MIDD Immunogenicity Workshop
June 9th, 2021 – 8:00am - 5:00pm

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
    - ***Ontology-based modeling and analysis of anti-coronavirus drugs***

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

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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