12th Annual

Immunogenicity & Bioassay Summit

VIRTUAL

Technologies and Strategies for Safe and Efficacious Products in the Clinic

October 6-9, 2020

Keynote & Featured Speakers:

Daniela Verthelyi, MD, PhD
Chief, Laboratory of Immunology, CDER, FDA

Boris Gorovits, PhD
Senior Director, BioMedicine Design, Pfizer, Inc.

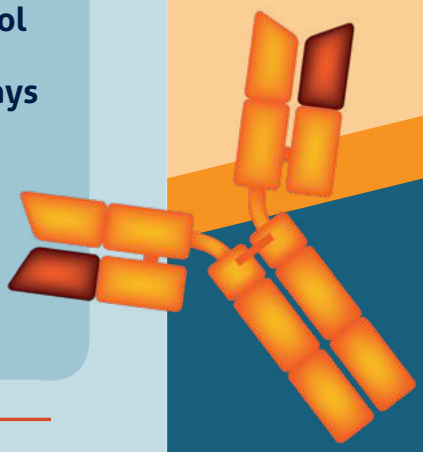
Alessandro Sette, PhD
Professor & Central Head, Vaccine Discovery & Infectious Disease, La Jolla Institute for Allergy & Immunology

Sumona Sarkar, PhD
Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

Soumi Gupta, PhD
Director, Translational Sciences, BioMarin Pharmaceutical

Conferences:

- Immunogenicity Assessment & Clinical Relevance
- Immunogenicity Prediction & Control
- Optimizing Bioassays for Biologics
- Symposium: Immunology for Biotherapeutics



[5 FDA Speakers for 2020!]

Plus!
5 Short Courses, exhibits, posters, and more.

Final Days to Register!

Organized by Cambridge Healthtech Institute

#ImmunoBio20 | ImmunogenicitySummit.com

Premier Sponsor

GYROS PROTEIN Technologies

Connect with Us #ImmunoBio20

Join us at the #1 Immunogenicity & Bioassay Event in the U.S.

Bringing Together Industry, Academia & Regulatory Authorities in a VIRTUAL Format

For the first time ever, CHI is excited to bring to you its Immunogenicity & Bioassay Summit from the comfort of your own home or office! Now in its 12th year, the Immunogenicity & Bioassay Summit will examine the challenges currently facing the industry. Hear from industry leaders, academics and the FDA who will share NEW case studies, NEW perspectives and NEW approaches. This year we present 3 Conference Programs, a Symposium, and 5 Short Courses. Through our virtual platform, you have the option to move between presentations taking place at the same time. Plus, delegates can enable a live chat feature, view a virtual exhibit & poster hall, attend happy hours, breakout discussions and more. **This virtual event is available "Live" & On-Demand and will take place on Eastern Daylight Time.**

Conference At-a-Glance

Tuesday | October 6

- Symposium 1: Immunology for Biotherapeutics
- **Tues AM SC1:** Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays
- **Tues PM SC2:** Overcoming Drug and Target Interference in ADA assays
- Happy Hour

All times are Eastern Daylight Time

Wednesday | October 7

- **C1:** Immunogenicity Assessment & Clinical Relevance
- **Wed AM *over lunch* | SC3:** Validation of ADA Assays and Cut Point Calculations
- Happy Hour

Thursday | October 8

- **C1:** Immunogenicity Assessment & Clinical Relevance
- **C2:** Immunogenicity Prediction & Control
- **C3:** Optimizing Bioassays for Biologics
- **Thurs AM *over lunch* | SC4:** Recent Advances with Gene and Cell Therapy
- Happy Hour

Friday | October 9

- **C2:** Immunogenicity Prediction & Control
- **C3:** Optimizing Bioassays for Biologics
- **Fri PM *over lunch* | SC5:** Advice on Putting Together an Integrated Summary of Immunogenicity

Benefits of Immunogenicity & Bioassay Summit Virtual

- **VIRTUAL CONFERENCE** accessible from the comfort of your home or office
- **INSPIRING KEYNOTE PRESENTATIONS** from world-renowned experts and visionaries
- **INTERACTIVE NETWORKING** with live Q&A sessions, breakout discussions, poster viewing, live chat with exhibitors, sponsors, and fellow delegates
- **RESEARCH POSTERS** engage with researchers presenting the latest in biotherapeutics discovery
- **SPONSORED TALKS** by leading technology and service providers showcasing new offerings
- **ON-DEMAND LIBRARY** with an archive of presentations to access on your own time

SPONSORSHIP, EXHIBIT & LEAD GENERATION OPPORTUNITIES

Comprehensive sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

Premier Sponsor *(Limited Availability)*

- 20-Minute Presentation
- Pre- & Post-Email Blast to all attendees
- Post-event, CHI will provide full contact information (GDPR-compliant) for your specific session and the full conference attendee list
- Virtual Exhibit Booth Space
- And much MORE!

Corporate Sponsorship Presentation

- 20-Minute Presentation
- Post-event, CHI will provide full contact information for your specific session
- Virtual Exhibit Booth Space
- And much MORE!

Corporate Support Sponsor

- Virtual Exhibit Space
- Two (2) main conference registrations
- Corporate logo placed on conference materials
- And MORE!

Virtual Exhibit Booth

- Branding
- Company Description
- Product & Service Tags (searchable via product directory)
- Videos & Downloadable Files to Highlight Products & Services
- Booth Personnel – Contacting booth personnel will be available live (if they are present) by scheduling a video call, or by inquiring with an attendee's email address provided (virtual business card exchange)
- Networking Options: matchmaking, create a favorite list, send a message, request 1:1 meetings
- Advanced Analytics (details about booth visitors, time spent visiting booth & products)
- Two (2) conference registrations
- Additional conference registrations available at a discount for your staff – limited to 5

Looking for additional ways to drive leads to your sales team?

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Live Webinars
- White Papers
- Market Surveys
- Podcasts and More

For more information regarding exhibit and sponsorship, please contact:

Jon Stroup
Sr. Business Development Manager
781.247.5483 | jstroup@healthtech.com

Premier Sponsor

GYROS PROTEIN Technologies

Corporate Sponsors

ImmunXperts

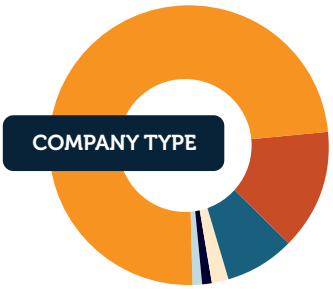
The Jackson Laboratory

PROIMMUNE www.proimmune.com

Corporate Support Sponsor

MilliporeSigma

2019 ATTENDEE DEMOGRAPHICS



Biotech & Pharma	74%
Government & Academic	14%
Services	8%
CRO	2%
Societies	1%
Other	1%

USA	82%
Europe	13%
Asia	4%
Rest of World	1%

US BREAKDOWN

East Coast	79%
West Coast	14%
Midwest	7%

Scientist/Technologist	36%
Executive + Director	32%
Sales & Marketing	15%
Manager	15%
Professor	1%
Assistant	1%





5 FDA Speakers for 2020!

Distinguished Faculty

Barry Byrne, MD, PhD, Professor and Associate Chair, University of Florida

Etienne Caron, PhD, Assistant Professor, CHU Sainte-Justine Research Center, University of Montreal

Saso Cemerski, PhD, Vice President and Head of Discovery and Translational Immunology, Cue Biopharma

John Chappell, BSc, CChem, CSci, FRSC, Application & Service Director EMEA and Asia Pacific, Gyros Protein Technologies

Lukasz Chlewicki, PhD, Principal Research Scientist, Eli Lilly and Company

Shan Chung, PhD, Associate Director & Principal Scientist, Bioanalytical Sciences, Genentech

Sivan Cohen, PhD, Scientist, Genentech

Manuela Corti, PhD, Assistant Professor, Child Health Research Institute, University of Florida

Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

Bo Feng, PhD, Associate Principal Scientist, Process R&D, Merck & Co., Inc.

Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

Daron Forman, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb

Dan Fowler, MD, CMO, Rapa Therapeutics

Theresa Goletz, PhD, President, Theresa Goletz Consulting

Boris Gorovits, PhD, Senior Director, Pharmacokinetics, Pharmacodynamics & Metabolism, Pfizer Inc.

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

Mohamed Hassanein, PhD, Associate Director, Clinical Assay Lead (Biologics), Pfizer

Timothy Hickling, PhD, Head of Immunosafety, Roche

Wojciech Jankowski, PhD, Commissioner's Fellow, CBER, FDA

Emilee Knowlton, PhD, Senior Immunology Sales Specialist, ProImmune

Daniel LaGasse, PhD, Research Regulator, CBER, FDA

David Lansky, PhD, President, Precision Bioassay, Inc.

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

Chang Liu, PhD, Associate Scientist, BioAnalytical Sciences, Genentech Inc.

Bernard Maillere, PhD, Research Director, Immunology, CEA

Ronit Mazor, PhD, Principal Investigator, CBER, FDA

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

Jos Melenhorst, PhD, Director, Product Development & Correlative Sciences, Center for Cellular Immunotherapies, University of Pennsylvania

Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

Paul Moore, PhD, Vice President, Cell Biology & Immunology, MacroGenics, Inc.

Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb

Kannan Natarajan, PhD, Staff Scientist, NIH NIAID

Simone Nicholson, PhD, Discovery Safety Specialist, AstraZeneca

Michael Partridge, PhD, Associate Director, Bioanalytical Sciences, Regeneron Pharmaceuticals

Cheryl Pickett, MD, PhD, Associate Research Physician, Cancer Therapy Evaluation Program, Investigational Drug Branch, NIH NCI

Qiang Qu, Principal Scientist, EMD Serono

Theo Rispens, PhD, Head of Lab/PI, Sanquin

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Ethan Shevach, MD, Senior Investigator, Cellular Immunology, Laboratory of Immune System Biology, NIH NIAID

Basile Siewe, Director, Business Development, The Jackson Laboratory

Renu Singh, PhD, Scientific Leader, GSK

Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

Weifeng Xu, PhD, Principal Scientist & Group Leader, PPDM, Merck Research Labs

Tatyana Yun, PhD, Senior Scientist, Merck

Jeff Zhu, Senior Investigator, Laboratory of Immune System Biology, NIAID, NIH

undefined

Morten Nielsen, PhD, Professor, Department of Health Technology, Technical University of Denmark

Sofie Pattijn, Founder & CTO, ImmunXperts SA

Sandra Prior, PhD, Senior Scientist, National Institute for Biological Standards and Control (NIBSC, a centre of the MHRA)

Nancy Sajjadi, Independent Quality Consultant

Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

Tim Schofield, Owner & Consultant, CMC Sciences LLC

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA

Wen Jin Wu, MD, PhD, Senior Investigator, Biotechnology Products, CDER, FDA

Short Courses*

October 6-8, 2020

**Separate registration is required, see Registration Page for pricing details*

TUESDAY, OCTOBER 6 11:35 AM-1:05 PM

SC1: Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays

Instructors:

Shan Chung, PhD, Associate Director & Principal Scientist, Bioanalytical Sciences, Genentech

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

The development of neutralizing antibody assays is a daunting task that is complicated by the specific nature of each biotherapeutic. Many factors must be assessed to choose the proper assay format, to develop a robust assay and choosing when to invest in the development and implementation of these assays. This short course will focus on these topics and provide examples of current industry practices and publications. Specific focus will be given to a mechanism of action-based approach to selecting the assay format and relevant case studies will be provided.

TUESDAY, OCTOBER 6 2:35-4:35 PM

SC2: Overcoming Drug and Target Interference in ADA Assays

Instructors:

Weifeng Xu, PhD, Principal Scientist & Group Leader, PPDM, Merck Research Labs

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

Lynn Kamen, PhD, Senior Scientist, BioAnalytical Sciences, Genentech Inc.

Soluble drug, drug target and matrix can often interfere in the detection of anti-drug antibodies including neutralizing Abs. Although not always straightforward, it can be addressed and mitigated in a properly designed immunoassay. This short course will give an overview of the different types of interferences and current methodologies and approaches being utilized to resolve or reduce them.

WEDNESDAY, OCTOBER 7 11:55 AM-1:55 PM

SC3: Validation of ADA Assays and Cut Point Calculations

Instructors:

Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb

Angela Yang, PhD, Scientist, Bioanalytical Sciences, Regeneron Pharmaceuticals, Inc.

This short course will focus on the validation of ADA assays and cut point evaluations. We will provide an in-depth overview of the basic considerations around ADA assay validation, with significant focus on the process of evaluating different types of cut-points, and the translation of the cut-point established during validation to the real-world implementation during a preclinical or clinical study.

THURSDAY, OCTOBER 8 11:40 AM-1:10 PM

SC4: Recent Advances with Gene and Cell Therapy

Instructors:

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

Topics to be Covered Include:

- Immunogenicity assessment of cell therapies
- Examining recent developments with CAR-T cells and edited stem cell
- Immunogenicity assessment of gene therapies
- Recent data on pre-existing reactivity for AAV
- Advances with redosing
- Application of current guidance to novel modalities
- What is your product? The vector, the expressed product?

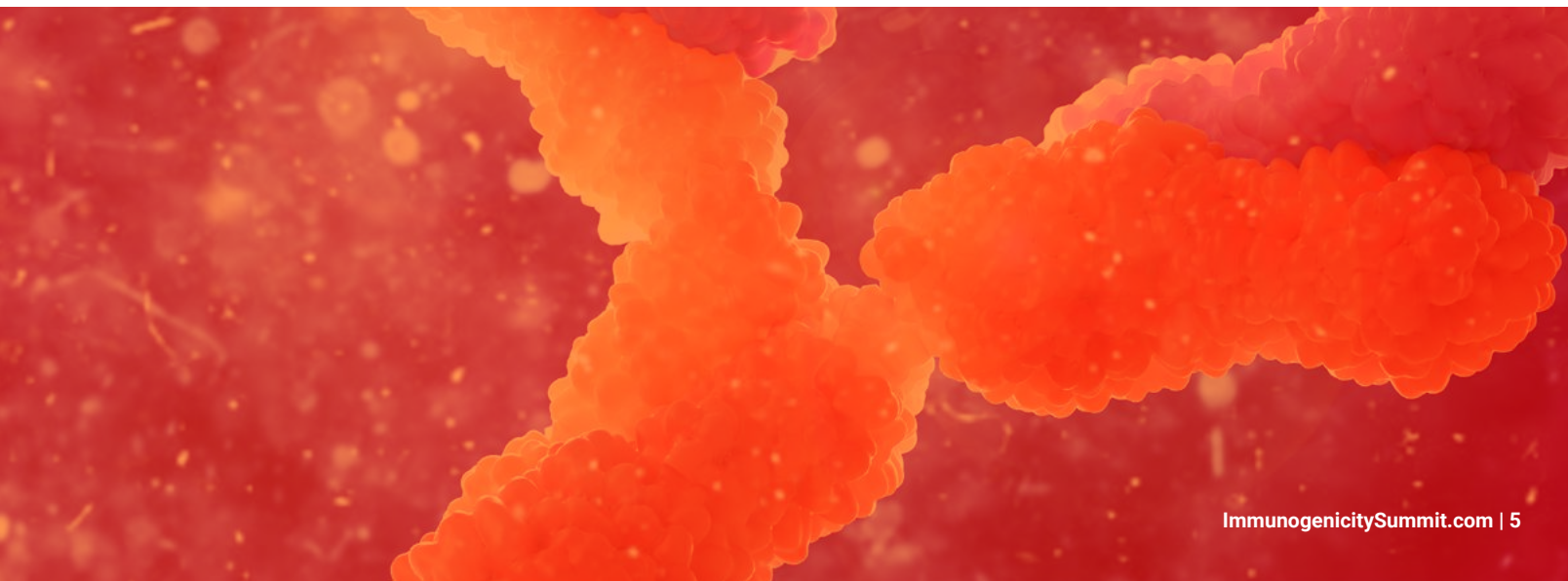
FRIDAY, OCTOBER 9 12:05-1:35 PM

SC5: Advice on Putting Together an Integrated Summary of Immunogenicity

Instructor:

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

The purpose of this workshop is to share experience gained in preparing and reviewing the "Integrated Summary of Immunogenicity", with case examples to illustrate the multi-disciplinary information that is most useful for the regulator assessing the scale of risk of undesirable immunogenicity for overall clinical benefit vs. risk. It will examine the sponsor team's role and provide examples of how to address potential issues (and avoid introducing any new ones!) by generating a well-thought-out and constructed integrated summary.



Symposium: Immunology for Biotherapeutics

Understanding and Manipulating the Immune System for Therapeutic Advantage

October 6, 2020

TUESDAY, OCTOBER 6

CURRENT UNDERSTANDING OF IMMUNE MECHANISMS

9:05 am KEYNOTE PRESENTATION: Current Understanding of the Role of T Regulatory Cells and Their Modulation

Ethan Shevach, MD, Senior Investigator, Cellular Immunology, Laboratory of Immune System Biology, NIH NIAID

The immune system consists of several distinct cell types and each type plays a unique role. Dysregulation of the immune system can result in responses against self-antigens and in the development of autoimmune diseases. A specialized subset of T lymphocytes, termed T regulatory (Treg) cells, functions to suppress anti-self responses. Modulation of Treg function with drugs or biologics represents a major approach to the treatment of autoimmune disease.

9:25 Antigen Processing and Presentation: T Cell Activation and Interaction between the Cells of the Immune System

Kannan Natarajan, PhD, Staff Scientist, NIH NIAID

Antigen Presenting Cells process protein antigens into peptides for binding by either Major Histocompatibility Class I (MHC-I) or Class II (MHC-II) molecules, which are then displayed at the cell surface as peptide/MHC complexes, where they are recognized by T cell receptors leading to T cell activation. Cell biological, biochemical, and structural details of these processes as we now understand them will be discussed.

9:45 T Helper and Innate Lymphoid Cell Subsets

Jeff Zhu, Senior Investigator, Laboratory of Immune System Biology, NIAID, NIH

Specific T helper and innate lymphoid cell subsets mediate crucial functions during different types of protective immune response. Inappropriate Th responses and ILC activation may lead to chronic infection and/or tissue damage. In addition, aberrant Th cell and ILC activation may result in many inflammatory allergic or autoimmune diseases. I will discuss the similarities and differences between Th cell and ILC subsets, and their functional crosstalk during immune responses.

10:05 Coffee Break - View Our Virtual Exhibit Hall

HARNESSING THE IMMUNE SYSTEM FOR BIOTHERAPEUTICS

10:20 Applying Bispecific Technology to Modulate the Immune Response for Therapeutic Intervention

Paul Moore, PhD, Vice President, Cell Biology & Immunology, MacroGenics, Inc.

Bispecific antibody-based molecules afford therapeutic opportunities not feasible with single-target antibodies or combinations. The most advanced clinical strategy in oncology exploits the ability of bispecific molecules to co-engage T cells with tumor cells, resulting in tumor cell lysis and T cell expansion. Additional approaches to leverage immune cells through bispecific targeting are being explored in oncology, autoimmunity, and infectious diseases. These will be discussed regarding molecule design and target selection.

10:40 Immunology Safety Considerations for Biotherapeutics

Simone Nicholson, PhD, Discovery Safety Specialist, AstraZeneca

Biotherapeutics are currently used in the treatment of numerous diseases which encompass oncology and autoimmune inflammatory disorders. Investigators are challenged to predict, monitor and mitigate if possible, potential adverse effects in patients while ensuring efficacy and satisfying the regulatory requirements for drug approval. Examples of these safety concerns and how their challenge is met and managed are the subject of this presentation.

11:00 Biopharmaceutical Product Immunogenicity: What Causes It and What Are the Safety and Efficacy Consequences?

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Biopharmaceuticals contribute significantly to treatment of serious diseases, including chronic inflammatory and autoimmune diseases, genetic deficiencies, and cancer. Unwanted immunogenic responses against some of these products can occur, reducing efficacy and sometimes causing safety consequences, such as hypersensitivity, immune complex disease, and autoimmune syndromes. I will discuss factors that affect the degree to which the immune system responds, and the degree to which the response affects the efficacy and safety.

11:20 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Ethan Shevach, MD, Senior Investigator, Cellular Immunology, Laboratory of Immune System Biology, NIH NIAID

Panelists:

Kannan Natarajan, PhD, Staff Scientist, NIH NIAID

Jeff Zhu, Senior Investigator, Laboratory of Immune System Biology, NIAID, NIH

Paul Moore, PhD, Vice President, Cell Biology & Immunology, MacroGenics, Inc.

Simone Nicholson, PhD, Discovery Safety Specialist, AstraZeneca

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

11:35 Recommended Short Course*

SC1: Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays

**Separate registration required. See short course page for details.*

11:35 Lunch Break - View Our Virtual Exhibit Hall

IMMUNO-ONCOLOGY

1:05 pm Harnessing the Body's Natural Immune Response to Fight Cancer

Daron Forman, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb

Checkpoint inhibitors have shown remarkable response rates in some previously hard-to-treat cancers by redirecting the body's own immune system to recognize and eliminate tumor cells. Here, we will discuss the current state of checkpoint inhibitors in the clinic, challenges related to toxicities, biomarker approaches for patient stratification, and future directions of the field.

1:25 Adoptive T Cell Therapy

Jos Melenhorst, PhD, Director, Product Development & Correlative Sciences, Center for Cellular Immunotherapies, University of Pennsylvania

I will discuss the evolving field of adoptive T cell therapy, and compare and contrast tumor-targeting efforts with allogeneic, autologous, minimally manipulated to the TCR- and CAR-redirected T cells. Topics to discuss are safety, efficacy, toxicity; clinical trials in hematologic and solid tumors; and future directions to enhance immunogene therapy of cancer.

1:45 Oncolytic Viruses: Impact of the Virus on Tumor Cells, Local Microenvironment, and Systemic Adaptive Immune Response

Cheryl Pickett, MD, PhD, Associate Research Physician, Cancer Therapy Evaluation Program, Investigational Drug Branch, NIH NCI

Intratumorally injected oncolytic viruses infect, replicate, and lyse cancer cells. Through release of tumor-specific antigens and cytokines, they induce changes in local immune microenvironment, activating the adaptive immune system, and producing responses in non-injected lesions. These changes sensitize tumors to checkpoint inhibitors. We will review data on oncolytic viruses with attention to systemic responses and potential combination with other immunotherapy. We will also review delivery and safety issues.

2:15 Novel Humanized NSG™ Mouse Cytokine Release Syndrome Evaluation Study Platform

Basile Siewe, Director, Business Development, The Jackson Laboratory

The JAX® cytokine release syndrome evaluation study platform leverages PBMC humanized NSG™ mice to overcome limitations of *in vitro* assays in assessing the potential of immunotherapeutics to elicit CRS.

2:35 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Daron Forman, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb

Panelists:

Jos Melenhorst, PhD, Director, Product Development & Correlative Sciences, Center for Cellular Immunotherapies, University of Pennsylvania

Cheryl Pickett, MD, PhD, Associate Research Physician, Cancer Therapy Evaluation Program, Investigational Drug Branch, NIH NCI

Basile Siewe, Director, Business Development, The Jackson Laboratory

2:50 Happy Hour - View Our Virtual Exhibit Hall

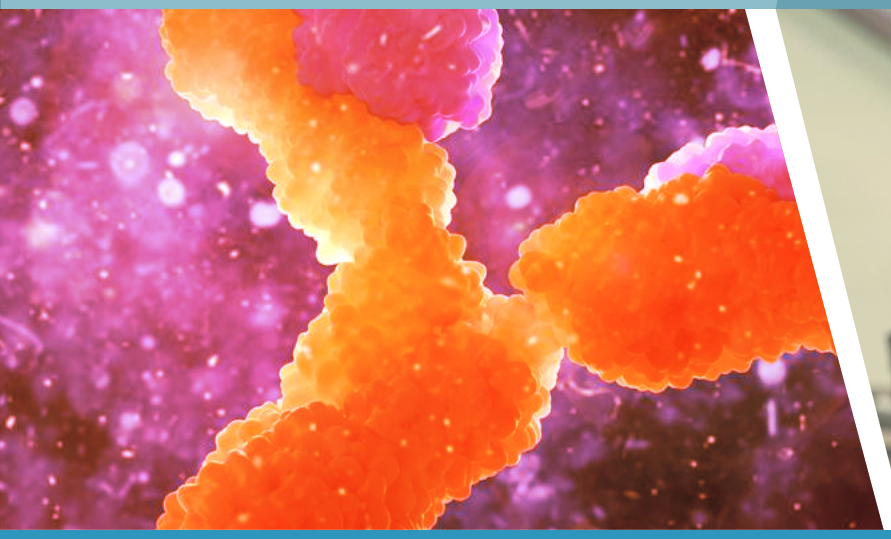
3:35 Close of Symposium

2:35 Recommended Short Course*

SC2: Overcoming Drug and Target Interference in ADA Assays

**Separate registration required. See short course page for details.*

Testimonials



"I learned a lot about bioanalytical challenges and needs on novel modalities, which ultimately translates into faster drug products delivered to those that need them."

- Bioanalytical Principal Investigator, Senior Scientist, Pfizer

"The Summit was a fantastic meeting. It was an exciting opportunity to connect with colleagues and collaborators and to discuss the cutting-edge developments in protein drug immunogenicity."

- Assistant Professor, The University of Kansas

"The Immunogenicity & Bioassay Summit was a real success. It was a very nice opportunity to meet talented scientists in the field."

- Research Director, Immunology, CEA

C1: Immunogenicity Assessment & Clinical Relevance

Assay Strategy for Meaningful Evaluation

WEDNESDAY, OCTOBER 7

CLINICAL RELEVANCE OF ADA

9:05 am FEATURED PRESENTATION: How to Determine if ADA Assays Are Clinically Relevant: If Clinical Impact of Immunogenicity Is Clear, Does Further Optimization of ADA Assay Performance Add Value Post-Marketing?

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

In this presentation, I will share a comparison of two case studies where 100% ADA incidence was detected in both sets of treated patients. I will highlight the methods used to investigate clinical relevance in each case and share the clinical decision-making and trial design changes that were made as a result.

9:25 Clinical Impact of ADA and Therapeutic Drug Monitoring

Theo Rispens, PhD, Head of Lab/PI, Sanquin

Immunogenicity is one of the factors that may impact efficacy and safety of therapeutic antibodies in patients. Nevertheless, linking immunogenicity assessment to clinical correlates has proved challenging. This presentation will discuss measurement of ADA to therapeutic monoclonal antibodies, and its clinical relevance in terms of drug tolerance, the relation with pharmacokinetics (PK), and the impact on efficacy.

9:45 Session Break

10:05 PANEL DISCUSSION: Assessing the Clinical Relevance of ADA

Moderator: Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

- Cost of developing assays and new techniques
- Optimal methods for collecting good data
- Effectively detecting ADA
- Interaction and feedback from the FDA

Panelists:

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

Theresa Goletz, PhD, President, Theresa Goletz Consulting

Theo Rispens, PhD, Head of Lab/PI, Sanquin

10:25 Coffee Break - View Our Virtual Exhibit Hall

ASSAY DEVELOPMENT AND VALIDATION

10:55 KEYNOTE PRESENTATION: Selecting Optimal Format for ADA Assay to Ensure Fit-for-Purpose Assay Characteristics, including Assay Cut-Point

Boris Gorovits, PhD, Senior Director, Pharmacokinetics, Pharmacodynamics & Metabolism, Pfizer Inc.

Anti-drug antibody detecting assay characteristics significantly depend on the assay format and conditions chosen. Selecting appropriate assay set up will ensure that the assay delivers fit-for-purpose characteristics, including assay cut-point, sensitivity, and more. Methods allowing for relevant assay development, as well as alternative methodologies for assay cut-point calculation will be discussed.

11:15 A Case Study on an Alternative Approach for ADA Assay Cross-Validation for the Purpose of Supporting Global Clinical Studies

Qiang Qu, Principal Scientist, EMD Serono

Global clinical studies may utilize multiple bioanalytical labs at various geographical locations for sample analysis. Data comparability among labs is expected to be established before the decision of pooling or comparing immunogenicity results. Currently, there is no clear regulatory guidance on immunogenicity assay cross-validation and acceptance criteria. Here, a case study is presented on an alternative approach when using incurred study samples was not operationally feasible.

DEVELOPMENT OF NEUTRALIZING ANTIBODY ASSAYS

11:35 Challenges in Developing Alternative Formats of Neutralizing Antibody Assays

Tatyana Yun, PhD, Senior Scientist, Merck

11:55 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

Panelists:

Boris Gorovits, PhD, Senior Director, Pharmacokinetics, Pharmacodynamics & Metabolism, Pfizer Inc.

Qiang Qu, Principal Scientist, EMD Serono

Tatyana Yun, PhD, Senior Scientist, Merck

11:55 Recommended Short Course*

SC3: Validation of ADA Assays and Cut-Point Calculations

**Separate registration required. See short course page for details.*

12:10 pm Lunch Break - View Our Virtual Exhibit Hall

2:25 Immunogenicity Monitoring for Low-Risk Molecules: How Much Is Needed?

Michael Partridge, PhD, Associate Director, Bioanalytical Sciences, Regeneron Pharmaceuticals

Requirements for immunogenicity monitoring are applied to all biotherapeutics, regardless of the molecule's risk profile. This places an unnecessary burden on low-risk human mAbs. Frequent patient sampling and early collection times increase the detection of clinically irrelevant ADA. Furthermore, NAb assays implemented in registrational studies may add little value when information about low ADA incidence, as well as titer, persistence, PK, PD, etc., is available from other assays.

IMMUNOGENICITY OF IMMUNO-ONCOLOGY DRUGS

2:45 Bioanalytical Challenges in Patients with Prior Exposure to Class-Specific Biologics and Possible Mitigation Strategies

Mohamed Hassanein, PhD, Associate Director, Clinical Assay Lead (Biologics), Pfizer

Monoclonal antibodies (mAbs) are the leading biotherapeutic modality in the IO space. Patients experiencing disease recurrence, non-responders, or those developing resistance may enroll in new clinical trials involving mAbs specific for the same targets. Therefore, bioanalytical challenges may arise, including cross-reactivity in immunoassays from previous therapies, and increase the risk of developing pre-existing ADA. This talk will highlight some of these potential challenges and propose mitigation strategies to overcome them.

ASSAY DEVELOPMENT AND VALIDATION

3:05 Development of an SPR-Based Assay for the Measurement of Purified Pre-Existing Antibodies against Biotherapeutic Proteins

Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

We report a novel method based on a surface plasmon resonance (SPR)-measurement of the test molecule binding to immunoglobulins (Ig) purified from drug-naïve subjects' sera. Isolation of the Ig and concentration normalization eliminates matrix effect and enables comparison across subjects. By using a high-density surface, PRA of a wide range of affinity to the test molecule can be identified, making this approach a sensitive alternative to the ELISA-based methods.

3:25 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

Panelists:

Michael Partridge, PhD, Associate Director, Bioanalytical Sciences, Regeneron Pharmaceuticals

Mohamed Hassanein, PhD, Associate Director, Clinical Assay Lead (Biologics), Pfizer

3:40 Happy Hour - View Our Virtual Exhibit Hall

4:15 Close of Day

THURSDAY, OCTOBER 8

REGULATORY FEEDBACK

9:00 am **KEYNOTE PRESENTATION: Predicting Immune Responses to Therapeutic Proteins**
Wojciech Jankowski, PhD, Commissioner's Fellow, CBER, FDA

Non-clinical assays that can be used in the early stages of clinical development and to identify at-risk individuals and sub-populations in the clinic are an important unmet need. We have been developing new approaches and assays for immunogenicity assessments and applying these to specific proteins and immunogenicity issues. Thus, my talk will not only lay out the broad principles, but also provide specific examples where our approaches have been useful.

9:20 **Immunogenicity Risk Assessments as Part of an IND Submission**
Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb

Scientists have been applying risk-based strategies for immunogenicity assessments of biotherapeutics and there is a 2019 publication providing advice on how to present this information in dossiers. However, practices across the industry on the content of immunogenicity risk assessments may vary. The goal of this presentation is to provide examples on the presentation of immunogenicity risk assessments and write a fictitious report with help from the audience.

9:40 **Coffee Break - View Our Virtual Exhibit Hall**

ADVANCES WITH NOVEL MODALITIES

10:10 **Management of Immune Responses to AAV Gene Therapies and Redosing**
Manuela Corti, PhD, Assistant Professor, Child Health Research Institute, University of Florida

Adeno-associated virus (AAV) gene therapy is a potential treatment for a variety of genetic disorders. A critical challenge for the success of AAV-mediated gene therapy is the host immune response, which may constitute a barrier to long-term efficacy and safety. Careful immunosurveillance following systemic administration of the vector demonstrates that immunomodulation can prevent the humoral response and activation of the complement classical-pathway, triggered by capsid antigen-IgM complexes.

10:30 **Importance of Pre-Existing Abs to the Viral Capsid During Immunogenicity Assessment of Viral Vectors Based Gene Therapy**
Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

10:50 **PANEL DISCUSSION: Live Q&A with Session Speakers**
Moderator: Barry Byrne, MD, PhD, Professor and Associate Chair, University of Florida
Panelists:
Wojciech Jankowski, PhD, Commissioner's Fellow, CBER, FDA
Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb
Manuela Corti, PhD, Assistant Professor, Child Health Research Institute, University of Florida
Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

11:05 **Coffee Break - View Our Virtual Exhibit Hall**

11:20 **Interactive Breakout Discussions - View Our Virtual Exhibit Hall**

BREAKOUT: Assessing Vaccine Efforts for COVID-19
Theresa Goletz, PhD, President, Theresa Goletz Consulting

BREAKOUT: Value of Bioanalytical PMRs – Learnings from Late-Stage Clinical Studies
Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

BREAKOUT: Preclinical Immunogenicity Risk Assessment
Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

BREAKOUT: Assessing the Clinical Relevance of ADA
Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

BREAKOUT: AAV Gene Therapies and Redosing
Barry Byrne, MD, PhD, Professor and Associate Chair, University of Florida

11:40 **Recommended Short Course***

SC4: Recent Advances with Gene and Cell Therapy
**Separate registration required. See short course page for details.*

12:00 pm **Lunch Break - View Our Virtual Exhibit Hall**

1:25 **Close of Immunogenicity Assessment & Clinical Relevance Conference**

"The immunogenicity summit is one of the highlights of the year for me."
- Biotech Quality and Immunogenicity Reviewer, Biotechnology Products, CDER, FDA

"A great opportunity to meet FDA colleagues and interact with experts in different fields."
- Bioanalytical Principal Investigator, Senior Scientist, Pfizer

"I think your conference is one of the best ones focused on immunogenicity. Your ability to attract multiple FDA speakers is a big plus."
- CSO, Selecta Biosciences

C2: Immunogenicity Prediction & Control

Regulatory Perspectives, Risk Factors, and Management

THURSDAY, OCTOBER 8

TRANSLATION INTO THE CLINIC

1:30 pm Assessment and Prediction of Immunogenicity of Antibody-Drug Conjugates

Renu Singh, PhD, Scientific Leader, GSK

Presentation will focus on challenges associated with assessing and predicting clinical immunogenicity of antibody-drug conjugates (ADCs). ADCs are complex therapeutic modalities, with several bioanalytical species in systemic circulation which complicates *in vitro in vivo* correlation of immunogenicity data and its interpretation. Speaker will provide insight on this challenging topic with some case studies.

1:50 Validation of De-Immunization Strategies for Antibodies Using Cynomolgus Macaque as a Surrogate for Human

Lukasz Chlewicki, PhD, Principal Research Scientist, Eli Lilly and Company

There is little direct information on the predictability of *in silico/in vitro* tools to predict and reduce immunogenicity *in vivo*. We used *in silico* tools to de-immunize antibodies and used cynomolgus macaque as a surrogate for human. The resultant antibodies demonstrated similar biophysical properties, reduced ADA levels, and improved PK in primates; and points to the relevance of using non-human primates as an important *in vivo* model for antibody optimization.

2:10 Mastering Immunogenicity in Biologics Development PROIMMUNE www.proimmune.com

Emilee Knowlton, PhD, Senior Immunology Sales Specialist, ProImmune

Immunogenicity is one of the most complex issues to address in drug design and development and requires intelligent application of integrated platforms to mitigate the risk to your biologic. In this talk I will present case studies to illustrate the range of solutions that ProImmune provides including DC-T/T cell proliferation assays for lead selection/optimization, MAPPS assays for characterization of antigen presentation; HLA-peptide binding assays to characterize individual epitopes & undiluted whole blood cytokine storm assays.

2:30 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Panelists:

Renu Singh, PhD, Scientific Leader, GSK

Lukasz Chlewicki, PhD, Principal Research Scientist, Eli Lilly and Company

Emilee Knowlton, PhD, Senior Immunology Sales Specialist, ProImmune

2:45 Refresh Break - View Our Virtual Exhibit Hall

PREDICTIVE STUDIES AND PREDICTIVE TOOLS

3:00 FEATURED PRESENTATION: T Cell Response to Biopharmaceuticals: From Basic Immunology to Immunogenicity Prediction

Bernard Maillere, PhD, Research Director, Immunology, CEA

ADA response to biopharmaceuticals (BP) is a frequent event, although their sequence is humani(zed) and expected to lead to T cell tolerance. Autoreactive T cells are indeed negatively selected in the thymus by self-peptides. Identification of immunogenic sequences in therapeutic antibodies and human hormones, using cells collected from healthy donors and patients, reveals multiple mechanisms of tolerance, ignorance, and T cell activation, Understanding of these mechanisms contribute to anticipate immunogenicity risk.

3:20 Applying Immunopeptidomics Technologies to Control Tumor Immunogenicity

Etienne Caron, PhD, Assistant Professor, CHU Sainte-Justine Research Center, University of Montreal

Mass spectrometry profiling of peptides associated to human leukocyte antigen (HLA) – referred herein as immunopeptidomics – has become a dynamic new frontier in immunology, vaccine, and immunotherapy. In this presentation, we will describe the latest advances in the field. In particular, we will describe the importance of dissecting the molecular architecture that shapes the global composition of the immunopeptidome to understand and control tumor immunogenicity.

3:40 The Influence of T Cell Epitopes on Antibody Somatic Hypermutation Pathways

Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

Next-generation sequencing (NGS) of paired-antibody heavy and light chains has opened up new possibilities for studying human antibody repertoires. Here, we applied high-throughput interrogation of human antibody responses and paired these data with large-scale T cell epitope prediction. We reveal new trends in antibody development that reduce antibody immunogenicity. These findings have broad implications for the identification and discovery of new antibody therapeutics with reduced immune rejection.

4:00 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Panelists:

Bernard Maillere, PhD, Research Director, Immunology, CEA

Etienne Caron, PhD, Assistant Professor, CHU Sainte-Justine Research Center, University of Montreal

Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

4:15 Immunogenicity & Bioassay Summit Connects - View Our Virtual Exhibit Hall

4:45 Close of Day

FRIDAY, OCTOBER 9

ADVANCES WITH NOVEL MODALITIES

9:00 am KEYNOTE PRESENTATION: Immunogenicity of AAV Vectors in Gene Therapy

Ronit Mazor, PhD, Principal Investigator, CBER, FDA

Adeno-associated viruses (AAV) are potent vectors used for gene delivery in gene therapy products. Recent clinical findings revealed immunogenicity related challenges including pre-existing antibodies, formation of neutralizing antibodies after the first administration, innate activation and formation of a cytotoxic immune response against transfected cells. In this talk I will provide a review of current state of the art of immunogenicity of AAV vectors and strategies for mitigation of it.

9:20 Immune-STATs: A Novel Biologics Platform for Selective and Specific T Cell Modulation in the Patient

Saso Cemerski, PhD, Vice President and Head of Discovery and Translational Immunology, Cue Biopharma

A key consideration for successful immunotherapy of cancers, autoimmunity and chronic infectious disease is the selective and specific modulation of the immune repertoire while avoiding systemic immune modulation and related safety liabilities. To that end, we have developed a unique biologics platform termed Immuno-STAT that provides the opportunity to directly target and modulate the antigen-specific T cell repertoire in the patient.

9:40 Clinical Development of Immune-Tolerizing Therapy Using Hybrid TREG/Th2 Cells

Dan Fowler, MD, CMO, Rapa Therapeutics

Regulatory T (T_{REG}) cells hold promise for modulation of Th1-driven processes, including autoimmune and neurodegenerative disease, transplantation complications (graft rejection, GVHD), and foreign protein immunogenicity. Because T_{REG} and Th2-type cells counter-regulate Th1 responses, we developed an *ex vivo* manufacturing process that generates a T cell product of hybrid T_{REG}/Th2 phenotype. A phase I clinical trial of hybrid T_{REG}/Th2 cells has been developed for therapy of amyotrophic lateral sclerosis.

10:00 Coffee Break - View Our Virtual Exhibit Hall

10:25 Interactive Breakout Discussions - View Our Virtual Exhibit Hall

BREAKOUT: Overcoming Technical Issues with Assays to Assess Innate Immune Response Modulating Impurities
Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA

BREAKOUT: Immunogenicity Prediction in the Real World: Feedback from the Users
Bernard Maillere, PhD, Research Director, Immunology, CEA

BREAKOUT: Mechanisms of Immunogenicity of Gene Therapy Products
Ronit Mazor, PhD, Principal Investigator, CBER, FDA

BREAKOUT: Different Strategies to Predict Immunogenicity
Sivan Cohen, PhD, Scientist, Genentech

BREAKOUT: Viability of Immune Tolerance Strategies for the Treatment of Human Disease
Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

BREAKOUT: New Molecular Insights for Antibody and Protein Drug Immunogenicity
Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

RISK ASSESSMENT STRATEGIES

11:05 KEYNOTE PRESENTATION: Assessing the Immunogenicity Risk of Impurities
Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA

Product and process related impurities are critical quality attributes as they can modify the immunogenicity risk of biologics. This talk will discuss the role of impurities in product immunogenicity and the potential and limitations of clinical and preclinical studies designed to assess their risk.

11:25 Predicting Immunogenicity of Biopharmaceuticals through Integrating *in silico*, *in vitro*, and Immune Systems Data
Timothy Hickling, PhD, Head of Immunosafety, Roche

Unwanted immune responses to therapeutic proteins can adversely affect clinical outcomes and may complicate product development. Reducing the risk of immunogenicity through application of 'predictive' assays during molecular design is appealing, though useful prediction via a single assay is not currently possible. I will describe an approach to integrate data relating to molecules and patients to simulate the outcome of clinical trials, including the introduction of an Immunogenicity Simulator consortium.

11:45 CO-PRESENTATION: *In Silico* Prediction Models Complement *in Vitro* Immunogenicity Assessment of Protein Drugs
Morten Nielsen, PhD, Professor, Department of Health Technology, Technical University of Denmark

Chloé Ackaert, PhD, Senior Scientist, Immunogenicity, ImmunXperts

Risk assessment of protein drugs is most often performed using MHC-Associated Peptide Proteomics (MAPPs) and/or T cell activation assays. In this talk, we demonstrate how *in silico* methods trained on MS HLA eluted ligand data can effectively and accurately complement these assays for the risk assessment of protein drugs.

12:05 pm PANEL DISCUSSION: Live Q&A with Session Speakers
Moderator: Ronit Mazor, PhD, Principal Investigator, CBER, FDA
Panelists:
Dan Fowler, MD, CMO, Rapa Therapeutics
Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA
Timothy Hickling, PhD, Head of Immunosafety, Roche
Morten Nielsen, PhD, Professor, Department of Health Technology, Technical University of Denmark
Chloé Ackaert, PhD, Senior Scientist, Immunogenicity, ImmunXperts

12:05 Recommended Short Course*

SC5: Advice on Putting Together an Integrated Summary of Immunogenicity
**Separate registration required. See short course page for details.*

12:20 Lunch Break - View Our Virtual Exhibit Hall

2:00 *In vitro* T Cell Assay to Predict Immunogenicity of Biotherapeutic Products
Sivan Cohen, PhD, Scientist, Genentech

Treatment of patients with biotherapeutic protein products may result in immune responses of varying clinical relevance, including development of life-threatening anti-drug antibodies (ADA) that can limit product efficacy. Predicting the risk for immunogenicity of biotherapeutic products at early stages is a crucial need. This presentation will focus on *in vitro* T cell assay studies to characterize the immunogenic potential of different biotherapeutic proteins and the clinically observed outcome.

2:20 FEATURED PRESENTATION: Fc-Fc Receptor Mediated Interactions: Implications for Modulating Fc-Fusion Protein Immunogenicity
Daniel LaGasse, PhD, Research Regulator, CBER, FDA

Fusing the human immunoglobulin G1 (IgG1) constant region (Fc-domain) to therapeutic proteins or peptides increases their circulating plasma half-life via neonatal Fc receptor (FcRn) binding and recycling. However, Fc-mediated interactions with other molecules including complement C1q and Fc gamma receptors (FcγR) can have immunological consequences. This presentation will highlight recent reports of Fc-Fc receptor interactions and discuss their implications for the modulation of Fc-fusion protein immunogenicity.

IMMUNE TOLERANCE

2:40 Specific Immune Tolerance for Facilitating Gene/Protein Replacement Therapy – Clinical Experience and Future Perspectives
Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

The efficacy and mechanisms of action of negatively charged, antigen-encapsulating, carboxylated poly(lactide-co-glycolide) (PLG) nanoparticles (Ag-PLG) for gliadin tolerance induction in a Phase 2 clinical trial in celiac disease patients will be discussed. In addition, data showing the efficacy of Ag-PLG tolerance in inducing tolerance in a preclinical model of gene therapy using AAV-expressing green fluorescent protein will be presented and prospects for clinical translation for gene therapy discussed.

3:00 PANEL DISCUSSION: Live Q&A with Session Speakers
Moderator: Ronit Mazor, PhD, Principal Investigator, CBER, FDA
Panelists:
Sivan Cohen, PhD, Scientist, Genentech
Daniel LaGasse, PhD, Research Regulator, CBER, FDA
Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

3:15 Close of Summit

C3: Optimizing Bioassays for Biologics

Case Studies Demonstrating Successful Bioassay Development

THURSDAY, OCTOBER 8

INNOVATIVE STRATEGIES TO DESIGN BIOASSAYS

1:25 pm Conference Overview

Nancy Sajjadi, Independent Quality Consultant

1:30 A Simple Way to Select the Concentrations to Fit 4PL Curves for Potency Assays

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

A challenging aspect of potency assays is choosing the ideal concentrations for the concentration-response curve analysis. Common optimal design methods are not suited for this type of analysis, as they fail to account for the constraint in a laboratory, as well as the variability between runs that affect the estimation of the relative potency and the similarity test. This talk proposes a simple way to find an efficient concentration range.

1:50 International Standards for Bioassays: A Global Effort to Harmonise the Bioactivity of Monoclonal Antibodies

Sandra Prior, PhD, Senior Scientist, National Institute for Biological Standards and Control (NIBSC, a centre of the MHRA)

As technical and regulatory tools for the development and control of biotherapeutic monoclonal antibody products evolve for new modalities and biosimilars, this fast-developing market encounters new challenges. Manufacturers' reference standards and reference medicinal products are insufficient to ensure product consistency between manufacturers, jurisdictions, and over time. The impact of using international standards on the harmonisation of complex bioassay data will be discussed in light of recent international collaborative studies.

2:10 Optimizing ADA assay tolerance towards drug product using automated acid dissociation in a microfluidic CD-based format

GYROS PROTEIN Technologies

John Chappell, BSc, CChem, CSci, FRSC, Application & Service Director EMEA and Asia Pacific, Gyros Protein Technologies

Recently regulatory agencies have lowered sensitivity requirements for anti-drug antibody (ADA) bioassays. Reaching lower sensitivity levels while maintaining drug tolerance may necessitate lengthy acid dissociation pre-treatment steps, affecting assay quality. We present miniaturized, microfluidic ADA immunoassays with an automated acid dissociation step that demonstrate high sensitivity, high-quality, and drug-tolerant assays.

2:30 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Nancy Sajjadi, Independent Quality Consultant

Panelists:

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

Sandra Prior, PhD, Senior Scientist, National Institute for Biological Standards and Control (NIBSC, a centre of the MHRA)

John Chappell, BSc, CChem, CSci, FRSC, Application & Service Director EMEA and Asia Pacific, Gyros Protein Technologies

2:45 Refresh Break - View Our Virtual Exhibit Hall

3:00 Ensuring Fitness for Use throughout the Bioassay Lifecycle

Tim Schofield, Owner & Consultant, CMC Sciences LLC

Many opportunities exist to ensure that bioassay measurement is fit for use. This includes but is not limited to strategic development, controls, suitability testing, and standard qualification. All of these must be linked to the bioassay ATP to deliver on their goal. This talk will describe the introduction and maintenance of these throughout the bioassay lifecycle, and how they differ across bioassay uses.

3:25 Strategic Ways to Create and Exploit Modularity in Bioassay Design and Analysis

David Lansky, PhD, President, Precision Bioassay, Inc.

Bioassays optimization is complex with many inputs and their application to different sized units. Combining practical laboratory constraints with design of experiments is easier with layered or modular design components. The properties of reported values for each of several different intended uses can be supported from a single efficient experiment. Modular design and analyses support efficient development and robustness experiments supporting adjustments to the assay format as the assay matures.

3:45 An *in vitro* Transcytosis Assay for Predicting *in vivo* Clearance of Therapeutic Antibodies in Humans

Chang Liu, PhD, Associate Scientist, BioAnalytical Sciences, Genentech Inc.

Proper evaluation of candidate drugs for desirable pharmacokinetic (PK) properties is imperative to successful biotherapeutic development. We have developed an *in vitro* cell-based assay to measure transcytosis of monoclonal antibodies (mAbs), which showed a notable correlation between the transcytosis readouts of more than 50 mAbs and their clearance in humans. This assay may serve as a screening tool for predictive assessment of non-specific clearance of antibody-based drug candidates in humans.

4:05 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Nancy Sajjadi, Independent Quality Consultant

Panelists:

Tim Schofield, Owner & Consultant, CMC Sciences LLC

David Lansky, PhD, President, Precision Bioassay, Inc.

Chang Liu, PhD, Associate Scientist, BioAnalytical Sciences, Genentech Inc.

4:20 Immunogenicity & Bioassay Summit Connects - View Our Virtual Exhibit Hall

4:45 Close of Day

FRIDAY, OCTOBER 9

USP CHAPTERS

9:00 am PANEL DISCUSSION: The USP Bioassay Chapters: How Can We Help?

Moderator: Steven Walfish, Principal Scientific Liaison, Global Science & Standards, USP

In this interactive panel discussion, members of the USP Bioassay Panel will discuss current issues and future goals of the USP suite of bioassay chapters. The audience will be able to interact through an open dialogue to ask questions and give feedback on areas where chapters can be improved to be more user-friendly. Do not miss your chance to be a part of the change!

Panelists:

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

David Lansky, PhD, President, Precision Bioassay, Inc.

Tim Schofield, Owner & Consultant, CMC Sciences LLC

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

10:00 Coffee Break - View Our Virtual Exhibit Hall

10:25 Interactive Breakout Discussions - View Our Virtual Exhibit Hall

BREAKOUT: Potency Assay Readouts and Criteria for Gene Therapies

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

POTENCY ASSAYS

11:05 Development of Enzymatic Functional Potency Assays for Antibody Therapeutic Product Development at Later Phase

Bo Feng, PhD, Associate Principal Scientist, Process R&D, Merck & Co., Inc.

Two functional bioassays which better reflect the MoA of antibody drug by measuring antibody binding-induced target protein enzymatic activity changes are developed to replace and/or supplement an early-phase binding ELISA potency assay. The enzymatical potency assays showed equivalent performance in comparison with binding assay regarding linearity/range, accuracy and precision. The stability-indicating capacity of the enzymatical functional bioassays has also been demonstrated using stability and force-degraded samples.

11:25 Building Bridges That Last: Working through Process and Method Changes for Potency and Viral Titer

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

With higher expectations for potency assay performance, these analytical methods are refined earlier in drug development and have improved capability of detecting process-related differences. Clinical study design changes and evolving technologies for cell and gene therapies have introduced further instances where process, material, or method bridging are required later in development. Case studies will be reviewed with strategies to determine the most appropriate path to bridge these changes.

11:45 Session Break

12:05 pm PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

Panelists:

Bo Feng, PhD, Associate Principal Scientist, Process R&D, Merck & Co., Inc.

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

12:05 Recommended Short Course*

SC5: Advice on Putting Together an Integrated Summary of Immunogenicity

**Separate registration required. See short course page for details.*

12:20 Lunch Break - View Our Virtual Exhibit Hall

FDA INSIGHTS

2:00 FEATURED PRESENTATION: Bioassays for Bispecific Antibodies

Wen Jin Wu, MD, PhD, Senior Investigator, Biotechnology Products, CDER, FDA

Bispecific antibody IND submission has increased enormously in recent years, however, more than 70% of INDs have not developed a bioassay for release and stability. While it is acceptable for the early stage of drug development, it also indicates that developing a suitable bioassay for quality control of bispecific antibodies is challenging. This presentation will focus on analysis of bioassays, and discuss regulatory issues of bioassays used for bispecific antibodies.

BIOASSAYS FOR NEW MODALITIES

2:20 KEYNOTE PRESENTATION: Measurement Assurance, Control Strategies and Documentary Standards for the Development of Bioassays for Cell Therapy

Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

The characterization and testing of cellular therapeutic products (CTPs) is a critical aspect of product development, translation and release. Here I will describe recent efforts in the standardization of the characterization and testing of CTPs. I will also describe recently published standards on cell counting as well as NIST technical programs for increasing confidence in cell count and viability assays.

2:40 Development of *in vitro* Functional Bioassays for Potency and Immunogenicity Screening of Cell and Gene Therapy Products: Challenges and Opportunities

Sofie Pattijn, Founder & CTO, ImmunXperts SA

Cell and gene therapies have the potential to cure previously untreatable diseases, and fundamentally alter the trajectory of many other diseases. However, the development of new therapeutics comes with a series of challenges and risks. In contrast to traditional therapeutics, large-batch manufacturing and quality testing for these individual batches of cell products, the selection and development of a suitable *in vitro* bioassay comes with certain challenges.

3:15 Close of Conference

3:00 PANEL DISCUSSION: Live Q&A with Session Speakers

Moderator: Sofie Pattijn, Founder & CTO, ImmunXperts SA

Panelists:

Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

Wen Jin Wu, MD, PhD, Senior Investigator, Biotechnology Products, CDER, FDA

"This event has a great atmosphere for networking and learning about new expectations in our always changing field."

- Senior Group Leader, Immunogenicity, PPD, Inc.

PRESENT A POSTER AND SAVE $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the virtual poster sessions. To ensure your poster presentation is included in the conference materials, your full submission must be received, and your registration paid in full by September 4, 2020.

Virtual scientific poster presentation materials will include:

- **Poster title**
- **Text-only abstract.** It can be an in-depth, one-page abstract, or just a short description.
- **3-5 minute voice-over PowerPoint presentation.** You may substitute the PowerPoint with a one-page, static PDF of your poster
- Discuss your research and collaborate with other attendees during designated chat times

Media Partners

Lead Sponsoring Publications

GEN Genetic Engineering & Biotechnology News

PharmaVOICE

Sponsoring Publications

American Laboratory

American Pharmaceutical Review

Bio-IT World

INSIGHT PHARMA REPORTS

Pharmaceutical Outsourcing

pathogens

Web Partners

BioSpace

SelectScience

Immunogenicity & Bioassay Summit VIRTUAL

October 6-9, 2020

Pricing & Registration Information

See website for complete details including discounts for groups and On-Demand participation.

	Commercial	Academic, Government, Hospital-Affiliated
PREMIUM VIRTUAL PRICING – BEST VALUE! *(Includes access to two conferences and the symposium. Includes virtual event benefits plus on-demand access. You're allowed to move between virtual sessions to attend presentations taking place at the same time. Plus! Save 10% off your short course registration.)*		
Advance Registration Discount Until September 25, 2020	$1,199	$549
Registrations September 25, 2020 and On-site	$1,299	$599
PREMIUM ON-DEMAND PRICING *(Includes recorded access to two conferences and the symposium. Does not include networking, Q&A, or other virtual event benefits. You're allowed to move between virtual sessions to attend presentations taking place at the same time. Plus! Save 10% off on-demand short courses.)*		
Advance Registration Discount Until September 25, 2020	$1099	$449
Registrations September 25, 2020 and On-site	$1199	$499
STANDARD VIRTUAL PRICING *(Includes Access to one conference and the symposium. Includes virtual event benefits plus on-demand access. You're allowed to move between virtual sessions to attend presentations taking place at the same time.)*		
Advance Registration Discount Until September 25, 2020	$799	$399
Registrations September 25, 2020 and On-site	$899	$449
STANDARD ON DEMAND PRICING *(Includes access to one conference and the symposium. You're allowed to move between virtual sessions to attend presentations taking place at the same time. Does not include networking, Q&A, or other virtual event benefits.)*		
Advance Registration Discount Until September 25, 2020	$699	$349
Registrations September 25, 2020 and On-site	$799	$399
SYMPOSIUM VIRTUAL PRICING		
October 6, 2020	$499	$249
SYMPOSIUM ON DEMAND PRICING		
October 6, 2020	$399	$199
SHORT COURSE PRICING		
One Short Course	$299	$199
Two Short Courses	$399	$299
Three Short Courses	$549	$399
Four Short Courses	$649	$449
Five Short Courses	$749	$499

CONFERENCE DISCOUNTS

Alumni Discount – SAVE 20%: CHI appreciates your past participation at the Immunogenicity and Bioassay Summit. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

POSTER SUBMISSION - DISCOUNT ($50 OFF): Poster materials are due by September 4, 2020. Once your registration has been fully processed, we will send an email with a unique link and instructions for submitting your abstract and other materials. If you do not receive this email within 5 business days, please contact jring@healthtech.com.

**CHI reserves the right to publish your poster title and abstract in various marketing materials and products*

Group Discounts: Special rates are available for multiple attendees from the same organization. For more information on group discounts contact Uma Patel, 781-972-5447, upatel@healthtech.com.

**Alumni, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.*

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, and access to the on-demand library.

To view our Substitutions/Cancellations Policy, go to healthtech.com/regdetails

<table>
<tr><th>Tuesday | October 6</th><th>Wednesday | October 7</th><th>Thursday | October 8</th><th>Friday | October 9</th></tr>
<tr><td rowspan="2">Symposium 1: Immunology for Biotherapeutics</td><td>SC1: Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays</td><td rowspan="2">C1: Immunogenicity Assessment & Clinical Relevance</td><td colspan="2">C1: Immunogenicity Assessment & Clinical Relevance</td><td rowspan="2">C2: Immunogenicity Prediction & Control</td><td rowspan="2">C3: Optimizing Bioassays for Biologics</td></tr>
<tr><td>SC2: Overcoming Drug and Target Interference in ADA Assays</td><td>C2: Immunogenicity Prediction & Control</td><td>C3: Optimizing Bioassays for Biologics</td></tr>
<tr><td colspan="2"></td><td>SC3: Validation of ADA Assays and Cut Point Calculations</td><td colspan="2">SC4: Recent Advances with Gene and Cell Therapy</td><td colspan="2">SC5: Advice on Putting Together an Integrated Summary of Immunogenicity</td></tr>
</table>

Cambridge HEALTHTECH Institute

A Division of Cambridge Innovation Institute

250 First Avenue, Suite 300
Needham, MA 02494
Healthtech.com
Fax: 781-972-5425

How to Register: ImmunogenicitySummit.com

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **2027F** when registering!