combination in 1L Melanoma

4. Andrzej M. Kierzek, Ph.D, Certara
   • Quantitative Systems Pharmacology approach to predicting and managing impact of immunogenicity on pharmacokinetics of therapeutic proteins

5. Live Q/A with all speakers (20min)

20 min intermission, resume at 10:30am

10:30am – 12:10pm

Session 2: Data needs for improved in silico immunogenicity modeling

1. Atul Butte, MD, Ph.D – UCSF
   • Translating a Trillion Points of Data into Therapies, Diagnostics, and New Insights into Immunological Disease
2. Malachi Griffith, Ph.D. – Washington University
   - Bioinformatics and immunogenomics approaches for neoantigen target identification

3. Morten Nielsen, Ph.D. – Danish Technical University
   - The use of HLA class II antigen presentation prediction in the context of immunogenicity assessment of biologics

4. Brandon Dekosky, Ph.D – Kansas University
   - Exploring Personalization of Human Immune Responses with High-Throughput Immune Receptor Data

5. Live Q/A with all speakers (20min)

50 min intermission, resume at 1:00pm

1:00pm – 2:50pm

Session 3: Modeling of desired immunogenicity to inform development of vaccines/allergenics

1. Yongqun He, Ph.D., University of Michigan
   - COVID-19 vaccine machine learning, ontology modeling, and Cov19VaxKB

2. Peter Gilbert, Ph.D., Fred Hutch Institute
   - Learning Immune Correlates of Protection from Vaccine Efficacy Trials

3. Richard White, Ph.D., Sophie Rhodes, Ph.D. - London School of Hygiene and Tropical Medicine
   - Using Epidemiological and Immunostimulation/Immunodynamic modelling to estimate TB vaccine impact and optimise vaccine dose

4. Ryoko Sawamura, Ph.D., Daiichi Sankyo
   - QSP Application to COVID-19 Vaccine Clinical Development

5. Live Q/A with all speakers (20min)

10 min intermission, resume at 3:00pm
3:00pm – 4:00pm

Session 4: Unmet needs in immunogenicity modeling in advanced therapies

1. Guangping Gao, Ph.D. – University of Massachusetts School of Medicine
   • *Vector-related immunogenicity as a potential roadblock to AAV gene therapy - assessment and mitigation*

2. Nirjal Bhattarai, Ph.D. – US FDA, Center for Biologics Evaluation and Research
   • *Immunogenicity of Chimeric Antigen Receptor T Cells*

3. Jochem Gokemeijer, Ph.D. - Bristol-Myers Squibb
   • *Pre-clinical immunogenicity risk assessment tools and strategies for novel modalities*

4. Live Q/A with all speakers (15min)

4:00pm – 4:50pm

Session 5: Round Table Discussion

1. Tim Hickling, Ph.D. – Roche
2. Piet Van der Graaf, Ph.D. – Certara
3. Xiaofei Wang, Ph.D. - FDA – CBER – Office of Tissues and Advance Therapies
4. Catherine Wu, MD - Harvard University
5. Sophie Rhodes, Ph.D. - London School of Hygiene and Tropical Medicine

4:50pm – 5:00pm

Closing Remarks

Zuben Sauna, Ph.D, FDA – CBER – Office of Tissues and Advance Therapies