

2025
CONFERENCE
PROGRAMS

 ENGINEERING

 ONCOLOGY

 MULTISPECIFICS

 IMMUNOTHERAPY

 EXPRESSION

 ANALYTICAL

 IMMUNOGENICITY

 EMERGING
THERAPEUTICS

 MACHINE LEARNING

 SC SHORT COURSES

 TS Training SEMINARS

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The Essential Protein & Antibody Engineering Summit



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Puja Sapra, PhD
Senior Vice President,
AstraZeneca Pharmaceuticals, Inc.

Ellen Puré, PhD
Professor & Chair
University of Pennsylvania

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Experience the Future of Biotherapeutic Drug Development at the World's Leading Biologics Event

The 2025 PEGS Boston Summit is set to build on the remarkable success of previous years, continuing its legacy as the premier event for biologics and protein engineering. Bringing together a global community of experts, innovators, and leaders in the field, the Summit will offer cutting-edge insights into the latest advances in drug development, protein and antibody engineering, immunotherapy, radiotherapy, and AI/ML-driven biologics research. With over 300 presentations, breakout sessions, and interactive seminars, attendees will have unparalleled opportunities to network, learn, and engage in meaningful collaborations. The exhibit hall will once again feature top product and service providers, creating a gathering space for discovery, innovation, and fun. Join us at the PEGS Boston Summit to be part of the next wave of breakthroughs shaping the future of biologics.

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**SUNDAY
MAY 11**

**TUESDAY
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**PART A
MONDAY -
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**PART C
THURSDAY/FRIDAY MORNING
(MAY 15-16)**

AFTERNOON SHORT COURSES

DINNER SHORT COURSES

Display of Biologics	Engineering Antibodies	Machine Learning Approaches for Protein Engineering
Antibodies for Cancer Therapy	Emerging Targets for Oncology & Beyond	Driving Clinical Success in Antibody Drug Conjugates
TS: Introduction to Multispecifics	Advancing Multispecific Antibodies and Combination Therapy to the Clinic	Engineering Bispecific and Multifunctional Antibodies
Advances in Immunotherapy	Engineering Cell Therapies	Next-Generation Immunotherapies
Difficult-to-Express Proteins	Optimizing Protein Expression	Maximizing Protein Production Workflows
ML and Digital Integration in Biotherapeutic Analytics	Biophysical Methods	Characterization for Novel Biotherapeutics
TS: Introduction to Immunogenicity	Predicting Immunogenicity with AI/ML Tools	TS: Bioassay Development and Analysis
Biologics for Immunology Indications	Radiopharmaceutical Therapies	Next-Generation Immunotherapies
ML and Digital Integration in Biotherapeutic Analytics	Predicting Immunogenicity with AI/ML Tools	Machine Learning Approaches for Protein Engineering

Training SEMINARS

By Cambridge Healthtech Institute

TS3A: Introduction to Multispecific Antibodies: History, Engineering, and Application

TS7A: Introduction to Immunogenicity

TS9A: Introduction to Protein Engineering

TS10A: Antibody Drug Discovery: From Target to Lead

TS9B: Introduction to Machine Learning for Biologics Design

TS10B: Introduction to Antibody-Drug Conjugate Design: Targets, Payloads, and Linkers

TS11B: Introduction to Analytical Characterization and Method Validation for Biological Products

TS7C: Bioassay Development and Analysis

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Plenary Keynote Sessions



MONDAY, MAY 12: 4:25 – 5:10 PM

The Role of Protein Engineering in Developing New Innovative Modalities

PUJA SAPRA, PHD
Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

MONDAY, MAY 12: 5:10 – 5:55 PM

YOUNG SCIENTIST KEYNOTE



Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade

JESSICA C. STARK, PHD
Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints – interactions of cancer glycans with inhibitory glycan-binding receptors called lectins – have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.



WEDNESDAY, MAY 14: 8:50 – 9:35 AM

Ex vivo and in situ Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

ELLEN PURÉ, PHD
Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARTs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

THURSDAY, MAY 15: 11:35 AM – 12:25 PM

PLENARY FIRESIDE CHAT

Riding the Next Biotech Wave

Trends in Biotech Investments, Partnering, and M&As



MODERATOR:
JAKOB DUPONT, MD
Executive Partner, Sofinnova



PANELIST:
MICHAL PREMINGER, PHD, MBA
Regional Head, Johnson & Johnson Innovation, East North America



PANELIST:
SHYAM MASRANI
Partner, Medicxi



PANELIST:
UCIANE SCARLETT, PHD
Former Principal, MPM BioImpact



PANELIST:
ANTHONY B. BARRY, PHD
Executive Director, ES&I Lead, Biotherapeutics, Technologies and Digital, Pfizer Inc.

- Emerging Biotherapeutic Modalities, Technologies and Innovations – ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Investing in platforms versus assets

- Introduction to different strategies for investments, M&As, partnering, licensing, etc.
- Advice on funding options for start-ups, early-to-late stage clinical programs, etc.

SUNDAY, MAY 11 2:00-5:00 PM

SC1: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

Instructors:

Mehdi Boroumand, PhD, Associate Principal Data Scientist, Machine Learning, AstraZeneca

Henriette Capel, PhD Student, University of Oxford

Vinodh B. Kurella, PhD, Biotherapeutic Computational Modeler, Takeda Pharmaceuticals, Inc.

Robert Vernon, PhD, Associate Director, Amgen

Given the exciting pace in the evolution of machine learning tools towards antibody design and developability predictions, we plan to present an overview in this field specificity geared towards antibody design and developability predictions. There will be a live demo as well of few ML tools.

SC2: Safety & Efficacy of Bispecifics and ADCs

Instructor:

Rakesh Dixit, PhD, DABT, President & Founder, Bionavigen Oncology, LLC and Regio Biosciences

Bispecific immunotherapies and ADCs are the two most rapidly advancing cancer therapeutics in the war against cancer. However, efficacy and safety challenges limit their therapeutic effectiveness in resistant and refractory cancers. The short course will discuss the translational aspects of bispecifics and ADCs; efficacy and safety challenges originating from poorly constructed ADCs; five rights of the targets, effector arms, and constructs for attaining the best therapeutic index for bispecifics and ADCs as well as strategies to minimize toxicities of bispecific and ADCs.

SC3: Challenges and Opportunities in Solid Tumor and Autoimmune Disease Therapeutic Innovations

Instructor:

Tony R. Arulanandam, DVM, PhD, CEO and Founder, Synaptimmune Therapeutics

This course offers advanced insights into developing next-generation immunotherapies for solid tumors and autoimmune diseases, focusing on identifying new biological targets and therapeutic methods. It includes detailed analyses of the solid tumor microenvironment and the autoimmune diseases space,

addressing challenges and showcasing successful therapeutic strategies across T cell engagers, blocking bispecific antibodies, ADCs, CAR-Ts, radioligand therapy and targeted protein degraders. Additionally, the course will explore the use of machine learning and generative AI to identify novel therapeutic targets and accelerate the development of treatments.

TUESDAY, MAY 13 6:30-9:00 PM

SC4: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies

Instructor:

Ross Chambers, PhD, Vice President, Antibody Discovery, Integral Molecular, Inc.

Complex membrane proteins are important therapeutic targets and together represent the majority of protein classes addressed by therapeutic drugs. Significant opportunities exist for targeting complex membrane proteins with antibodies, but it has been challenging to discover therapeutic antibodies against them. This course will examine emerging technologies and strategies for enabling the isolation of specific and functional antibodies against GPCRs, ion channels, and transporters, and highlight progress via case studies.

SC5: Targeting the Target: Aligning Target and Biologic Format Biology to Achieve Desired Outcomes

Instructor:

Tariq Ghayur, PhD, Tariq Ghayur Consulting, LLC; Entrepreneur in Residence, FairJourney Biologics

Receptor – ligand interactions have co-evolved to maintain specificity of downstream signaling. However, biologics are not natural ligands and, therefore, different biologics to the same target (receptor or ligand) can have distinct outcomes. Recent advances in various high-throughput analytical technologies, biologic-based therapeutic formats, and our understanding of disease heterogeneity are & will challenge us to “re-evaluate” our discovery and development paradigm(s). In this course we will explore, with examples, potential avenues on how to apply these new technologies/understanding to select “better” lead candidates to achieve “better” desired outcomes.

SC6: Developability of Bispecific Antibodies

Instructor:

Nimish Gera, PhD, Vice President, Biologics, Mythic Therapeutics

Bispecific antibodies are a rapidly growing and clinically validated class of antibodies with marketed drugs and multiple candidates in clinical trials. Targeting multiple antigens in a synergistic manner can confer enhanced therapeutic benefit and potentially uncover novel biological mechanisms. However, multiple formats and a tedious candidate selection process to select functional and developable bispecific antibodies makes such programs cumbersome. This short course highlights the rapid growth in the field, therapeutic applications, and focuses on challenges with discovery and development of bispecific antibodies. We will use an approved bispecific antibody as a case study to understand the varied aspects of discovery and development of bispecific antibody programs.

SC7: Nuts and Bolts of Building a Radiopharmaceutical Therapy Agent

Instructor:

Diane S. Abou, PhD, Principal Radiochemist, Assistant Professor, Mallinckrodt Institute of Radiology, Washington University School of Medicine in St. Louis

This session details the path to converting an antibody or an engineered fragment into a radiopharmaceutical therapy. Methods to preparing radioimmunoconstructs into alpha-/beta-emitting drugs will be discussed. This path includes choosing adequate therapeutic isotopes for the application of interest, tailoring the radiolabeling strategy to preserve immune reactivity, and developing a drug formulation for extended shelf-life. Detailed quality control methods will be discussed specific to therapeutic isotopes and radiopharmaceuticals characterization.

Training SEMINARS

By Cambridge Healthtech Institute

Training Seminars Will Be Held
In Person Only

To ensure a cohesive and focused learning environment, moving between conference sessions and the training seminars is not allowed.

MONDAY, MAY 12, 2025 8:30 AM - 6:05 PM
| TUESDAY, MAY 13, 2025 8:30 AM - 12:45 PM

TS3A: Introduction to Multispecific Antibodies: History, Engineering, and Application

Instructor:

G. Jonah Rainey, PhD, Associate Vice President, Eli Lilly and Company

Introduction to Multispecific Antibodies is an informative and practical guide to getting up to speed on critical aspects of multispecific antibody therapeutics. Topics will include historical successes, failures, and lessons learned. Specific practical instruction will span mechanisms of action, engineering, developability, regulatory considerations, and translational guidelines. Perspectives on ideal implementation of multispecifics as targeted and immunomodulatory approaches will be discussed.

TS7A: Introduction to Immunogenicity

Instructors:

Chloé Ackaert, PhD, Senior Scientist, Immunogenicity, ImmunXperts, a Q2 Solutions Company

Sofie Pattijn, Founder & CTO, ImmunXperts, a Q2 Solutions Company

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

This 1.5-day training seminar provides a practical, comprehensive overview of immunogenicity—the causes, how to assess, predict, and prevent, and what to do if you observe immunogenicity during preclinical, clinical, and post-market approval. The seminar begins by detailing the science behind immunogenicity, the latest international guidance, followed by assay and bioanalytical assessment strategies for traditional and emerging biologics. Other topics include predictive models, the role of AI/ML, and reporting immunogenicity.

TS9A: Introduction to Protein Engineering

Instructor:

David Bramhill, PhD, Founder, Bramhill Biological Consulting LLC

This course presents a comprehensive tutorial in the concepts, strategies, and latest tools of protein engineering applied to biotherapeutic research and development, particularly antibody-related products. The class is for scientists new to industry or working in support roles, academics, and protein scientists wanting a detailed update on the current state of the field.

TS10A: Antibody Drug Discovery: From Target to Lead

Instructor:

Zhiqiang An, PhD, Professor, Robert A. Welch Distinguished University Chair in Chemistry; Director, Texas Therapeutics Institute; Director, CPRIT Core for Antibody Drug Discovery; Vice President, Drug Discovery, University of Texas Health Science Center at Houston

At least 100 antibody therapies have been approved for the treatment of cancer, immune disorders, metabolic, cardiovascular, and infectious diseases, and among the top 20 bestselling prescription medicines in 2020, 14 are antibody-based. This trend will continue as about 50% of the new drugs in various stages of clinical development are antibodies. This course will review state-of-the-art concepts, methodologies, and current trends in therapeutic antibody discovery and development.

TUESDAY, MAY 13, 2025 2:20 PM
- 6:10 PM | WEDNESDAY, MAY 14,
2025 10:20 AM - 6:40 PM

TS9B: Introduction to Machine Learning for Biologics Design

Instructors:

Christopher R. Corbeil, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

Francis Gaudreault, PhD, Associate Research Officer, Human Health Therapeutics, National Research Council Canada

This course offers an introduction to concepts, strategies, and machine learning methods used for biologics design. It includes presentations and demonstrations of the methods used in the field, covering techniques such as triaging sequences, modulating affinity, and designing antibody libraries, along with increasing manufacturability. The course is directed at scientists new to the field and protein engineers wanting an introduction to how machine learning can aid in guiding biologics design.

TS10B: Introduction to Antibody-Drug Conjugate Design: Targets, Payloads, and Linkers

Instructors:

Robert J. Lutz, PhD, CSO, Iksuda Therapeutics

Nathan L. Tumey, PhD, Associate Professor, Pharmaceutical Sciences, SUNY Binghamton

In this training seminar, your instructors will take you on a journey through the history of ADC technology, the current status of the ADC field, and the most promising up-and-coming technologies that

will shape the ADCs of tomorrow. We will place particular emphasis on design principles that can be applied to next generation ADC programs, whether in oncology applications or in a myriad of other therapeutic applications. We will introduce various assay strategies, experimental approaches, and technical insights that will enable participants to have both a practical and a theoretical understanding of the inner-workings of a successful ADC program. Your instructors are seasoned ADC experts that have been involved in numerous ADC programs in academia, in big pharma, and in biotechnology companies.

TS11B: Introduction to Analytical Characterization and Method Validation for Biological Products

Instructor:

Kevin Zen, PhD, Senior Director, IGM Biosciences

This interactive training seminar introduces a full spectrum of analytical procedures and characterization methods in biologics development. The instructor will describe how to apply QbD/DoE to develop, qualify and validate analytical procedures with case study based on the newer ICH guidelines. The curriculum is meticulously designed to cover the practical aspects of the commonly used analytical procedures to address product identity, purity and impurity, strength and potency, process-related impurities, and contaminants. The extended characterization and analytical comparability will elaborate structure elucidation by HRMS, MAM, primary and secondary structure, PTM, glycan profiling, charge variant analysis, biophysical characterization of HOS and aggregation. The class is for academics, newcomers in industry, and veterans wanting an update on new analytical technologies.

THURSDAY, MAY 15, 2025 8:30 AM - 5:30 PM
| FRIDAY, MAY 16, 2025 8:30 AM - 12:30 PM

TS7C: Bioassay Development and Analysis

Instructor:

Steven Walfish, Owner, Statistical Outsourcing Services

This course will focus on factors to be considered in the design, development, and validation of bioassays. The course introduces terminology and important statistical tools and best practices. Examples and case studies will be provided to help solidify understanding on the topics of design and development, robustness, validation, and post-validation. Relevant pharmacopeial and EUA regulations will be highlighted.

ENGINEERING STREAM

Engineering Biologics with Novel Functionalities and Mechanisms of Action



The PEGS Boston Engineering Stream brings together leaders in protein engineering to highlight novel discovery platforms and their application, precision targeting and conditional activation, and the increasing role of machine learning and AI in discovery and engineering. Leading industry and academic researchers join this stream every year at PEGS Boston to stay current on the most important advances in this dynamic field.

ENGINEERING STREAM CONFERENCES

MAY 12-13

Display of Biologics

AGENDA

MAY 13-14

Engineering Antibodies

AGENDA

MAY 15-16

Machine Learning Approaches for Protein Engineering

AGENDA



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

ADVANCES IN YEAST DISPLAY

8:20 Chairperson's Remarks

K. Dane Wittrup, PhD, C.P. Dubbs Professor, Chemical Engineering & Bioengineering, Massachusetts Institute of Technology

8:30 Spatiotemporal Mapping and Rewiring of Immune Phosphosignaling

Xin Zhou, PhD, Assistant Professor, Biological Chemistry & Molecular Pharmacology, Dana-Farber Cancer Institute, Harvard Medical School

Activation and deactivation of immune receptor tyrosine-based motifs are key mechanisms regulating T cell responses, transducing signals from antigen receptors, integrins, cytokine receptors, checkpoint receptors, and more. However, genetically encoded methods to specifically report and manipulate immune tyrosine motif activities are lacking. Using a novel protein binder design combined with yeast display technology, we present an approach to map and rewire immune signaling activities in living cells and tissues.

9:00 Chemically Expanded Antibody Engineering on the Yeast Surface

James A. Van Deventer, PhD, Associate Professor, Chemical and Biological Engineering, Tufts University

Small molecules have many features that are difficult to access within antibodies, including both covalent functionalities and pharmacophores that modulate target activity. We have established a chemically expanded antibody engineering platform that enables access to small molecule features during antibody discovery and engineering. This talk will describe examples of 1) semi-rational "covalentizing" of existing antibodies; and 2) high-throughput discovery of pharmacophore-modified, enzyme-inhibiting antibodies.

9:30 Rapid Engineering of Soluble TCRs for High Affinity and Specificity

Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab

Soluble T cell receptor (TCR)-based bispecific therapeutics can co-opt T cells to eradicate infected and cancerous cells via peptide-HLA (pHLA) and CD3 recognition. However, native TCRs require extensive affinity maturation for efficacy in clinically validated bispecific formats, posing a significant barrier to their development. Here, we describe the development and application of a high-throughput yeast-based platform to rapidly generate and characterize TCR variants.

ANTIBODY DISPLAY TECHNOLOGIES

10:00 Presentation to be Announced



10:29 Networking Coffee Break

10:59 Chairperson's Remarks

Joao Goncalves, PhD, Full Professor, Microbiology & Immunology, University of Lisbon

11:00 Mammalian Display to Secretion Switchable Libraries for Antibody Preselection and High-Throughput Functional Screening

Achim Doerner, PhD, Scientific Director, Antibody Discovery & Protein Engineering, Merck Healthcare KGaA, Darmstadt

Mammalian display libraries can be interrogated consecutively for manufacturability and specificity. Similarly, libraries secreting antibodies are a perfect match for microfluidics-assisted high-throughput function first screens. The versatility and fruitful options arising from combining these emerging technologies will be discussed.

11:30 Cystine-Knot Peptide Inhibitors of HTRA1 Bind to a Cryptic Pocket within the Active Site Region

Yanjie Li, PhD, Scientist 4, Peptide Therapeutics, Genentech Inc.

Cystine-knot peptides (CKPs) are naturally occurring peptides that exhibit exceptional chemical and proteolytic stability. We leveraged CKPs as scaffolds to construct phage-displayed libraries and yield highly selective and potent picomolar inhibitors of HTRA1. Our findings reveal an intriguing mechanism for modulating the activity of HTRA1, and highlight the utility of CKP-based phage-display platforms in uncovering potent and selective inhibitors against challenging therapeutic targets.

12:00 pm Session Break

12:10 LUNCHEON PRESENTATION: Pan-Reactive MABs for Membrane Proteins to Enable Pre-Clinical Development in Underutilized Mammalian Models

Ross Chambers, Vice President of Antibody Discovery, Antibody Discovery, Integral Molecular Inc

Monoclonal antibodies (MAbs) often lack cross-species reactivity with mammalian orthologs, limiting the use of preclinical disease models. We present a novel method that leverages chickens to generate MAbs that cross-react with many, and in some cases all, mammalian orthologs tested, including NHPs, mice, ferrets, pigs, and bats. Immunization with RNA and Lipoparticles (VLPs) focuses the immune response on conserved mammalian epitopes. This approach successfully produced pan-reactive MAbs against numerous cellular membrane proteins, including GPRC5D, CD56, and CCR8.

12:40 Talk Title to be Announced

Andrew Bradbury, Chief Scientific Officer, Specifica, an IQVIA business

1:10 Session Break

PECULIARITIES OF TME AND HOW TO OVERCOME THEM

1:15 Chairperson's Remarks

Andrew R.M. Bradbury, MD, PhD, CSO, Specifica, an IQVIA business

1:20 Let It Go: Conditionally Masked Bispecifics for Specific Cytosolic Delivery of Protein Cargoes

Harald Kolmar, PhD, Professor and Head, Institute for Organic Chemistry and Biochemistry, Technische Universität Darmstadt

We have developed a modular approach for cytosolic penetration of tumor cells based on bispecific antibodies containing a masked cytosol-penetrating Fab on one arm and a tumor-targeting scFv linked via an endosomal cleavable linker on the other arm. Such TME-dependent as well as TAA-specific cytosol-penetrating antibodies have the potential to serve as a platform to deliver macromolecular cargoes for addressing intracellular targets in tumor cells.



**1:50 Severely Polarized Extracellular Acidity
around Tumor Cells**

Jinming Gao, PhD, Professor, Cancer Research, University of Texas Southwestern

Warburg metabolism has been known for almost a century. Using proton transitor nanoprobes, we recently discovered a severely polarized extracellular acidic region (SPEAR) both at single-cancer-cell and tumor-tissue level. The severe tumor acidity is well tolerated by cancer cells but is highly toxic to T cells, suggesting an immune evasive mechanism by tumor glycolytic metabolism.

**2:20 LockBody Technology—Simplified Conditionality for
Tissue-Localized Immune Engagement**

Jonny Finlay, PhD, CEO, Centessa

LockBody technology allows full steric control of antibody binding without the need for affinity masking. This presentation will exemplify the broad utility of the platform in multi-mechanism immune cell engagement and its application in oncology and inflammatory disease settings.

2:50 Talk Title to be Announced

*Marc Van Dijk, CSO Discovery and Engineering,
FairJourney Biologics*

**3:20 Networking Refreshment Break****4:05 Transition to Plenary Keynote Session****PLENARY KEYNOTE SESSION****4:15 Plenary Keynote Introduction**

*Jennifer R. Cochran, PhD, Senior Associate Vice Provost
for Research and Macovski Professor of Bioengineering,
Stanford University*

**4:25 The Role of Protein Engineering in
Developing New Innovative Modalities**

*Puja Sapra, PhD, Senior Vice President, Head
R&D Biologics, Engineering and Oncology Targeted
Discovery, AstraZeneca*

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE**5:10 Antibody-Lectin Chimeras for Glyco-
Immune Checkpoint Blockade**

*Jessica C. Stark, PhD, Underwood-Prescott Career
Development Professor, MIT*

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

**5:55 Welcome Reception in the Exhibit Hall
with Poster Viewing****YOUNG SCIENTIST MEET-UP****Co-Moderators:**

*Iris Goldman, Production, Cambridge Innovation Institute
Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab
Julie Sullivan, Production, Cambridge Innovation Institute*

7:20 Close of Day**TUESDAY, MAY 13****7:30 am Registration and Morning Coffee****MENTORING MEET-UP****Creating and Fostering a Productive and Effective
Mentor-Mentee Relationship**

*Carter A. Mitchell, PhD, CSO, Purification & Expression,
Kemp Proteins, LLC
Deborah Moore-Lai, PhD, Vice President, Protein Sciences,
ProFound Therapeutics*

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists: IN-PERSON ONLY

**ALTERNATIVE SCAFFOLDS FOR
RADIOPHARM AND CHEMOTHERAPY****8:30 Chairperson's Remarks**

*Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research
and Macovski Professor of Bioengineering, Stanford University*

**8:35 Miniprotein Radioconjugates for Treatment
of Solid Tumors**

*Dasa Lipovsek, PhD, Vice President, Lead Discovery, Aktis Oncology
Inc.*

Miniproteins combine the benefits of (1) complex three-dimensional surfaces capable of supporting high-affinity, specific binding to tumor-associated antigens and (2) small size that ensures fast clearance by kidney filtration. The Aktis discovery engine includes yeast surface display and medicinal chemistry by solid-phase peptide synthesis. Our most advanced asset, AKY-1189, has demonstrated efficacy against Nectin-4-expressing xenografts in mice and favorable biodistribution in human patients.

9:05 DARPs for Radiotherapy

*Christian Reichen, PhD, Associate Director, Oncology Research, Lead
Generation, Molecular Partners AG*

DARPs (Designed Ankyrin Repeat Proteins) are small, naturally-derived binding proteins of 15 kDa that can be generated against a broad range of tumor targets. We developed MP0712, a half-life-extended DLL3 Radio DARPIn Therapeutic (RDT), utilizing Lead-212 (Pb-212), an alpha particle-emitting isotope with a 10.6-hour half-life, which is well-suited for targeted alpha therapy (TAT) due to its unique physical properties.

**9:35 Expanding the Reach of Targeted Cancer Therapy
Using Multispecific Peptide-Drug Conjugates**

Caitlyn Miller, PhD, CEO & Co-Founder, TwoStep Therapeutics

Tumor-targeting therapies have begun to transform the oncology treatment landscape, but current agents are only suitable for a limited patient population. TwoStep Therapeutics leverages an engineered tumor-targeting peptide (PIP) that can selectively bind several tumor-associated integrins, offering broad applicability across solid tumors. This talk will focus on the development of PIP-drug conjugates and their efficacy and safety.

**NOVEL STRATEGIES IN DISPLAY OF
BIOLOGICS**

10:05 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with
Poster Viewing**11:15 KEYNOTE PRESENTATION: The History
of *in vitro* Antibody Discovery***James D. Marks, MD, PhD***11:45 Utilizing Functional Yeast Display for Engineering
Lysosomal Enzymes Suitable as ERTs***Ahlam N. Qerqez, PhD, Scientist Lab Leader, Protein Engineering,
Denali Therapeutics Inc.*

Peripherally administered enzyme replacement therapies (ERTs) to address lysosomal storage disorders are limited in their ability to target the CNS. Such ERTs are also limited by their instability in serum. To generate enzymes with sustained activity in serum we developed a novel enzyme engineering strategy utilizing both yeast surface display and secretion.

12:15 pm Presentation to be Announced



12:45 Session Break

**12:50 LUNCHEON PRESENTATION: AI-Powered
Immune Repertoire Mining and Multi-objective
Antibody Engineering***Barry Duplantis, Director of Global Business Development, Ailux
Biologics*

Artificial intelligence (AI) is transforming antibody discovery and engineering. Ailux's platform synergistically combines the best of our comprehensive wet lab, AtlaX biologics database, and three proprietary AI engines. We will explore our latest case studies that exemplify our AI-driven approach for tackling challenging targets, identifying unique functional antibodies, and achieving multi-objective optimization. This presentation provides our realistic and evidence-based perspective on AI's impact on developing next-generation antibody therapeutics.

1:20 Luncheon Presentation to be Announced



1:50 Close of Display of Biologics Conference

6:30 Recommended Dinner Short Course

**SC5: Targeting the Target: Aligning Target and Biologic Format
Biology to Achieve Desired Outcomes**

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

**SUNDAY, MAY 11**

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

CHALLENGING INDICATIONS WITH ENGINEERING SOLUTIONS

2:20 Chairperson's Remarks

*Benjamin J. Hackel, PhD, Professor, Chemical Engineering & Materials Science, University of Minnesota***2:30 Antibody Engineering to Target *Staphylococcus aureus***
Dominique M. Missiakas, PhD, Professor, Microbiology, University of Chicago

Staphylococcus (S.) aureus infection is a frequent cause of sepsis in humans, a disease associated with high mortality and exacerbated by antibiotic-resistant strains. The development of immune therapeutics against *S. aureus* has been thwarted by the formidable array of virulence mechanisms of this pathogen that together inhibit the antibody's functions and subvert host immune defenses. Here, we describe engineered antibodies that escape bacterial-mediated inhibition, display extended half-life, and improve bacterial killing.

3:00 CNS Drug Delivery Using Bispecific Antibodies Targeting CD98hc and Transferrin Receptor*Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan*

The inability of diverse biomolecules to readily penetrate the blood-brain barrier is a key limitation to their use in research, diagnostic, and therapeutic applications. We are developing bispecific antibodies that engage either CD98hc or transferrin receptors and efficiently transport biomolecules into the CNS. We will discuss the unique advantages of each shuttling pathway, our progress in developing second-generation shuttles, and their drug delivery applications.

3:30 Presentation to be Announced

3:45 Presentation to be Announced



4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING**How Many New Contacts Can You Make?***Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute*

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

NEXT-GENERATION BIOLOGICS FOR TREATMENT OF OBESITY**4:40 Therapeutic Strategies for GIP Antagonists in Obesity***Michael Wolfe, MD, Professor, Physiology and Biophysics, Case Western Reserve University*

Glucose-dependent insulinotropic polypeptide (GIP) plays a major physiological role in nutrient deposition and storage. GIP is overexpressed in obese individuals, and enhanced postprandial secretion initiates a vicious cycle characterized by increased nutrient uptake and storage in adipocytes, leading to insulin resistance and hyperinsulinemia, further increasing adipocyte nutrient uptake and storage. Both genetic abrogation and immunoneutralization of GIP signaling have been shown to reduce the development of obesity in preclinical models.

5:10 *De novo* Design and Engineering of Novel GLP1R Agonist Miniprotein*Ben Meinen, PhD, Head, Protein Design, AI Proteins*

De novo designed miniproteins represent a groundbreaking new modality, offering unprecedented flexibility in engineering biologics with an array of desirable features tailored for specific applications. We developed a novel GLP1R agonist miniprotein designed *de novo* to exhibit improved biased signaling with a strong emphasis on G protein-coupled signaling, while significantly reducing β -arrestin signaling. Our well-folded and stable agonist shows blood glucose lowering in diabetic db/db mice.

**5:40 KEYNOTE PRESENTATION:
Spatiotemporal Programming of Cytokine Immunotherapy for Cancer***K. Dane Wittrup, PhD, C.P. Dubbs Professor, Chemical Engineering & Bioengineering, Massachusetts Institute of Technology*

On-target, off-tumor toxicity severely limits systemic dosing of cytokines and agonist antibodies for cancer. Intratumoral administration is increasingly being explored to mitigate this problem. Full exploitation of this mode of administration must include a mechanism for sustained retention of the drug; otherwise, rapid diffusion out of the tumor eliminates any advantage. We will present recent work from our lab developing new molecules and design principles for such intratumoral immune therapeutics.

6:10 Close of Day

6:10 Dinner Short Course Registration

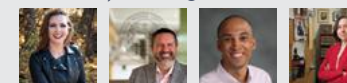
6:30 Recommended Dinner Short Course

SC4: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies

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

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

WORKFORCE INNOVATION BREAKFAST**7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (Continental Breakfast Provided) Co-Organized with Thinkubator Media***Moderator: Lori Lennon, Founder & CEO, Thinkubator Media*

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

**Panelists:**

Jared Auclair, PhD, Interim Dean, Northeastern University
College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer,
Pontikes Law, LLC

PLENARY KEYNOTE SESSION**8:45 Plenary Keynote Introduction**

Laszlo G. Radvanyi, PhD, Professor, Department of
Immunology, University of Toronto

**8:50 Ex vivo and in situ Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis**

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences,
University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARTs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of ex vivo and in situ engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing**ENTREPRENEUR MEET-UP****Fostering Entrepreneurship and Models for Start-Ups**

Natalie Galant, PhD, CEO, Paradox Immunotherapeutics

Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

10:25 PANEL DISCUSSION: Near-Term Challenges for AI/ML in Biotherapeutic R&D

Moderator: Peter M. Tessier, PhD, Albert M. Mattocks Professor,
Pharmaceutical Sciences & Chemical Engineering, University of
Michigan

- Benchmarking ML/AI methods compared to traditional approaches
- Development of human-relevant training data
- Expanding AI/ML prediction capabilities from molecular interactions to complex biological systems
- Extending ML/AI to genomic medicines and cell therapies
- Identifying and addressing core challenges in de novo designs
- Integrating AI/ML with existing R&D workflows

Panelists:

Sarel J. Fleishman, PhD, Professor, Biomolecular Sciences, Weizmann
Institute of Science; Chief Scientist, Scala Biodesign

Kadina Johnston, PhD, Senior Specialist, Discovery Biologics, Merck &
Co., Inc.

Vincent Ling, PhD, Chief Business Officer, Morphocell Technologies;
Consultant Advisor, Bill & Melinda Gates Foundation

Arvind Rajpal, PhD, SVP, Xaira

Max Vasquez, PhD, Chief Computing Officer, Adimab LLC

11:25 Presentation to be Announced**11:55 Session Break****12:30 pm LUNCHEON PRESENTATION:
De novo Protein Sequencing for Identification
of Neutralizing Antibodies in Human Plasma**

Thierry Le Bihan, Principal Scientist, Polyclonal Antibody Sequencing,
Rapid Novor

While B-cell sequencing aids human antibody discovery, it may miss the full diversity of circulating antibodies, as only 2-3% of B cells are in circulation, and not all produce antibodies. We demonstrate a mass spectrometry proteomics-based approach to sequencing neutralizing antibodies from serum of a patient vaccinated against SARS-CoV-2. Following de novo sequencing, we recombinantly expressed 12 antibodies and exhibited similar or higher binding affinities than the original polyclonal Ab.

12:30 Luncheon Presentation to be Announced**INTERACTIVE DISCUSSIONS****1:00 Find Your Table and Meet Your Discussion Moderator****1:10 Interactive Discussions**

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

**BREAKOUT DISCUSSION: Integrating AI/ML to Transform
Biologics Design and Optimization**

Kallol Ray, PhD, Vice President & Head, Global Biologics, Takeda
Pharmaceuticals Inc.

**MACHINE LEARNING USE CASES IN
PROTEIN ENGINEERING****1:55 Chairperson's Remarks**

Jennifer A. Maynard, PhD, Henry Beckman Professor, McKetta
Department of Chemical Engineering, Cockrell School of Engineering,
University of Texas Austin

**2:00 AI/ML in Biologics Drug Design: From Current
Innovations to Future Possibilities**

Kallol Ray, PhD, Vice President & Head, Global Biologics, Takeda
Pharmaceuticals Inc.

Advances in AI/ML are transforming biologics drug design by optimizing antibody engineering, enhancing prediction of protein structures, and accelerating discovery timelines. This presentation will explore recent breakthroughs and real-world applications of machine learning in designing innovative biologics, with a focus on antibodies. The discussion will also highlight emerging trends, future possibilities, and the potential of AI-driven approaches to overcome complex challenges in engineering antibodies for diverse therapeutic applications.

**2:30 LLM Embedding Coupled with Shallow Machine
Learning Predicts the Expression Level of mAb and VHH in
Mammalian Cells**

Rahmad Akbar, PhD, Senior Data Scientist, Antibody Design, Novo
Nordisk

We discuss herein the utility of deep learning in capturing the latent embedding space to describe long-range interaction, biophysical properties, and downstream prediction task. The value of combining deep and shallow learning to operationalize AI for antibody design.





And, we exemplify the application AI for antibody design by combining LLM embedding and shallow machine learning to predict the expression level of mAb and VHH in mammalian cells.

3:00 AlphaBind, a Domain-Specific Model for Prediction and Optimization of Antibody-Antigen Binding Affinity

Randolph Lopez, PhD, CTO and Co-Founder, A-Alpha-Bio

Antibodies are versatile therapeutic molecules that utilize immense combinatorial sequence diversity to cover a vast fitness landscape. However, designing optimal antibody sequences remains a major challenge. We introduce AlphaBind, a transformer-based model pre-trained on millions of antibody-antigen affinity measurements. In four parental antibody systems, we show that AlphaBind accurately predicts affinity using just one round of unguided data generation, allowing effective sequence optimization while preserving diversity and key biophysical properties.

3:30 Presentation to be Announced

DNASCRIPT

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

4:40 Interpretable Machine Learning for Modeling Non-Specific Binding of Biologics

Valentin Stanev, PhD, Associate Principal Data Scientist, AstraZeneca

Screening for high levels of non-specific binding (NSB) is an important part of assessing the developability profile of biologics candidates. I will present a machine learning workflow for predicting BVP—a commonly used NSB assay. It helped identify several factors which tend to correlate with increase in NSB. The workflow is purely *in silico* and can dramatically reduce the cost and increase the throughput of the early NSB screening.

IMPROVING SPECIFICITY AND MITIGATING OFF-TARGET EFFECTS

5:10 Engineered Miniprotein Multivalency for Precision Targeting

Benjamin J. Hackel, PhD, Professor, Chemical Engineering & Materials Science, University of Minnesota

We have advanced multivalent miniprotein engineering platforms to achieve selective control of target engagement in a size-efficient manner. We will present the effects of different molecular formats for multivalent binding, including the impact of paratope linkages and monovalent affinity on resultant selectivity and utility across multiple applications.

5:40 Control of CMV-Infected Cells with TCR-Based Bispecific T Cell Engagers

Jennifer A. Maynard, PhD, Henry Beckman Professor, McKetta Department of Chemical Engineering, Cockrell School of Engineering, University of Texas Austin

Infection by human cytomegalovirus remains a concern for newborns and immunocompromised individuals. No vaccines or antibodies are available, but adoptive T cell therapy has shown promise. Accordingly, we engineered a human T cell receptor to have high affinity and peptide specificity for the immunodominant pp65/A2 complex on infected cells. After reformatting as a bispecific T cell engager, this protein potently activated T cells against peptide-pulsed and infected fibroblasts.

6:10 One-Shot Optimization of Protein Binding Affinity and Specificity by Computational Design

Sarel J. Fleishman, PhD, Professor, Biomolecular Sciences, Weizmann Institute of Science; Chief Scientist, Scala Biodesign

We are developing a strategy for antibody design that addresses antibody affinity and developability by combining atomistic design and machine-learning calculations. Our work demonstrates that affinity can be enhanced by designing mutations that stabilize light-heavy chain interfaces or the CDRs, and that these enhancements often correlate with improvements in stability and antibody expressibility. I will also discuss new work to design universal antibody repertoires for accelerated discovery of developable antibodies.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Engineering Antibodies Conference

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SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: *In silico* and Machine Learning Tools for Antibody Design and Developability Predictions

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

FURTHER ADVANCES ON ML/DL: NOVEL PLMs, CODON-BASED PLMs, INTERPRETABILITY, DIFFUSION

8:25 Chairperson's Remarks

Maria Wendt, PhD, Global Head, Preclinical Computational Innovation Strategy Research Platforms, R&D, Sanofi



8:30 KEYNOTE PRESENTATION: Generative AI to Accelerate Prediction and Design in Biomedicine and Sustainability

Debora S. Marks, PhD, Associate Professor, Systems Biology, Harvard Medical School

There's now an amazing opportunity to accelerate discovery across important 21st century challenges by using computation tightly coupled to biological experiments and clinical medicine. I will describe some recent approaches from my lab for these challenges where we have developed new machine learning methods that can exploit the enormous natural sequence diversity and our ability to sequence DNA at scale.

9:00 Large Language Models for mRNA Design

Sven Jager, PhD, Lead, Computational Science, Sanofi Germany GmbH

mRNA-based vaccines and therapeutics are increasingly popular and used for a variety of conditions. A key challenge in designing these mRNAs is sequence optimization. Even small proteins or peptides can be encoded by a vast number of mRNA sequences, each affecting properties such as expression, stability, and immunogenicity. To facilitate the selection of optimal sequences, we developed CodonBERT, a large language model (LLM) specifically for mRNAs.

9:30 Progress Report on AlphaFold and OpenFold-Driven Biomolecular Modeling

Nazim Bouatta, PhD, Senior Research Fellow, Lab of Systems Pharmacology and Systems Biology, Harvard Medical School

AlphaFold2 has transformed structural biology with groundbreaking advances in protein structure prediction. However, despite these advances, many challenges remain. In this talk, I will present a progress update on AlphaFold2 and share insights gained from OpenFold, an optimized and trainable variant of AlphaFold2. I'll also explore potential paths to address the limitations of AlphaFold-like systems.

10:00 *In silico*-Driven Strategies to Unlock the Therapeutic Potential of Rabbit-Derived Antibodies

Shuji Sato, Senior Director Client Relations, ImmunoPrecise Antibodies

This session will explore effective strategies for accelerating lead selection from a diverse panel of antibodies. Key techniques presented include proprietary methods for leveraging the unique immune system of rabbits, early epitope landscape profiling, and the use of IPA's *in silico*-driven diversification and optimization workflows, resulting in the rapid delivery of optimized antibodies ready for clinical development.

10:15 Sponsored Presentation (*Opportunity Available*)

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

DEVELOPABILITY AND OPTIMIZATION

1:55 Chairperson's Remarks

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, an IQVIA business

2:00 Biophysical Cartography of the Native and Human-Engineered Antibody Landscapes Quantifies the Plasticity of Antibody Developability

Victor Greiff, PhD, Associate Professor, University of Oslo and Director of Computational Immunology, IMPRINT

Developing effective monoclonal antibody (mAb) therapies requires optimizing multiple properties, known as 'developability,' to ensure they can progress through the development pipeline. We analyzed 86 DPs across two million antibody sequences, finding key differences in the predictability and sensitivity of sequence- and structure-based DPs. Our findings reveal that human-engineered antibodies occupy a narrower space within the natural antibody landscape, offering a foundation for more precise mAb design.

2:30 Machine Learning-Guided Selection and Design Optimization of Chemically Stable Antibodies

Saeed Izadi, PhD, Senior Principal Scientist & Group Leader, Pharmaceutical Development, Genentech, Inc.

Chemical degradation poses significant risks in the developability of antibodies, potentially leading to loss of binding or liabilities like aggregation and immunogenicity. Here, I will present a machine-learning-driven approach to identify structural features crucial for chemical stability. I will share experimental evidence showing that targeted point mutations can effectively mitigate chemical liabilities without compromising binding, and discuss how these insights can inform the multi-parameter optimization of antibodies for enhanced stability.

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3:00 Insights from the Antibody Benchmarking Competition

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, an IQVIA business

This talk highlights the integration of strategic data collection and intelligent experimental design to advance AI-powered antibody discovery and optimization. We will share updates from the Antibody competition, a benchmarking initiative engaging the biotech, pharma, academia, and AI communities. These efforts, alongside tailored discovery campaigns for individual collaborators, aim to accelerate innovation and drive progress in early-stage therapeutic discovery.

3:30 Revolutionizing Antibody Expression: Leap-In Transposase® for Stable, Scalable Biologics Manufacturing



Speaker to be Announced, ATUM

As the demand for high-quality biologics accelerates, biopharmaceutical developers face increasing pressure to optimize cell line development for speed, quality, stability, and scalability. ATUM's Leap-In Transposase® technology is transforming the landscape of protein expression by enabling rapid, predictable, and high-yield stable cell line generation. Unlike traditional random integration methods, the Leap-In Transposase® system facilitates highly efficient transgene integration at transcriptionally active loci, leading to enhanced expression, improved genetic stability, and accelerated development timelines. In this presentation, we will showcase how Leap-In Transposase® technology is empowering biopharma teams to achieve faster workflows while eliminating the need for labor-intensive single-cell cloning. We will present case studies demonstrating its impact across monoclonal antibodies, multispecifics, and novel therapeutic proteins, highlighting significant improvements in titers, scalability, and manufacturability. Furthermore, we will discuss its seamless integration with CHO and HEK cell systems, making it an ideal solution for both early-stage discovery and commercial-scale production.

4:00 Networking Refreshment Break

4:30 Generative AI-Guided Design of Vaccine Immunogens

Reda Rawi, PhD, Staff Scientist and Co-Head, Structural Bioinformatics Core, NIH NIAID

Structure-based vaccine design campaigns that aim to stabilize full-length proteins will not succeed when the virus is evading immune response by sequence diversity. In this work, we capitalized on the recent major advances that have been achieved in protein design using generative AI tools. We *in silico* designed *de novo*

proteins that scaffold sequence-conserved epitope regions of the antigens of interest.

5:00 AbGPT: De novo Antibody Design via Generative Language Modeling

Amir Barati Farimani, PhD, Associate Professor, Machine Learning, Carnegie Mellon University

The adaptive immune response relies on B-cell receptors (BCRs) for pathogen neutralization, yet designing BCRs *de novo* remains challenging due to structural complexity. Here, we introduce Antibody Generative Pretrained Transformer (AbGPT), a fine-tuned model from a foundational protein language model. Using a tailored generation and filtering pipeline, AbGPT generated 15,000 high-quality BCR sequences, effectively capturing the intrinsic variability and conserved regions critical to antibody design.

5:30 Scaling Foundation Models for Protein Generation

Ali Madani, PhD, Founder and CEO, Profluent Bio

Language models learn powerful representations of protein biology. We introduce a new foundation model suite that directly investigates scaling effects for protein generation. We then apply this for applications in antibody and gene editor design.

6:00 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Delivering on the AI Antibody Promise: The Antibody Benchmarking Competition

Andrew R.M. Bradbury, MD, PhD, CSO, Specifica, an IQVIA business

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, an IQVIA business

- AI promises in antibody discovery and optimization: will they really revolutionize the field? or just another way of addressing solved problems?
- What can AI do now? And where are we seeing the greatest value relative to existing technologies?
- The Antibody benchmarking competition: Did AI deliver on the Antibody challenges?
- Ideas for future benchmarking competitions

BENCHMARKING AND AUTOMATION

8:25 Chairperson's Remarks

Victor Greiff, PhD, Associate Professor, University of Oslo and Director of Computational Immunology, IMPRINT

8:30 Closed-Form Test Functions for Biophysical Sequence Optimization Algorithms

Samuel Stanton, PhD, Machine Learning Scientist, Prescient Design, Computational Sciences, Genentech

Many researchers are trying to replicate the success of machine learning (ML) in computer vision and natural language processing in modeling biophysical systems. As a discipline, ML heavily relies on low-cost empirical benchmarks to guide algorithm development, but available benchmarks for biophysical applications have major shortcomings. Drawing inspiration from mutational landscape models, we propose Ehrlich functions, a new class of test functions for biophysical sequence optimization algorithms.

MACHINE LEARNING APPROACHES FOR PROTEIN ENGINEERING

Putting Theory into Practice and Streamlining Biologic Development

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9:00 Avoiding Pitfalls in ML Model Validation for Protein Design: The Importance of Data Splits

Norbert Furtmann, PhD, Head, Computational and High-Throughput Protein Engineering, Large Molecule Research, Sanofi

This presentation will explore the development of machine learning models for protein property prediction. Focusing on customized protein language models for the NANOBODY modality, it will demonstrate the implementation of a downstream thermostability predictor. Using this example, the talk will emphasize the critical importance of meaningful data splits in model training and validation.

9:30 Closing the Loop: Ultra-Fast Wet Lab Validation for AI-Guided Protein Design

Julian Englert, MS, Co-Founder and CEO, Adaptyv Biosystems

Adaptyv accelerates data generation for training and validating AI models with a high-throughput lab that companies can access via our software interface and API. We empower protein-design teams to validate their AI models many times faster than before, without the need to run in-house wet labs. We're partnering with dozens of companies—from techbio startups to major pharma—and generated lab data for thousands of novel proteins.

10:00 Presentation to be Announced

absci

10:30 Networking Coffee Break

11:00 End-to-End Antibody Discovery against 100s of Targets per Year: From Antigen to AI-Driven Insights

André A. R. Teixeira, PhD, Senior Director, Antibody Platform, Institution for Protein Innovation

At IPI, we perform 300 antibody and VHH discovery campaigns per year against human targets. Our end-to-end antibody discovery platform integrates antigen production, yeast display libraries (Fab and VHH), next-generation sequencing, antibody production, and biophysical characterization. With a success rate exceeding 85%, this platform generates antibodies that benefit the community. Also, the data sets offer powerful opportunities for AI and machine learning applications, driving innovation in antibody discovery and development.

11:30 The IMMREP TCR-Epitope Prediction Challenge: Lessons Learned and Future Directions

Justin Barton, PhD, AI Scientist, Xaira Therapeutics

The IMMREP23 competition evaluated TCR-pMHC interaction prediction methods from 53 participating teams submitting 398 sets of predictions. Results showed reasonable performance for "seen" pMHC targets but near-random performance for "unseen" peptides, highlighting an unsolved generalization challenge. Here we discuss what has been learned from detailed analysis of predictions and provide insights for improving future benchmarks by carefully addressing biases in dataset construction.

12:00 pm DALSA—DTU Arena for Life Science Automation

Timothy Patrick Jenkins, PhD, Assistant Professor and Head, Data Science, DTU Bioengineering

The DTU Arena for Life Science Automation (DALSA) is a pioneering initiative aimed at advancing the technologies and use of automation within Life Science R&D and manufacturing for academia as well as industry. Our mission is to establish a central and open access hub for technology development and educational advancement in life science automation, serving as a test bed for the full-scale implementation of DALSA.

12:30 Close of Summit

ONCOLOGY STREAM

Novel Approaches and Challenges in Advancing Molecules into the Clinic



The Oncology Stream at PEGS Boston 2025 brings together three cutting-edge events focused on revolutionizing cancer treatment. The **Antibodies for Cancer Therapy** conference explores innovative approaches and optimization of antibody-based treatments, as well as lessons learned in mitigating risks and maximizing patient outcomes. The **Emerging Targets for Oncology & Beyond** conference delves into novel target discovery, and development of new approaches for targeting the tumor microenvironment. Finally, the **Driving Clinical Success in Antibody-Drug Conjugates** conference showcases advancements in ADC design, novel payloads and engineering strategies to enhance efficacy and increase therapeutic window. Collectively, these conferences present the exciting promise of a next wave in personalized medicine and targeted therapies.

ONCOLOGY STREAM CONFERENCES

MAY 12-13

**Antibodies
for Cancer
Therapy**

[AGENDA](#)

MAY 13-14

**Emerging Targets
for Oncology
and Beyond**

[AGENDA](#)

MAY 15-16

**Driving Clinical
Success in
Antibody-
Drug Conjugates**

[AGENDA](#)



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: Safety & Efficacy of Bispecifics and ADCs

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

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

THE NEXT WAVE IN ANTIBODY-BASED THERAPIES: RADIOPHARMACEUTICALS AND PROTEIN DEGRADERS

8:20 Chairperson's Remarks

Horacio G. Nasti, PhD, Vice President, Protein Science and Technology, Incyte Corporation

8:30 Development and Translation of Radiolabeled Antibodies for Cancer Therapy and Diagnostics

Anna M. Wu, PhD, Chair and Professor, Immunology & Therapeutics, Center for Theranostic Studies, City of Hope

Recent approvals of radiopharmaceuticals for prostate and neuroendocrine cancers have renewed interest in antibodies for targeted radionuclide therapy. Advantages include the potential for paired imaging to evaluate target expression, delivery, and response to radioimmunotherapy ("theranostics"); disadvantages include extended circulation of antibodies leading to hematologic toxicity. PK-optimized engineered antibodies and fragments can provide novel agents for non-invasive imaging (of tumors and immune cells) and localized delivery of therapeutic radionuclides.

9:00 Development and Optimization of Radiopharmaceuticals for Combination with Immunotherapies

Zachary S. Morris, PhD, MD, Department Chair and Endowed Professor of Human Oncology, University of Wisconsin Madison

Radiopharmaceuticals can elicit immunogenic tumor cell death and phenotypic changes in surviving tumor cells as well as inflammatory changes in the tumor microenvironment—and this may alter tumor immunogenicity in a way that enables cooperative therapeutic effects in combination with certain immunotherapies. Further preclinical and clinical research is needed to clarify mechanisms whereby radiopharmaceutical therapies may affect anti-tumor immunity and response to cancer immunotherapies.

9:30 AbTACs, KineTACs & TrainTACs: Three Platforms for Extracellular Targeted Protein Degradation

Josef Gramespacher, PhD, Co-Founder, EpiBiologics

By ablating all disease-associated functions of a given protein at once, targeted protein degradation has emerged as a promising therapeutic strategy to overcome limitations of traditional occupancy-based inhibitors. To this end, at EpiBiologics, we are developing three fully recombinant and modular bispecific antibody-based platforms—AbTACs, KineTACs, & TrainTACs—that can be applied to effectively mediate degradation of cell-surface and extracellular proteins.

10:00 Unmask Antibody Specificity: A Novel High-Density Protein Microarray Platform for Diagnostic and Therapeutic Applications



Xuan Liu, SVP, OriGene

Antibody specificity is critical for ensuring accurate diagnostic and therapeutic outcomes. Cross-reactivity, however, poses significant risks, including erroneous results and potential misdiagnoses. To address this challenge, OriGene has developed high-density protein microarrays featuring 10K and 17K protein chips, enabling comprehensive antibody specificity testing. These arrays allow for rapid profiling of antibody binding behavior. This approach streamlines the selection of optimal antibodies from multiple candidates within a development pipeline. This presentation will introduce the features and capabilities of this novel platform. Two case studies will highlight its value, showcasing instances where the platform not only revealed antibody non-specificity but also identified unsuspected cross-reacting targets.

10:30 Networking Coffee Break

MITIGATING RISKS AND MAXIMIZING PATIENT OUTCOMES IN ANTIBODY THERAPEUTICS



11:00 KEYNOTE PRESENTATION: Nonclinical Immunogenicity Risk Assessment and Mitigation for Bispecific Antibodies

Paul J. Carter, PhD, Genentech Fellow, Antibody Engineering, Genentech

Immunogenicity risk assessment and mitigation is desirable to aid successful engineering of protein therapeutics including antibodies. Multiple *in silico* and *ex vivo* assays suggest that some mutations (knob-into-hole and Fab) used to facilitate *in vivo* assembly of bispecific IgG represent a low risk for immunogenicity. Common light chains may reduce

the immunogenicity risk of bispecifics. Key immunogenicity challenges for engineered proteins therapeutics will be discussed including steps towards addressing them.



11:30 KEYNOTE PRESENTATION: Advancing TCRm Antibody Therapy: Insights and Lessons Learned for Maximizing Patient Outcomes

Scott Chunhua Shi, PhD, Associate Director Institute & Head of Biological Discovery, ORBIT Therapeutic Discovery, MD Anderson Cancer Center

Tumor cells present specific peptides on HLA-I molecules, which can be targeted by TCRm antibodies to address otherwise undruggable proteins. However, the limited peptide copies and the specificity challenges of targeting these epitopes pose therapeutic hurdles. This presentation will share key insights and lessons learned from our various projects across different development stages, highlighting how we aim to overcome these challenges to ultimately benefit patients.

12:00 pm Session Break

12:10 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:10 Session Break

DESIGN AND ENGINEERING OF ANTIBODY-CYTOKINE FUSIONS/MIMETICS

1:15 Chairperson's Remarks

Daniel A. Vallera, PhD, Lion Scholar and Professor, Director, Section on Molecular Cancer Therapeutics; Professor, Therapeutic Radiology, University of Minnesota Masonic Cancer Center

1:20 Discovery and Design of Anti-Cytokine Antibodies for Cancer Immunotherapy

Jamie B. Spangler, PhD, Associate Professor, Biomedical and Chemical & Biomolecular Engineering, Johns Hopkins University

Cytokines coordinate all facets of immune biology and thus harbor great therapeutic potential. However, endogenous cytokines are poorly suited as drugs due to their pleiotropy and poor pharmacological properties. Complexing cytokines with anti-cytokine antibodies enhances their specificity and developability, but translating a mixed cytokine/antibody complex is impeded by stability concerns. We overcame these limitations by engineering



single-agent cytokine/antibody fusion proteins (immunocytokines) that bias the immune response for various disease applications.

1:50 Not Just a Targeted Cytokine: Functionally Specific IL-18 (F-18) Fused to Anti-PD-1 is a Bifunctional Checkpoint Inhibitor with Enhanced Anti-Tumor Activity

Brian A. Rabinovich, PhD, CSO, R&D, Fuse Biotherapeutics

Anti-PD-1 antibodies demonstrate strong cPOC, but innate/acquired resistance remains a challenge. Anti-PD-1-cytokine fusions enhance antigen-experienced/tumor-specific T cell activity but the nature and/or potency of the cytokine negates checkpoint inhibition due to toxicity—and drives terminal exhaustion. We engineered PD-1-targeted IL-18 variants attenuated >10,000-fold which regain activity when bound to PD-1+/IL-18R+ T cells, act to enhance PD-1+ tumor-specific T cells, and can be dosed safely to levels consistent with checkpoint inhibition.

2:20 Protein Engineering Using Novel Chemical Methods to Access PD1-Based Immunocytokines

Arnaud Goepfert, PhD, Director, Protein Sciences, Bright Peak Therapeutics

Antibody-cytokine conjugates leverage orthogonal mechanisms of action (MoA) in one molecule to induce potent antitumor immune responses. At Bright Peak, we generate immunocytokines through site-specific chemical conjugation of cytokine to “off-the-shelf” human IgG antibodies. During the talk, I will focus on our PD-1-targeting conjugates and share compelling preclinical data supporting the future development of BPT567, a PD1-IL18 immunocytokine.

2:50 Sponsored Presentation (Opportunity Available)

3:20 Networking Refreshment Break

4:05 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:15 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research and Macovski Professor of Bioengineering, Stanford University



4:25 The Role of Protein Engineering in Developing New Innovative Modalities

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE



5:10 Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade

Jessica C. Stark, PhD, Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

5:55 Welcome Reception in the Exhibit Hall with Poster Viewing



YOUNG SCIENTIST MEET-UP

Co-Moderators:



Iris Goldman, Production, Cambridge Innovation Institute
Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab
Julie Sullivan, Production, Cambridge Innovation Institute

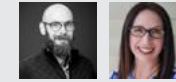
7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists:
IN-PERSON ONLY

ADVANCES IN T-CELL ENGAGERS AND CO-STIM PATHWAYS

8:30 Chairperson's Remarks

Daniel Chen, MD, PhD, Founder & CEO, Synthetic Design Lab

8:35 ISB 2001, a First-in-Class Trispecific BCMA and CD38 T Cell Engager Designed to Overcome Mechanisms of Escape from Multiple Myeloma Treatments

Mario Perro, PhD, Head of Biologics Research, Ichnos Glenmark Innovation

Downregulation of targets limits the efficacy of monotherapy T cell engagers (TCE). ISB 2001, a first-in-class TCE targeting both CD38 and BCMA, demonstrated superior tumor cytotoxicity *in vitro*, *in vivo*, and *ex vivo* using patient samples when compared to teclistamab. Clinically, ISB 2001 demonstrated an overall response rate of 75% across all dose levels and a favorable safety and tolerability profile in heavily pretreated patients with r/r MM.

9:05 Bispecific Vy9Vδ2-T Cell Engagers for Cancer Immunotherapy

Hans van der Vliet, MD, PhD, CSO, Lava Therapeutics

Vy9Vδ2-T cells constitute a relatively homogeneous population of pro-inflammatory immune effector cells. This presentation will focus on the preclinical and early clinical development of bispecific Vy9Vδ2-T cell engagers as a novel approach for cancer immunotherapy.

**9:35 PANEL DISCUSSION: Engineering Multi-Pathway Inhibition in the Same Molecule: PD1/PD(L)1 x VEGF**

Moderator: Daniel Chen, MD, PhD, Founder & CEO, Synthetic Design Lab

- Technology, applications, and advantages of multi-pathway targeting
- How does the strategy enhance anti-tumor immune responses, overcome resistance mechanisms, and reduce toxicity?
- What's happening in the tumor microenvironment?
- Challenges in maintaining binding affinity and specificity for multiple targets
- Reviewing data on efficacy of combined PD-1/PD-L1 and VEGF inhibition
- Ongoing clinical trials of promising candidates
- Comparison of single molecule vs. combination therapy

Panelists:

Rakesh K Jain, PhD, A. W. Cook Prof, Radiation Oncology & Tumor Biology, Massachusetts General Hospital

Yulei Wang, PhD, Senior Fellow, Translational Medicine Oncology, Genentech Inc.

Dan G. Duda, DMD, PhD, Professor, Radiation Oncology, Harvard Medical School; Director, Translational Research in GI Radiation Oncology, Massachusetts General Hospital

10:05 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Harnessing Protein Engineering to Modulate Immune Responses via CD28 Costimulatory Pathways

Gregory L. Moore, PhD, Senior Director, Protein Engineering, Xencor, Inc.

T cells require T cell receptor engagement by peptide-major histocompatibility complexes coupled with CD28-mediated costimulation for optimal activation. Tumor cells typically lack expression of CD28 ligands; we hypothesized that CD28 signaling at the T cell/tumor cell interface could enhance anti-tumor activity. We generated tumor-associated antigen (TAA) x CD28 bispecific antibodies that provide CD28 costimulation only in the presence of TAA and TCR engagement and show enhanced activity over traditional bispecifics.

11:45 Selective Tumor Regression in MUC16-Positive Lung and Pancreatic Cancer Models Using a Bispecific Antibody Apoptosis Trigger, Cancerlysin IMV-M

Victor S. Goldmacher, PhD, CSO, R&D, ImmuVia

The first-in-class bispecific antibody IMV-M targets MUC16 and death receptor 5. It is uniquely designed to cluster DR5 effectively, but only in MUC16-positive cancer cells, directly activating apoptosis to induce cancer cell death. This mechanism differentiates IMV-M from ADCs, which rely on cytotoxic drugs, and from bispecific immune cell engagers. IMV-M has demonstrated potent efficacy in various xenograft cancer models and shown safety in non-human primates.

12:15 pm Sponsored Presentation (*Opportunity Available*)

12:45 Session Break

12:50 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Enjoy Lunch on Your Own**

1:50 Close of Antibodies for Cancer Therapy Conference

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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





TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

TARGET DISCOVERY, PREDICTION, AND VALIDATION

2:20 Chairperson's Remarks

Daniel A. Vallera, PhD, Lion Scholar and Professor; Director, Section on Molecular Cancer Therapeutics; Professor, Therapeutic Radiology, University of Minnesota Masonic Cancer Center

2:30 AI-Based Target Identification and Antibody Discovery in Oncology

Xiaole Shirley Liu, PhD, CEO, GV20 Therapeutics

GV20's STEAD platform leverages proprietary AI to decode the human immune system and uncover tumor targets and functional antibodies directly from patient tumor profiles. The power of STEAD is demonstrated by the unprecedented 3-year timeline from target research to IND of the lead program GV20-0251 against a novel immune checkpoint IGSF8, and validated by GV20-0251's favorable safety and promising monotherapy efficacy in advanced metastatic cancer patients in US clinics (NCT05669430).

3:00 Identification of Next-Generation Brain Shuttles and Shuttle Targets and Using Multiplexed *in vivo* Screening with Protein Barcodes

Karen E. Duffy, PhD, Principal Scientist, Protein Engineering, Manifold Biotechnologies Inc.

TfR1 shuttles show promise for Alzheimer's treatment, but toxicities remain limiting. Powered by AI and Manifold's protein barcoding technology, we introduce a high-throughput *in vivo* screening method to identify novel brain shuttles. Our approach reveals new shuttle targets and shuttles with diverse properties, particularly PX1, which enhances anti-A β antibody delivery without the hematological toxicity of TfR1 shuttles. This work highlights the power of large-scale *in vivo* testing.

3:30 Sponsored Presentation (*Opportunity Available*)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING



How Many New Contacts Can You Make?

Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

NOVEL APPROACHES FOR REINVIGORATED TARGETS

4:40 Preclinical Development of Affibody-Based Drug Conjugates Targeting HER3

Torbjörn Gräslund, PhD, Professor, Department of Protein Science, KTH Royal Institute of Technology

HER3 overexpression is relatively common in breast and other cancers, and the development of HER3-targeted drugs is therefore warranted. Affibody molecules are small engineered alternative scaffold affinity proteins that can be site-specifically loaded with cytotoxic drugs to create homogenous conjugates with a desired drug-to-affibody ratio. We have explored HER3-targeted affibody molecules loaded with the cytotoxic drug DM1 in xenograft models and determined their biodistribution and therapeutic potential.

5:10 GPC3-Targeting ARTEMIS T Cell Therapy for Hepatocellular Carcinoma: Preclinical and Clinical Results

Cheng Liu, PhD, President & CEO, Eureka Therapeutics, Inc.

This presentation will outline the design of ARTEMIS (AbTCR) T cell engineering technology to improve solid tumor T cell infiltration and reduce CRS, particularly the targeting of Glypican 3 (GPC3) in advanced hepatocellular carcinoma (HCC). Preclinical and clinical data of GPC3-targeting ARTEMIS T cell therapy for HCC patients will be shared.

5:40 The Development of VT1021, a First-in-Class Therapeutic Peptide That Modulates Tumor Immune Microenvironment

Jing Watnick, PhD, COO, Vigeo Therapeutics Inc.

VT1021, a cyclic peptide designed to stimulate thrombospondin-1 expression by replicating the biological activity of prosaposin, has been shown to stimulate TSP-1 production in the tumor microenvironment (TME). In the first-in-human study, the safety and tolerability, clinical response, and biomarker profile of VT1021 are reported. The modifications of the TME correlates with VT1021 treatment, from one that is immunosuppressive and tumor-promoting to one that is immune-active and tumor-inhibiting.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC5: Targeting the Target: Aligning the Target and Biologic Format Biology to Achieve Desired Outcomes

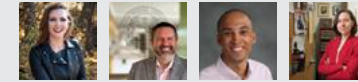
*Separate registration required. See short course page for details.

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (*Continental Breakfast Provided*) Co-Organized with Thinkubator Media



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC



PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP

Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics

Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

NOVEL/EMERGING TARGETS

10:20 Chairperson's Remarks

Rajkumar Noubade, PhD, Director, Oncology, Gilead Sciences



10:25 KEYNOTE PRESENTATION: GlycoRNA Biology in Health and Disease

Ryan A. Flynn, PhD, Assistant Professor, Stem Cell and Regenerative Biology, Boston Children's Hospital

I will discuss glycoRNAs in mammalian cells which would represent a third scaffold for glycosylation. Highlights of the chemical biology used to uncover glycoRNAs will be reviewed, with a focus on our more recent work defining the precise linkage between N-glycans and RNA, the organizational basis for glycoRNA presentation on the cell surface.

10:55 KEYNOTE PRESENTATION: Targeting mCALR in MPN Diseases

Horacio G. Natri, PhD, Vice President, Protein Science and Technology, Incyte Corporation

Calreticulin (CALR) mutations are responsible for MPNs in 20-30% of patients. Insertions or deletions of CALR in exon 9 create positively charged C-terminus variants lacking the KDEL endoplasmic-reticulum retention signal. Mutant CALR (mutCALR) transits with the thrombopoietin receptor (TPO-R) forming an extracellular neoantigen that constitutively activates the JAK2/STAT signaling. INCA033989 is an antibody-targeting mutCALR, selective for cells expressing mutCALR that allows targeting neoplastic cells without compromising normal hematopoiesis.

11:25 Quick 'n' Clean: High-Throughput Bispecific Antibody (BsAb) Production for Optimal Pairing Screening at Discovery Stage

Jiansheng Wu, Head of CRO Services, WuXi Biologics USA LLC

Finding the optimal pairing of bsAb requires producing a large number of bsAb molecules at the 1–5 mg scale to support *in vitro* binding assays and cell-based screening. However, high-purity, low-endotoxin bsAb production is often time-consuming and cost-prohibitive. Quick 'n' Clean leverages fit-for-purpose molecule designs to enable high-throughput bsAb purification at small scale, achieving >99% heterodimer purity and ultralow endotoxin levels (<0.1 EU/mg). This meets the stringent requirements of immune cell-based assays and other demanding applications. Quick 'n' Clean accommodates various bsAb formats, including those with two different light chains.

11:55 Session Break



12:00 pm Luncheon Presentation to be Announced

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: What Format for What Disease? How do different antibody formats stack up versus CAR-T, T cell engagers, multispecifics, protein degraders, RNA etc?

Catherine Hutchings, PhD, Independent Consultant

- How are different antibody formats performing vs. other Ab-related therapeutic modalities to address efficacy and success in the clinic?
- Hematological vs. solid tumors (and target tissue)
- Oncology vs. non-cancer indications (what have we learned from each)
- Format and target biology challenges
- The role of Fc domain, epitope, target combinations, IgG versus fragments (Fab, VHH, etc.)





TARGETS FOR CANCER IMMUNOTHERAPY

1:55 Chairperson's Remarks

Marie-Eve Beaulieu, PhD, Co-Founder & CSO, Drug Development, Peptomyc SL

2:00 Leveraging TCR-Mimic Antibodies to Target Driver-Gene Neoantigens

Brian Mog, MD/PhD Candidate, Ludwig Center, Johns Hopkins School of Medicine

Clonal mutations in driver genes such as TP53 and KRAS can be therapeutically targeted when mutated peptide fragments are presented on human leukocyte antigens (HLA). However, these neoantigens occur at extremely low numbers on the surface of cancer cells—often fewer than 10 per cell. Here, we describe the development of T cell receptor (TCR)-mimic antibodies and demonstrate their utility in chimeric TCRs for targeting a common TP53 neoantigen.

2:30 Discovery of TTX-080: Developing a Highly Specific Clinical HLA-G Antibody in Collaboration with Tizona Therapeutics

Paul Widboom, PhD, Senior Director, Antibody Engineering, Adimab LLC

Human leukocyte antigen-G (HLA-G) is a target with high therapeutic potential, as it is involved in immunosuppression through interaction with ILT2 and ILT4. The high percent identity of HLA-G to other class I HLA molecules makes specific binding a crucial property of a therapeutic antibody. Here we present the discovery of an HLA-G-specific antibody (TTX-080) with our partner Tizona Therapeutics, and its development to a clinical program.

3:00 PANEL DISCUSSION: The Ups, Downs, and Revitalization of IO Targets

Moderator: Marie-Eve Beaulieu, PhD, Co-Founder & CSO, Drug Development, Peptomyc SL

- TIGIT, CD40, and other targets that haven't lived up to expectations
- OX-40, 4-1BB, LAG3, and other reviving targets: lessons learned and future perspectives

Panelists:

Rajkumar Noubade, PhD, Director, Oncology, Gilead Sciences

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

3:30 Sponsored Presentation (Opportunity Available)

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

TARGETING THE TUMOR MICROENVIRONMENT

4:40 Delivery Strategies for Making Biologics against Intracellular Targets a Reality

Sankaran Thayumanavan, PhD, Distinguished Professor, Chemistry, University of Massachusetts Amherst

Most of the current targeted protein degradation approaches have focused on discovering new pathways for degradation and designing small molecule degraders against disease-relevant targets. Polymeric scaffolds have the potential to rather uniquely impact this vibrant field. This presentation will focus on the new frontiers in targeted protein degradation that are uniquely enabled by polymeric materials.

5:10 Nano-Antibody (SBT-100) Inhibits KRAS and STAT3—And Penetrates the Blood-Brain-Barrier

Sunanda Singh, Founder & CEO & President, Singh Biotechnology LLC

SBT-100 is a nano-antibody that inhibits STAT3 and KRAS mutations G12D and G13D, and wild KRAS. According to our preclinical studies, SBT-100 is a safe and well-tolerated pan-KRAS inhibitor. It effectively inhibits human cancers with KRAS mutations G12D and G13D. Although it has a short half-life in blood, it has a very long biological life.

5:40 Clinical Potential of Oncofetal-Chondroitin Sulfate for Pan-Cancer Therapies

Elena Vidal-Calvo, PhD, PostDoc, Immunology & Microbiology, University of Copenhagen

ofCS is a carbohydrate expressed in the tumor microenvironment (stromal and cancer cells) in nearly all cancer types. It is also found in distant metastases and plays a role in immune evasion, making it an ideal target for antibody-based therapies. Our highly specific ofCS antibodies, functionalized into antibody drug conjugates, eradicated tumors in 10+ cancer models without recurrence or toxicity, underscoring the remarkable tumor-specificity of the ofCS carbohydrate molecule.

6:10 Engineering Cell-Type Selective Immunotherapies via Cis-Targeting to Enhance Anti-Tumor Activity

Yik Andy Yeung, PhD, CTO, Asher Biotherapeutics

IL-21 is a critical cytokine for T cell effector function but has limited clinical use due to pleiotropic effects. To maximize IL-21's therapeutic potential, we developed AB821, a cis-targeted IL-21 to selectively activate CD8+ T cells. Preclinical data show that AB821 activates IL-21R-high, antigen-experienced, exhausted CD8+ T cells in the tumors. AB821 restores their effector function and induces memory phenotypes, resulting in strong anti-tumor effects in multiple PD1-refractory mouse models.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Emerging Targets for Oncology and Beyond Conference

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: Safety & Efficacy of Bispecifics and ADCs

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

TUESDAY, MAY 13

6:30 pm Recommended Dinner Short Course

SC7: Nuts and Bolts of Building a Radiopharmaceutical Therapy Agent

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

DEGRADER-ANTIBODY CONJUGATES

8:25 Chairperson's Remarks

Greg M. Thurber, PhD, Associate Professor, Chemical Engineering & Biomedical Engineering, University of Michigan

8:30 Degradation-Antibody Conjugates (DACs) Unlock Heterobifunctional Degradation through mAb-Like Pharmacokinetics and Excellent *in vivo* Efficacy

Jonas Helma-Smets, PhD, Founder & CSO, Tubulis GmbH

New ADC payload strategies are needed to address emerging drug resistance and limited treatment durability. Degradation-Antibody Conjugates (DACs) could significantly expand the number of druggable payload targets; however, conjugation and identification of suitable degradationers remain challenging. Here, we report a new DAC platform ensuring excellent DAC stability antibody-mediated delivery of functional degradationers enabling long-lasting responses even after single-dose injections in preclinical animal models.

9:00 The Design and Optimization of Degradation-Antibody Conjugates

Stephanie M. Monson, PhD, Principal Scientist & Group Leader, Conjugation & Chemical Biology, Genentech Inc.

Degradation Antibody Conjugates (DACs) represent a novel therapeutic approach that combines the specificity of antibodies with the potency of protein degradationers. The design and optimization of DACs involve careful consideration of factors such as antibody selection, linker chemistry, and TPD potency. By precisely

engineering these components, researchers aim to create highly effective and selective DACs for the treatment of various diseases, including cancer.

9:30 PROxAb Shuttle: A Plug & Play Solution for Targeted Antibody-Mediated Degradation Delivery

Hendrik Schneider, PhD, Principal Scientist, Merck KGaA, Darmstadt, Germany

Targeted protein degradation has emerged as a promising therapeutic strategy for addressing challenging molecular pathologies. However, achieving tissue selectivity remains challenging. The PROxAb Shuttle approach introduces a non-covalent platform for antibody-mediated targeted delivery of degradationers. By enhancing pharmacokinetics and prolonging degradationer half-lives from hours to days, this system aims to improve the selectivity and efficacy of tumor-targeting therapies, facilitating significant anti-tumor responses *in vivo*.

10:00 Sponsored Presentation (*Opportunity Available*)

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

NOVEL PAYLOADS AND MECHANISMS OF ACTION

1:55 Chairperson's Remarks

Philipp Spycher, PhD, CSO, Araris Biotech AG

2:00 Reviewing the Development of DXd ADC Technology & the Latest Clinical Results

Akiko Zembutsu, PhD, Senior Director, Group I, Discovery Research Laboratories I, R&D Division, Daiichi Sankyo Co., Ltd.

Trastuzumab deruxtecan, utilizing DXd ADC technology, is transforming HER2 treatment by demonstrating strong efficacy not only in HER2-high, but also in HER2 ultra-low cases. Daiichi Sankyo is applying this DXd ADC technology to various targeted antibodies and advancing clinical trials. In my presentation, I will introduce the unique features of the technology and present the latest nonclinical and clinical data.

2:30 Development of Glucocorticoid Receptor Modulator ADC for Inflammatory Diseases

Michael McPherson, PhD, Research Fellow, Antibody Drug Conjugates, Technology and Therapeutic Platforms, AbbVie

Glucocorticoids (GCs) are potent anti-inflammatory drugs, but their widespread use is limited by systemic side effects. To address this, we have developed Glucocorticoid Receptor Modulator (GRM) Antibody-Drug Conjugates (ADCs) for inflammatory diseases. By precisely targeting the drug, ADCs aim to minimize systemic exposure and reduce adverse effects, while maximizing therapeutic efficacy. This innovative approach holds significant promise for treating a variety of inflammatory conditions, including autoimmune diseases and allergic disorders.

3:00 PANEL DISCUSSION: Clinical Performance Evaluation of TOPO1 ADCs

Moderator: Rakesh Dixit, PhD, DABT, President & Founder, Bionavigen Oncology, LLC and Regio Biosciences

- Why TOPO1 ADCs are not succeeding in lung cancer
- What's next in the horizon for TOPO1 ADCs?

Panelists:

Hanspeter Gerber, PhD, CSO, Sutro Biosciences

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Robert J. Lutz, PhD, CSO, Iksuda Therapeutics



3:30 Sponsored Presentation (*Opportunity Available*)

4:00 Networking Refreshment Break

4:30 A Novel Antibody (Oligo)-Drug Conjugate to Treat Cancer

David M. Evans, PhD, Head of Discovery, Research, Sirnaomics Inc.

We have designed a novel siRNA containing gemcitabine in its backbone. This has demonstrated potent activity in preclinical models of pancreatic cancer, NSCLC and TNBC. This talk will demonstrate the synthesis and activity when conjugated to cetuximab for delivery to tumors *in vivo*.

5:00 FORCE Platform Enables Effective Delivery of Therapeutics for Rare Neuromuscular Disorders

Stefano Zanotti, PhD, Head, Neuromuscular Research, Dyne Therapeutics Inc.

FORCE is a modular platform which enables delivery of chemically diverse therapeutic payloads with widespread distribution to muscle and CNS. The FORCE platform is translating into the clinic with the ACHIEVE and DELIVER trials for DM1 and DMD, respectively. These encouraging clinical data and strong preclinical efficacy in FSHD and Pompe disease models support the potential of FORCE to address neuromuscular disorders with high unmet medical needs.

5:30 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Opportunities for Protein Engineering in ADC Development

Greg M. Thurber, PhD, Associate Professor, Chemical Engineering & Biomedical Engineering, University of Michigan

Antibody drug conjugates are showing tremendous promise in the clinic with multiple FDA approvals and clinical-state compounds. A significant effort has improved the linker, payload, and conjugation strategies, but less emphasis has been placed on engineering the protein. In this talk, we will present strategies for antibody engineering including the use of multivalent and/or biparatopic antibodies, epitope selection with antibody/ADC combinations, and Fc-engineering to improve the therapeutic window.

BREAKOUT DISCUSSION: ADCs for Autoimmune Diseases

Philipp Spycher, PhD, CSO, Araris Biotech AG

ENGINEERING ADCS – INCREASING THERAPEUTIC WINDOW, INTERNALIZATION, AFFINITY, AND TUMOR SELECTIVITY

8:25 Chairperson's Remarks

Robert J. Lutz, PhD, CSO, Iksuda Therapeutics



8:30 KEYNOTE PRESENTATION: Protein Engineering Strategies to Improve the Efficacy of Antibody-Drug Conjugates

Greg M. Thurber, PhD, Associate Professor, Chemical Engineering & Biomedical Engineering, University of Michigan

Antibody-drug conjugates are showing tremendous promise in the clinic with multiple FDA approvals and clinical-state compounds. A significant effort has improved the linker, payload, and conjugation strategies, but less emphasis has been placed on engineering the protein. In this talk, we will present strategies for antibody engineering including the use of multivalent and/or biparatopic antibodies, epitope selection with antibody/ADC combinations, and Fc-engineering to improve the therapeutic window.

9:00 Reversible Chemical Modification of Antibodies: Modulating FcγR Binding to Maintain Anti-Tumor Activity and Mitigate Systemic Immune Activation

Philip N. Moquist, PhD, Scientist, Chemistry, Pfizer Oncology

Here we present a method for tuning effector function inspired by antibody-drug conjugates. This methodology uses conjugation of polyethylene glycol (PEG) to native cysteines of an antibody to impair FcγR binding. Attenuated effector function can be permanent

or restored through a de-conjugation process. Impacts of reversible PEGylation were assessed and applied to an agonist CD40 antibody. The PEGylated constructs displayed significant reductions in systemic cytokine production *in vivo*, while retaining efficacy.

9:30 Exploring the Design of Selectively-Targeted Payloads with Quantitative Systems Pharmacology

Eshita Khera, PhD, Principal Scientist II, Modeling & Simulation & PK Sciences, Novartis BioMedical Research

Over 90% of clinical ADCs use pan-cytotoxic payloads, but there is emerging interest in selectively-targeted payloads such as protein inhibitors and degraders. However, designing ADCs with non-traditional payloads is even more complex than cytotoxic ADCs, and challenging to optimize empirically. The proposed talk will highlight some new guiding principles for designing non-traditional ADCs, guided by vignettes of integrated lab-to-model workflows powered by Quantitative Systems Pharmacology.

10:00 Enhancing ADCs Both within and outside the Tumor with Sutro's Platform Technologies Leads to a Higher Therapeutic Index

Hanspeter Gerber, PhD, CSO, Sutro Biosciences

The recent renaissance of ADCs was enabled by the dramatic increase in their therapeutic indexes, which can be achieved in two ways: either by making ADCs safer outside the tumors, resulting in an increased maximum tolerated dose—or inside the tumor, by improving their potency or reducing resistance formation. I will discuss several examples of how we achieved this goal with our next-generation Topo1 ADC platform.

10:30 Networking Coffee Break

11:00 Bicycle Drug Conjugates - Lessons from the Clinic

Lihong Chen, PhD, VP Platform Innovation, Bicycle Therapeutics

11:30 ADC Designs with Tumor-Selective Linkers and Novel ProAlk Payload for Differentiated Tolerability Profiles

Jutta Deckert, PhD, Vice President, Research & Development, Iksuda Therapeutics

- Highlight stable bioconjugation approaches for increased ADC stability *in vitro* and *in vivo*
- Describe tumor-selective linker designs that are aimed to improve the therapeutic index of ADCs by altering the toxicity profile and increasing tolerability
- Introduce ProAlk as a novel ADC payload with a differentiated mechanism of action and provide preclinical proof-of-concept studies

DRIVING CLINICAL SUCCESS IN ANTIBODY-DRUG CONJUGATES

Designing the Magic Bullet



12:00 pm Novel mavg-MMAU Linker-Payload Improves Both Efficacy and Tolerability of Auristatin ADCs

Juhani Saarinen, CEO, Glykos Finland Ltd.

- Auristatin glycoside ADCs with stabilized glycopeptide linker provide exceptionally wide therapeutic window and improved potency. Preclinical validation of CD33, TYRP-1, and HER2 targeting MMAU ADCs.
- The novel mavg-MMAU linker-payloads enabled simultaneous improvements in both *in vivo* efficacy and tolerability; bystander efficacy and resistance to MDR drug efflux; and improved PK and lower off-target toxicity compared to vedotin ADCs.

12:30 Close of Summit



MULTISPECIFICS STREAM

Creating Best-in-Class Multispecific Antibody Modalities



The multispecific antibodies stream at the PEGS Summit will take you through a review of late-breaking developments that include novel constructs, engineering and platform developments all the way to the review of preclinical and clinical results. The newest platforms, technologies, innovative approaches, combination strategies, and novel constructs are combining to yield unprecedented efficacy. Don't miss the most significant forum of the year to learn about the latest advances in the industry and meet face to face with leaders who are changing the future of biologics.

MULTISPECIFICS STREAM CONFERENCES

MAY 12-13

**TRAINING SEMINAR:
Introduction
to Multispecific
Antibodies**

AGENDA

MAY 13-14

**Advancing
Multispecific
Antibodies and
Combination
Therapy to the Clinic**

AGENDA

MAY 15-16

**Engineering
Bispecific and
Multifunctional
Antibodies**

AGENDA



MONDAY, MAY 12, 2025 8:30 AM - 6:05 PM | TUESDAY, MAY 13, 2025 8:30 AM - 12:45 PM

Introduction to Multispecific Antibodies: History, Engineering, and Application

Introduction to Multispecific Antibodies will be organized as an informative and practical guide to getting up to speed on critical aspects of multispecific antibody therapeutics. Topics will include historical successes, failures, and lessons learned. Specific practical instruction will span mechanisms of action, engineering, developability, regulatory considerations, and translational guidelines. Perspectives on ideal implementation of multispecifics as targeted and immunomodulatory approaches will be discussed.



Instructor:
G. Jonah Rainey, PhD, Senior
Director, Protein Engineering,
Eli Lilly and Company

Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered and solutions applied, and extensive coverage of the basic science underlying each topic. Experienced Training Seminar instructors offer a mix of formal lectures, interactive discussions, and activities to help attendees maximize their learning experiences. These immersive trainings will be of value to scientists from industry and academic research groups who are entering new fields—and to those working in supporting roles that will benefit from an in-depth briefing on a specific aspect of the industry.

Training Seminars will be held in person only. To ensure a cohesive and focused learning environment, moving between conference sessions and the training seminars is not allowed.

PRESENT A POSTER

SAVE \$50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure an onsite poster board and/or ensure your poster is included in the conference materials, your full submission must be received, and your registration paid in full by March 28, 2025.

Reasons you should present your research poster at this conference:

- Your research will be seen by our international delegation, representing leaders from top pharmaceutical, biotech, academic and government institutions
- Discuss your research and collaborate with other attendees
- Your poster will be published in our conference materials
- Receive \$50 off your registration



Register and indicate that you would like to present a poster. Once your registration has been fully processed, we will send an email with a unique link and instructions for submitting your materials.

ADVANCING MULTISPECIFIC ANTIBODIES AND COMBINATION THERAPY TO THE CLINIC

Creating the Killer Combo

MAY 13-14, 2025



MULTISPECIFICS
STREAM

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: Safety & Efficacy of Bispecifics and ADCs

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

TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

EMERGING BISPECIFIC STRATEGIES

2:20 Chairperson's Remarks

Eric Smith, PhD, Senior Director, Bispecifics, Regeneron Pharmaceuticals, Inc.

2:30 Combination Strategies to Enhance Anti-Tumor T Cell Responses

Eric Smith, PhD, Senior Director, Bispecifics, Regeneron Pharmaceuticals, Inc.

This presentation will describe preclinical data from Regeneron's new clinical approaches to enhancing anti-tumor efficacy of T cells, focusing on the combination of co-stimulatory bispecific antibodies with checkpoint blockade and T cell redirecting bispecifics. In addition, data from new classes of T cell-targeted enhancement strategies will be discussed, including preclinical data from our PD-1 targeted receptor masked IL2 that has entered clinical development.

3:00 T Cell Co-Stimulatory Bispecific Antibodies for Treating Solid Tumors

Shelley Force Aldred, PhD, Co-Founder and CEO, Rondo Therapeutics

T cell engaging bispecific antibodies targeting CD3 have tremendous success treating hematologic tumors but have shown limited efficacy in solid tumors. Employing safe and tunable bispecific antibodies for a wider variety of immune stimulating receptors may help address solid tumor-related challenges. Here, we describe bispecific platforms developed at Rondo Therapeutics and highlight progress on our lead program, RND0-564, a CD28 x Nectin-4 bispecific antibody for treatment of metastatic bladder cancer.

3:30 Presentation to be Announced



4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING



How Many New Contacts Can You Make?

Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

4:40 Bispecific T Cell Engagers for Oncology and Autoimmune Diseases

John R. Desjarlais, PhD, CSO, Xencor

Xencor has developed a versatile platform for the creation of bispecific antibodies, with a particular focus on T cell engagers. We'll discuss application of the platform to solid tumors as well as for the depletion of pathogenic CD20-positive or CD19-positive B cells in autoimmune diseases.

5:10 Total Recall: Boosting Memory T Cells with Co-Stimulatory Bispecifics

Koorosh Korfi, PhD, Biomarker and Experimental Medicine Leader, Early Biomarker Development Oncology, Roche Pharma Research and Early Development (pRED), Roche Innovation Center Zurich

Bispecifics targeting 4-1BB or CD28 have emerged in oncology to unlock the full potential of T cell bispecifics (TCBs), aiming for chemo-free treatments. The emerging clinical and biomarker data from Roche's Phase 1 trials combining co-stimulatory bispecifics with TCBs in hematologic malignancies show compelling safety and efficacy profiles, evidence of costimulatory action, and enhanced memory T cell responses, paving the way for novel and innovative combination therapies.

5:40 Targeted PD-1 Agonism for Autoimmune Indications

Tara Mahon, PhD, Associate Director, Protein Science Pipeline, Immunocore Ltd.

Immunocore has developed ImmTAAI, a new class of bispecific protein therapeutic designed to deliver targeted immunomodulation to treat autoimmune diseases. Using this targeted approach we have developed two distinct bispecific molecules, one which specifically targets pancreatic beta cells to treat Type I Diabetes

(T1D), and another which specifically binds an HLA unrestricted APC target in skin, to treat inflammatory skin diseases.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (Continental Breakfast Provided) Co-Organized with Thinkubator Media



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto

ADVANCING MULTISPECIFIC ANTIBODIES AND COMBINATION THERAPY TO THE CLINIC

Creating the Killer Combo

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MULTISPECIFICS
STREAM



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARTs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP

Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics

Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet-up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

BISPECIFICS FOR NON-ONCOLOGY APPLICATIONS

10:20 Chairperson's Remarks

Frank Comer, PhD, Director, Tumor Targeted Delivery, Early Oncology R&D, AstraZeneca

10:25 Multispecific Antibody Generation for Inflammatory Diseases: Form and Function

Dan Snell, PhD, Senior Vice President, Research and Preclinical Development, Numab Therapeutics AG

Multispecific antibodies hold significant advantages for the treatment of patients with inflammatory diseases. We will share important design principles for multispecific antibody construction and considerations for target selection in an increasingly crowded space. We will also present the advantages and some key examples of Numab's platform for the generation of best-in-class multispecific antibodies.

10:55 Bispecific Anti-KLK5/7 for Netherton and Atopic Dermatitis

Cecilia Chiu, PhD, Scientist IV, Genentech, Inc.

Serine proteases kallikreins KLK5 and KLK7 are critical for maintaining skin barrier function. Excessive KLK activities can lead to Netherton syndrome and atopic dermatitis. Our study demonstrated that combined treatment with inhibitory anti-mKLK5 and anti-mKLK7 antibodies improves skin integrity and reduces inflammation in mouse NS and AD models. We further generated a humanized bispecific anti-KLK5/7 inhibitory antibody, presenting a promising therapy for clinical development in NS and other inflammatory dermatoses.

11:25 Presentation to be Announced



11:55 Session Break

12:00 pm LUNCHEON PRESENTATION I: Talk Title to be Announced



Bob Chen, Vice President, Discovery Systems, Discovery Systems, OmniAb

12:30 LUNCHEON PRESENTATION: Sequence-Forward, Single B-Cell Solutions by LAMPIRE for Monoclonal Antibody Discovery across Multiple Species



John Majercak, PhD, Head of Antibody Discovery, LAMPIRE Biological Laboratories, Inc.

Leveraging decades of expertise in small and large animal immunizations, LAMPIRE Biological Labs has developed robust and cost-effective solutions to Monoclonal Antibody discovery. The keys to our "Sequence-Forward, Single B-cell" approach will be highlighted, including the development of proprietary markers to isolate antibody expressing B-lymphocytes across multiple

species. This approach combines FACS, NGS, *In Vitro* Screening and Sequence Analytics to isolate high-affinity, epitope-diverse, heavy+light chain antibodies, chicken IgYs, single-domain vHH Nanobodies and ultra-long CDR3 Picobodies for therapeutics, clinical assets and research applications.

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: T Cell Engaging Bispecific Antibodies for Treating Solid Tumors

Shelley Force Aldred, PhD, Co-Founder and CEO, Rondo Therapeutics

T-cell engaging bispecific antibodies have shown limited efficacy in solid tumors, with a few notable exceptions. Next-generation bispecific antibodies are becoming powerful tools for helping the immune system overcome the suppressive environment in solid tumors. In this presentation, we describe the bispecific immune-cell engager platforms developed at Rondo Therapeutics and highlight progress on our lead program, RND0-564, a CD28 x Nectin-4 bispecific antibody for the treatment of metastatic bladder cancer.

BREAKOUT DISCUSSION: Masking Approaches for TCEs

Marcela Guzman Ayala, PhD, Head of In Vitro Pharmacology, Molecular Partners

BISPECIFICS FOR NON-ONCOLOGY APPLICATIONS (CONT.)

1:55 Chairperson's Remarks

Nathan D. Trinklein, PhD, Co-Founder and President, Rondo Therapeutics

ADVANCING MULTISPECIFIC ANTIBODIES AND COMBINATION THERAPY TO THE CLINIC

Creating the Killer Combo



MAY 13-14, 2025

MULTISPECIFICS
STREAM

2:00 Development of SAB01, A Conditionally Active bsAb for the Depletion of Mast Cells

Peter Emtage, PhD, CEO, Santa Ana Bio

Mast cells (MCs) are a distinctive hematopoietic effector cell population that are sentinels of innate immunity and play an important role in orchestrating immune responses at barrier tissues. While well-known for their role in IgE-dependent type 1 hypersensitivity that underlies anaphylaxis and other acute manifestations of atopy, MCs are also associated with several other disease states.

CONDITIONALLY ACTIVE BISPECIFIC ANTIBODIES



2:30 KEYNOTE PRESENTATION: Developing Off-the-Shelf Bispecific T Cell Engagers to Treat Infectious Disease and Autoimmunity

JoAnn A. Suzich, PhD, Head, Research, Immunocore LLC

The bispecific platform (ImmTAX), initially focused on oncology, was adapted to address other disease areas. For HIV, molecules were designed to eliminate the provirus reservoir that is the main barrier to a functional cure. For autoimmune diseases, bispecifics encompassing a tissue targeting-arm and PD-1 agonist were designed to protect normal cells from T cell destruction. Successful programs require deep understanding of underlying disease biology coupled with innovative protein engineering.

3:00 Multispecific CD3 Switch-DARPin Ensure Tumor-Targeted T Cell Activation for Enhanced Efficacy and Safety in Solid Tumors

Marcela Guzman Ayala, PhD, Head of In Vitro Pharmacology, Molecular Partners

Multispecific CD3 Switch-DARPin T-cell engagers aim to overcome current therapeutic challenges, like lack of universal tumor target antigens (TAAs) and poor efficacy/toxicity profiles. Switch DARPins allow masking a T cell-engaging DARPin until a defined target or combination of targets is encountered on the surface of target cells. The increased tumor specificity allows for safely adding a co-stimulatory function for potent and sustained anti-tumor T cell responses and expanding the targetable TAA field.

3:30 Presentation to be Announced



4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

4:40 BA3182: A Novel EpCAM Targeting, Conditionally Active T Cell Engager

Gerhard Frey, PhD, Vice President, Technology Development, BioAtla LLC

EpCAM is a very attractive target since it is expressed in a wide variety of tumors. However, it is also widely expressed on normal tissues, making it a challenging target for traditional cancer therapies. BA3182 is a conditionally active T cell engager (TCE) targeting EpCAM. The Conditionally Active Biologic (CAB) technology enables selective binding to the EpCAM and CD3 targets only in the tumor microenvironment.

5:10 XTEN Polypeptide-Masked Protease-Activated T Cell-Engagers: XPAT Proteins—A Novel Format to Mitigate the on-Target, off-Tumor Problem

Volker Schellenberger, PhD, Senior Vice President, Research Oncology, Vir Biotechnology, Inc.

XPAT proteins are conditionally active TCEs designed to exploit the dysregulated protease activity in tumors. Preclinically, XPAT proteins demonstrated 1) strong masking of *in vitro* cytotoxicity by approximately 4 logs; 2) potent *in vivo* efficacy at doses similar to the efficacious doses of unmasked TCE controls; and 3) increased MTDs in NHP by greater than 100-fold. Clinical trials of XPAT proteins targeting HER2 and PSMA are currently ongoing.

5:40 A Novel Bispecific Antibody Targeting EGFR and VEGFR2 Is Effective against Triple Negative Breast Cancer via Multiple Mechanisms of Action

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

6:10 PANEL DISCUSSION: From Bispecific to Trispecific: How Much Engineering Do You Want to Put into One Swiss Army Knife?

Moderator: G. Jonah Rainey, PhD, Associate Vice President, Eli Lilly and Company

- What formats are available and are they developable?
- What other modalities could drive the same biology as a trispecific? Is trispecific the best choice?
- What are the best ways to co-optimize three specificities? Epitope, geometry, affinity.

Panelists:

Luis Álvarez-Vallina, PhD, Head, H120-CNIO Cancer Immunotherapy Clinical Research Unit, Spanish National Cancer Research Centre (CNIO)

Melissa Geddie, PhD, Vice President Drug Discovery, Diagonal Therapeutics

Ronnie R Wei, PhD, Head, Biologics Discovery, Modex Therapeutics

Nina E. Weisser, PhD, Director, Multispecific Antibody Therapeutics, Zymeworks, Inc.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Advancing Multispecific Antibodies Conference

ENGINEERING BISPECIFIC AND MULTIFUNCTIONAL ANTIBODIES

Achieving Unprecedented Efficacy



MAY 15-16, 2025

MULTISPECIFICS
STREAM

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

TUESDAY, MAY 13

6:30 pm Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

CONDITIONALLY ACTIVE BISPECIFIC ANTIBODIES

8:25 Chairperson's Remarks

Mahiuddin Ahmed, PhD, President and CSO, VITRUVIAE



8:30 KEYNOTE PRESENTATION: Therapeutic Proteins by Precision Gene Delivery

Andreas G. Plueckthun, PhD, Professor and Head, Biochemistry, University of Zurich

Our SHielded, REtargeted Adenovirus (SHREAD) is based on virus-like particles that are devoid of any viral genes, but contain 36 kb of DNA for multiple genes, can be targeted to any cell type, and are protected from the immune system. We will showcase expression of T cell engagers within the tumor, but also *in vivo* T cell and dendritic cell targeting for tumor control.

9:00 Switchable Bispecific T Cell Nanoengagers for Controllable Cancer Immunotherapy

Michael Mitchell, PhD, Skirkanich Assistant Professor of Innovation, Department of Bioengineering, University of Pennsylvania

The broader clinical use of bispecific T cell engagers for inducing anti-tumour toxicity is hindered by their on-target off-tumour toxicity and the associated neurotoxicity and cytokine-release syndrome. Here we show that the off-tumour toxicity of a supramolecular bispecific T cell engager binding to the T cell co-receptor CD3 and

to the human epidermal growth factor receptor 2 on breast tumour cells can be halted.

9:30 Targeted Desialylation and Cytolysis of Tumor Cells by Fusing a Sialidase to a Bispecific T Cell Engager

Peng Wu, PhD, Professor, Chemical Physiology, Scripps Research Institute

Bispecific engagers are off-the-shelf agents that recruit endogenous T and NK cells to eradicate tumor cells in a major histocompatibility complex (MHC)-independent manner. However, the promise of BiTE molecules in the treatment of solid tumors has been challenged by antigenic heterogeneity and the immunosuppressive tumor microenvironment (TME). We have developed bispecific engager-sialidase fusion proteins to address these challenges by targeted removal of aberrantly expressed sialoglycans in the TME.

10:00 Presentation to be Announced



10:15 Directed Luck®: Transposase targeting and Transposon Design Push Expression Beyond Limits



Anneliese Krueger, Scientist, Pharmaceutical Cell Line Development, ProBioGen AG

Transposases have eased cell line development. Taking this concept to a new level, we equipped our hyperactive transposase with epigenetic readers that targets highly active genomic sites in the host cell line and designed advanced transposons with optimized ITRs for most efficient and clean integration. DirectedLuck® delivers highly productive clones and bulk pools ready for manufacturing and is particularly suited for heterodimeric formats, polyclonal antibody cell lines and viral vector packaging cell lines.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

NOVEL MECHANISMS OF ACTION

1:55 Chairperson's Remarks

Eugene A. Zhukovsky, PhD, Co-Founder, ZM Scientific Consulting SNC

2:00 Leveraging Bispecific Antibodies with Cellular Targeting and a Tag-Binding Domain Enables the Attachment of Cargo to an Antibody via a Peptide Tag

Sara M. Mangsbo, PhD, Professor, Pharmacy, Uppsala University

We have developed a bispecific antibody-conjugate platform to enhance the multifunctional capabilities of antibodies. Several bispecific antibodies targeting CD20, HER2, and CD40 have been produced to enable a versatile antibody/drug conjugate tool via a simple mixing step. We have studied drug conjugates based on peptide and oligonucleotides-based cargoes using this technology and have investigated conjugate stability and its impact on *in vitro* and *in vivo* drug efficacy.

ENGINEERING BISPECIFIC AND MULTIFUNCTIONAL ANTIBODIES

Achieving Unprecedented Efficacy

MAY 15-16, 2025



MULTISPECIFICS
STREAM

SECOND-GEN T CELL ENGAGERS: NEW APPROACHES AND NEW DESIGNS

2:30 Addressing the Limitations of Cell Engagers via Protein Geometry, Receptor Selection, and Cytokine Inclusion

Brian A. Rabinovich, PhD, CSO, R&D, Fuse Biotherapeutics

Cell engagers are often detuned to reduce the risk of toxicity. This strategy can sacrifice the magnitude of cytotoxicity and addresses neither cell fitness nor response durability. Simultaneous adjustment of engager synaptic distance and apparent affinity allows for optimization of signal strength to establish a "cytokine window" at maximum cytotoxicity. Such engagers support the inclusion of functionally specific cytokines that promote proliferation and oppose functional exhaustion.

3:00 Next Generation T Cell Engagers with Embedded Autoregulation (AR)

Vincent Muczynski, PhD, Director, NovalGen

Major progress in the field of T cell redirecting therapies have contributed to the successful development of T cell engager (TCEs) and the recent approval of several molecules for haematological malignancies and solid tumours. Autoregulation (AR) provides an embedded mechanism that enables the specific inactivation of TCEs when there is a risk of T cell overactivation to limit T cell stimulation and preserve function.



3:30 Presentation to be Announced

4:00 Networking Refreshment Break

4:30 Synergizing Allogeneic T Cells with Bispecific Antibodies for Enhanced Anti-Tumor Responses

Riyaz Khan, PhD Candidate, T Cell Therapies, ETH Zurich

This talk will explore the use of engineered allogeneic T cells in enhancing bispecific antibody (biAb) cancer immunotherapy. By decoupling T cell receptor (TCR) binding from CD3 signaling, we maintain biAb-driven T cell activation while preventing harmful alloreactive responses. In a CD19+ tumor model, these engineered T cells, combined with the biAb blinatumomab, demonstrated effective tumor clearance without detectable alloreactivity, highlighting a promising approach for 'off-the-shelf' T cell therapies.

NON-TRADITIONAL BUILDING BLOCKS FOR ENGINEERING MULTISPECIFIC ANTIBODIES

5:00 Chairperson's Remarks

Shelley Force Aldred, PhD, Co-Founder and CEO, Rondo Therapeutics

5:01 Multispecific Antibodies Utilizing Shark-Derived VNAR Binding Domains

Helen Dooley, PhD, Associate Professor, Microbiology and Immunology, University of Maryland, Baltimore

Like camelids, sharks produce a heavy chain isotype, IgNAR. The variable domains of IgNAR, called VNARs, are structurally most similar to TCR and Ig light chain variable regions, possessing two CDRs and two hypervariable loops. We will discuss how we are exploiting the diverse structural repertoire and novel binding modalities of VNARs to generate bispecific and multispecific antibodies with extended binding profiles and improved function.

5:30 Grabbing the Bull by the Horns: Engineering Options of Cattle-Derived Ultralong CDR-H3 Paratopes for the Generation of Novel Multifunctional Antibody Architectures

Stefan Zielonka, PhD, Senior Director, Global Head of Antibody Discovery and Protein Engineering (ADPE) Research and Development, Merck Healthcare KGaA; Professor, Biomolecular Immunotherapy, Technische Universität Darmstadt

A subset of bovine antibodies displays a peculiarly long CDR-H3 which is composed of a stalk and a knob region. Importantly, the knob is primarily responsible for antigen binding. We have harnessed this specific diversity for the generation of mono- and multispecific antibody derivatives and also generated a novel symmetric bispecific antibody format by introducing the knob paratope into the CH3 domain of the Fc part of an IgG.

6:00 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format,

please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Next-Generation T Cell Engagers (TCEs)

Vincent Muczynski, PhD, Director, NovalGen

The principle of a bispecific antibody targeting CD3 to redirect cytotoxic T cells toward a tumor target has undeniably contributed to the success of T cell engagers and led to the recent approval of several molecules showing undisputed efficacy in both haematological malignancies and solid tumours. A broad range of research programs are now looking at ways to enhance the potential of these molecules and develop next-generation TCEs.

BREAKOUT DISCUSSION: BREAKOUT DISCUSSION: Safety Switches for T-Cell Engagers

Noor Momin, PhD, Assistant Professor, University of Pennsylvania

- Design parameters and objectives for T cell engagers
- Engineering strategies to improve their on-target (correct receptor) on-tissue (correct localization)
- Engineering strategies to reduce their on-target (correct receptors) off-tissue (wrong tissue localization)
- Considerations for the timing, reversibility, and translation of these approaches

BISPECIFICS FOR ONCOLOGY

8:25 Chairperson's Remarks

G. Jonah Rainey, PhD, Associate Vice President, Eli Lilly and Company



8:30 KEYNOTE PRESENTATION: Multispecific T Cell Engagers for the Treatment of Hematological Malignancies

Ulrike Philipp, PhD, Senior Director and Head, Oncology and Discovery Hematological Malignancies, Johnson & Johnson Innovative Medicine

Within the past decade, therapies that activate/engage T cells have changed the landscape of treatment of hematological malignancies. Successful T cell-engaging antibodies target antigens selectively expressed on tumors with minimal/no expression in other tissues and eliminate malignant cells resulting in long-term clinical benefit. Several bispecific T cell engagers have been approved in hematological

ENGINEERING BISPECIFIC AND MULTIFUNCTIONAL ANTIBODIES

Achieving Unprecedented Efficacy



MAY 15-16, 2025

MULTISPECIFICS
STREAM

malignancies. Recent research evaluates trispecific T cell engagers targeting two tumor-associated antigens in multiple myeloma/lymphoma.

9:00 SAIL66—A Next-Generation T Cell Engager Targeting CLDN—Potentiates Efficacy by Binding to CD3/CD137

Takayuki Kamikawa, Scientific Researcher, Discovery Research, Chugai Pharmaceutical Co Ltd.

Conventional T cell engagers (TCEs) for solid tumors face challenges of “on-target, off-tumor toxicity” and T cell dysfunction by CD3 activation alone. The newly developed SAIL66, a trispecific antibody targeting CLDN6/CD3/CD137, adopts a proprietary Dual-Ig to activate both of CD3 and CD137. Our CLDN6 specific Fab and the Dual-Ig platform with unique binding mode enabling superior T cell activation and potent anti-tumor effects to conventional TCEs.

9:30 Bispecific Dendritic-T Cell Engager Potentiates Anti-Tumor Immunity

Rony Dahan, PhD, Principal Investigator, Immunology, Weizmann Institute of Science

This presentation discusses the pivotal role of dendritic-T cell crosstalk in driving anti-tumor immunity and enhancing immunotherapy. I will highlight our recent studies that led to the development of new immunotherapies, harnessing dendritic cell-T cell interactions for optimal efficacy.

10:00 Presentation to be Announced

10:30 Networking Coffee Break



11:00 EVOLVE: A Novel CD2 Costimulatory T Cell Engager Platform

Jeremy S. Myers, PhD, Senior Vice President, R&D, EvolveImmune Therapeutics Inc.

CD3 bispecific T cell engagers redirect a patient's T cells to cancer cells and have emerged as a therapeutic strategy for the treatment of diverse cancers with 10 drug approvals, 9 approvals since 2022, including 2 approvals in solid tumors. EVOLVE integrates proprietary light-chain pairing, CD2 and CD3 affinity-tuned agonism to deliver potent tumor killing with balanced cytokine release in a highly developable platform.

USING AI AND COMPUTATIONAL MODELS IN THE DISCOVERY, OPTIMIZATION, AND DEVELOPMENT OF BISPECIFICS

11:30 Chairperson's Remarks

G. Jonah Rainey, PhD, Associate Vice President, Eli Lilly and Company

11:31 Understanding the Targeting Mechanisms of Multispecific Biologics in Immunotherapy with Multiscale Modeling

Yinghao Wu, PhD, Associate Professor, Systems and Computational Biology, Albert Einstein College of Medicine

The design of bispecific fusion proteins is a central challenge for the realization of new immunotherapeutic strategies. We developed a multi-scale computational framework to understand how bispecific fusion proteins target surface-bound membrane receptors. We found that proteins with long and flexible linkers are more efficient in targeting receptors.

11:50 AND-Body Medicines: Programmed Biologics That Enable More Efficacious and Better Tolerated Medicines

Daniel Blom, PhD, CSO, R&D, Ampersand Biomedicines

The development of therapeutic molecules is often limited by insufficient on-target efficacy and adverse effects related to on-target, off-tissue activity. Ampersand has developed a computationally powered drug-discovery approach that has identified tissue-specific addresses that in turn has enabled the generation of a new type of programmable biologic. The resulting AND-Body Therapeutics are designed to specifically target the site of disease and conditionally actuate biology after localizing, thus sparing healthy tissue.

12:10 pm A Novel Bivalent Bispecific Antibody Format for Infectious Diseases

Xiuling Li, PhD, Associate Director, Novel Multispecific Modalities, AstraZeneca

The majority of bispecific IgG molecules reported so far are asymmetric format that have monovalent binding on each epitope. We developed a novel bivalent bispecific antibody with a native IgG-like structure containing four Fabs that enhances binding avidity compared to traditional monovalent bispecific. This presentation will focus on the engineering, developability and applications of bivalent bispecifics in infectious diseases

12:30 Close of Summit

IMMUNOTHERAPY STREAM

Engineering Smarter, Targeted Immunotherapies for Cancer and Autoimmune



Part One delves into recent advancements in immunotherapies for solid tumors and autoimmune diseases, highlighting checkpoint inhibitors, immune cell engagers, TCR therapies, and exploring innovative targets and combination strategies. Part Two examines the development of fitter, more effective, and safer cellular immunotherapies tailored for cancer and autoimmune diseases, emphasizing engineering improvements that enhance therapeutic efficacy, endurance, and clinical outcomes. Part Three investigates emerging immune reprogramming technologies, featuring in vivo engineering, targeted delivery mechanisms to immune cells, and AI-driven methods for discovering new therapeutic targets. This section also covers next-generation T cell engagers, viral and microbial-based immunotherapies, offering a forward-looking perspective on the evolving landscape of immunotherapy across various modalities and clinical indications. Together, these sections provide a comprehensive overview of the current state and exciting future of immunotherapy development.

IMMUNOTHERAPY STREAM CONFERENCES

MAY 12-13

**Advances in
Immunotherapy**

AGENDA

MAY 13-14

**Engineering
Cell Therapies**

AGENDA

MAY 15-16

**Next-Generation
Immunotherapies**

AGENDA



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: Challenges and Opportunities in Solid Tumor and Autoimmune Disease Therapeutic Innovations

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

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

T CELL AND IMMUNE CELL ENGAGERS

8:20 Chairperson's Remarks

*Bruce Keyt, PhD, CSO, R&D, IGM Biosciences, Inc.***8:30 Unlocking the Full Potential of T Cell Engagers: The ENT1 Inhibitor EOS-984 Can Overcome Adenosine-Mediated Immunosuppression in Solid Tumors***Yvonne McGrath, PhD, CSO, iTeos Therapeutics SA*

Adenosine is a powerful T cell immunosuppressant, measurable at micromolar concentrations in a range of solid tumors. We have decoded an important but underappreciated mechanism whereby adenosine, taken up by T cells via the Equilibrative Nucleoside Transporter 1 (ENT1), poisons pyrimidine synthesis. EOS-984 is a clinical-stage ENT1 inhibitor with the potential to shield T cell-activating agents from this mechanism, unlocking their full potential in solid tumors.

9:00 TCR-Based Bispecific T Cell Engager Development and Clinical Applications*Zhimei Du, PhD, CSO, BlueSphere Bio*

TCR-T cell therapy is a promising approach with high specificity and sensitivity to low-abundance antigens, targeting both surface and intracellular proteins. In contrast, mAbs and CAR T cells only target surface antigens. However, challenges in manufacturing, cost, and accessibility exist. To address these, TCR-based bispecific T cell engagers (BiTEs) offer a potential solution. This presentation will outline the challenges and development pathway for TCR-based BiTEs in cancer treatment.

9:30 Making NK Cells Antigen-Specific Using Trispecific Killer Engagers (TriKEs) to Treat Cancer*Jeffrey Miller, MD, Deputy Director, Masonic Cancer Center; Professor of Medicine, Division of Hematology, Oncology and Transplantation, University of Minnesota*

Haploidentical NK cells can induce remissions in patients with refractory leukemia. However, they lack specificity. To make NK cells antigen-specific, we developed Trispecific Killer Engagers (TriKEs) that engage NK cells (camelid anti-CD16) and tumor-antigens with IL-15 between them. The goal of this therapy is to create immune synapses *in vivo* to target and activate endogenous NK cells to optimally treat leukemia (anti-CD33) and solid tumors (B7H3).

10:00 Presentation to be Announced

10:30 Networking Coffee Break

OVERCOMING THE LIMITS OF IMMUNOTHERAPY**11:00 Creating and Targeting Synthetic Neoantigens***Christoph Rader, PhD, CTO, Aethon Therapeutics*

Targeted therapy with covalent inhibitors of oncoproteins are initially effective but lack durability due to cancer cell resistance. MHC-I presentation of the covalently modified oncoprotein peptides on the cell surface creates synthetic neoantigens that can be targeted by antibodies with high specificity and affinity. As T cell engagers, these HapImmune antibodies afford a unique combination of targeted and immune therapy. Preclinical proof-of-concept studies based on oncoprotein KRAS^{G12C} will be presented.

**11:30 KEYNOTE PRESENTATION: The Limits of Immunotherapy***Alan J. Korman, PhD, Senior Vice President, Human Immunology, Vir Biotechnology*

Immune checkpoint blockade (ICB) and particularly the combination of multiple checkpoint inhibitors, while responsible for improved rates of survival in multiple malignancies, has suffered from recent clinical trial failures. The rationale behind combining multiple ICB molecules as well as the importance of Fc/FcγR interactions for antibody therapeutics will be described. The development of next-generation checkpoint inhibitors will be addressed.

12:00 pm Session Break

12:10 Luncheon Presentation to be Announced

12:40 Luncheon Presentation to be Announced Lightcast

1:10 Session Break

TARGETING THE TUMOR MICROENVIRONMENT

1:15 Chairperson's Remarks

*Zhimei Du, PhD, CSO, BlueSphere Bio***1:20 Targeting the Microenvironment of Solid Tumors with CD4+ T Cells***Joshua R Veatch, MD, PhD, Assistant Professor, Translational Science and Therapeutics, Fred Hutchinson Cancer Center*

Tumor-specific CD4 T cells correlate with better clinical outcomes and activation of myeloid and CD8 T cells across human cancers. Mouse models show that CD4 T cell therapy can control tumors through stimulation of CD8 T cells, and through CD8 T cell independent innate immune mechanisms. I will discuss methods to target CD4 T cells to solid tumors, and methods to understand and augment antitumor mechanisms.

1:50 Antigen Assimilating Multispecific Antibodies for Immunotherapy*Jason Price, PhD, Acting Assistant Professor & Principal Investigator, Ben Towne Centre, Seattle Childrens Research Institute*

Tumor-target heterogeneity presents a major obstacle for immunotherapies, often resulting in incomplete tumor elimination and treatment resistance. This talk will present our work advancing a novel class of T cell-redirecting multispecific antibodies that addresses this problem. Our single-molecule approach converts target-negative cells into target-positive cells by transforming endogenous tumor self-defense mechanisms into targetable vulnerabilities.

2:20 IOMX-0675: A Cross-Specific Antibody Selectively Inhibiting LILRB1 and LILRB2, Repolarizes Immunosuppressive Myeloid Cells and Activates T Cells*Christine Rothe, PhD, Chief Development Officer, iOmx Therapeutics AG*

IOMX-0675, a fully human, cross-specific antibody identified from iOmx's proprietary phage-display library, selectively antagonizes with high affinity the two immunosuppressive receptors LILRB1 and LILRB2, while binding only weakly to the closely related immune-activating family members LILRA1 and LILRA3. Its highly differentiated binding profile drives potent reprogramming of the immunosuppressive myeloid compartment and restores cytotoxic lymphoid cell activity in the tumor microenvironment. Promising preclinical data support a best-in-class **IOMX-0675**



**2:50 Unlocking the Power of Agonist Antibodies: A Strategic Analytical Development Approach for Immunotherapy & Autoimmunity**

Alpana Prasad, Director of Product Management, Eurofins DiscoverX

Agonist antibodies targeting TNF Receptor Superfamily (e.g. OX40) have been in development for immunotherapy and autoimmunity. There is an increasing focus on developing antibodies to activate co-inhibitory checkpoint receptors (e.g. PD-1). This presentation will showcase case studies that demonstrate the critical role of cell-based assays in assessing agonist activity and FcγR-mediated clustering, as a streamlined strategy for advancing the clinical development of agonist antibody therapies.

3:20 Networking Refreshment Break**4:05 Transition to Plenary Keynote Session****PLENARY KEYNOTE SESSION****4:15 Plenary Keynote Introduction**

Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research and Macovski Professor of Bioengineering, Stanford University

**4:25 The Role of Protein Engineering in Developing New Innovative Modalities**

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE**5:10 Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade**

Jessica C. Stark, PhD, Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

5:55 Welcome Reception in the Exhibit Hall with Poster Viewing**YOUNG SCIENTIST MEET-UP****Co-Moderators:**

Iris Goldman, Production, Cambridge Innovation Institute

Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab

Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day**TUESDAY, MAY 13****7:30 am Registration and Morning Coffee****MENTORING MEET-UP****Creating and Fostering a Productive and Effective Mentor-Mentee Relationship**

Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists:
IN-PERSON ONLY

IMMUNOTHERAPIES FOR AUTOIMMUNE DISORDERS**8:30 Chairperson's Remarks**

Taylor H. Schreiber, MD, PhD, CEO, Shattuck Labs

8:35 Bispecific Antibodies and CAR-T approaches – Turning from Oncology to Autoimmune Disorders

William Strohl, PhD, President & Owner, BiStro Biotech Consulting LLC

Over the past four years, it has become apparent that several CAR-T and T-cell engaging (TCE) bispecific antibody approaches, using constructs previously relegated primarily for treatment of cancer, may be used to deplete B cells producing pathogenic autoantibodies in autoimmune diseases. The various CAR-T and TCE bispecific antibody approaches being developed today for autoimmune diseases will be described and compared.

9:05 Stable Inhibition of TL1A Signaling through DR3 Blockade

Taylor H. Schreiber, MD, PhD, CEO, Shattuck Labs

TL1A-blocking antibodies have demonstrated promising clinical remission rates for patients with inflammatory bowel disease. TL1A promotes inflammation through binding to a single receptor, DR3. Preclinical studies demonstrated a dominant role for DR3 in suppressing inflammation relative to TL1A. The preclinical development, safety, PK, and PD of a DR3 blocking antibody, SL-325, now entering Phase 1 clinical development, will be presented.

9:35 Combination Immunotherapy with a PD-1+aLAG-3 Therapy

William Redmond, PhD, Member and Director, Immune Monitoring Laboratory, Earle A. Chiles Research Institute, Providence Cancer Institute

LAG-3 correlates with aPD-1 resistance but LAG-3hi tumor-bearing mice, resistant to aPD-1, responded to aPD-1+aLAG-3 therapy. The efficacy of combination aPD-1+aLAG-3 immunotherapy in mice and a cohort of patients with metastatic melanoma was associated with Treg destabilization. These data indicate that combination aPD-1+aLAG-3 immunotherapy drives Treg phenotypic plasticity, which represents a novel biomarker of response and a putative therapeutic target to improve outcomes.



10:05 Presentation to be Announced

10:35 Coffee Break in the Exhibit Hall with
Poster Viewing



ENGINEERING IMMUNOCYTOKINES

11:15 Trifunctional Immunocytokines for Cancer Therapy

Dafne Müller, PhD, Group Leader, Institute of Cell Biology and Immunology, University of Stuttgart

We develop trifunctional antibody-fusion proteins composed of a tumor-directed antibody moiety and two different immunomodulatory molecules—common gamma chain receptor cytokines & costimulatory ligands of the TNF-superfamily. Aiming for improved localization and efficacy at the tumor site, the design focuses on targeted presentation and combined mode of action.

11:45 Gut Bacteria Engineered to Surface Display Cytokines for TME Modulation

Rizwan Romee, PhD, Associate Professor Medicine, Harvard Medical School and Dana-Farber Cancer Institute

We have successfully engineered non-pathogenic gut bacteria to surface-display various cytokines, including IL15, IL18, and IL21. The bacteria displaying decoy-resistant IL-18 demonstrated safety and potent efficacy in murine colorectal cancer and melanoma mouse models alone and synergistically with checkpoint blockade, curing a significant proportion of mice. Further, treatment with the bacteria also boosted the migration and efficacy of human CAR NK cells in NSG mice bearing mesothelioma.

12:15 pm Sponsored Presentation (*Opportunity Available*)

12:45 Session Break

12:50 LUNCHEON PRESENTATION: How Specific are Antibody Drugs? Revealing insights from a new generation of specificity assays



Rachel Fong, Director of Sales & Alliances, Integral Molecular

Off-target binding is a significant hurdle in the development of antibody-based therapies, contributing to both drug attrition and adverse events in patients. Recent analysis from our own work identified a surprisingly high off-target rate across the industry, with up to one third of antibody drugs displaying off-target binding. In this presentation, we will discuss the emergence of cell-based protein arrays, including the Membrane Proteome Array, as an alternative and improved technology to assess antibody specificity.

1:20 LUNCHEON PRESENTATION:



Costimulatory Tri-Specific T Cell Engager: Next-Generation TCE Platform for Enhanced Efficacy, Persistence, and Safety

Jianqing Xu, Sr Director & Head of Lead Optimization, Protein Design & Engineering Excellence Ctr, WuXi Biologics

Tri-specific TCEs (TriTCEs) incorporating CD28/4-1BB co-stimulation enhance T cell activation and persistence in solid tumors, overcoming limitations of bispecific TCEs. We developed a novel TriTCE platform using structural/affinity optimization to balance CD3/co-stimulatory signals, achieving tumor-selective activation. This platform demonstrated improved T cell killing potency and minimal off-target effects, supporting clinical translation as a next-generation TCE therapy.

1:50 Close of Advances in Immunotherapy Conference

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: Challenges and Opportunities in Solid Tumor and Autoimmune Disease Therapeutic Innovations

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

TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

ENGINEERING SMARTER CELL THERAPIES

2:20 Chairperson's Remarks

Shannon K. Oda, PhD, Principal Investigator & Associate Professor, Center for Childhood Cancer Research, Seattle Children's Research Institute

**2:30 KEYNOTE PRESENTATION: Engineering More Effective, Safer CAR T Cell Therapies**

Eric L. Smith, MD, PhD, Director of Translational Research, Immune Effector Cell Therapies, Dana-Farber Cancer Institute

CAR T cell therapies, which can be more potent than ADCs, can be made further efficacious by leveraging structural (paratope-epitope) knowledge to generate biparatopic designs that can prevent emerging antigen-driven resistance. CAR T cell therapies can be made safer by screening for on-target/off-tumor toxicity, and engineering with binders of different affinity to convey an optimal therapeutic window.

3:00 FEATURED PRESENTATION: Clinical Biomarkers of Response to Ciltacabtagene Autoleucl in Patients with Relapse or Refractory Multiple Myeloma

Katherine Li, Director, Clinical Sciences, Oncology Translational Research, Johnson & Johnson Innovative Medicine

Cilta-cel has demonstrated deep and durable response in patients with len-refractory MM as early as first relapse, including significantly improved progression-free survival, overall survival, and sustained MRD negativity vs. SoC. Biomarkers were investigated in the randomized, Phase 3 CARTITUDE-4 trial (NCT04181827) on patients with len-refractory MM with ≥ 1 prior line of therapy to evaluate their association with clinical outcomes.

3:30 Sponsored Presentation (Opportunity Available)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

**How Many New Contacts Can You Make?**

Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

IMPROVING CELL FITNESS, ACTIVITY AND RESPONSE

4:40 Leveraging Transcription Factors to Enhance CAR T Cell Fitness

Evan W. Weber, PhD, Assistant Professor, Pediatrics, University of Pennsylvania

CAR T cell therapies are limited by T cell exhaustion and poor CAR T persistence, which result in suboptimal antitumor activity in patients. Transcription factors govern these processes, and thus have emerged as ideal targets for enhancing CAR T cell potency. My talk will introduce a conceptual framework for how T cell fitness impacts CAR T cell efficacy and describe transcription factor engineering approaches for enhancing CAR T cell fitness.

5:10 Enhancing CAR T Cell Activity through Recruitment of Proximal T Cell Signaling Pathways

Maria C. Rotiroti, PhD, Research Fellow, Pediatrics, Dana-Farber Cancer Institute

Loss or downregulation of the target antigen has emerged as a major mechanism of resistance to CAR T cells. Conventional CAR T cells are susceptible to immune escape because they require high target antigen density for activation. By engineering intracellular signaling, we have developed a novel platform that amplifies the CAR T cell response to low antigen density, enabling the targeting of tumors with heterogeneous antigen expression.

5:40 Engineering CAR T Cells to Overcome Mechanisms of Resistance in Lymphoma

Zinaida Good, PhD, Assistant Professor (incoming), Division of Immunology and Rheumatology, Stanford University

This talk will present research on response and toxicity correlates in chimeric antigen receptor (CAR) T cell therapy for large B cell lymphoma (LBCL). It will discuss CAR T regulatory cells and a novel subset of tumor-associated macrophages as emerging mechanisms of resistance to CD19-CAR T cell therapy in LBCL, and will conclude with unpublished work on modeling these resistance mechanisms and CAR T cell designs to overcome resistance.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC5: Targeting the Target: Aligning Target and Biologic Format Biology to Achieve Desired Outcomes

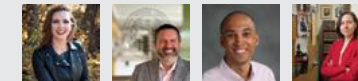
*Separate registration required. See short course page for details.

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (Continental Breakfast Provided) Co-Organized with Thinkubator Media



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC



PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP

Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics

Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet-up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

IMPROVING RESPONSE RATES, OVERCOMING HOST CELL IMMUNE EVASION

10:20 Chairperson's Remarks

Zinaida Good, PhD, Assistant Professor (incoming), Division of Immunology and Rheumatology, Stanford University

10:25 Engineering T Cells to Catalyze Multicellular Antitumor Immunity

Shannon K. Oda, PhD, Principal Investigator & Associate Professor, Center for Childhood Cancer Research, Seattle Children's Research Institute

Tumor heterogeneity is a major obstacle to effective cancer therapy. To overcome this issue, we developed a T cell engineering strategy that promotes *in vivo* persistence and catalyzes a multicellular antitumor immune response, providing enhanced eradication of hematological and solid tumors.

10:55 Immune Evasion for Allogeneic Cell Therapy

Karlo Perica, Assistant Attending Physician, Michel Sadelain Lab, Memorial Sloan Kettering Cancer Center

Autologous CAR T cell manufacturing is costly and complex, leading to delays in treatment and barriers to access. Allogeneic cell products from a healthy donor or a pluripotent stem cell are readily available 'off-the-shelf,' but limited by host immune rejection. I will describe our recently developed approaches to host immune evasion based on 1) manipulating cell adhesion and 2) using viral immune evasion.

11:25 Sponsored Presentation (Opportunity Available)

11:55 Session Break

12:00 pm LUNCHEON PRESENTATION: Expanding Access to Antibody Discovery: Novel Transgenic Mouse Models for Therapeutic Development



Speaker to be Announced, The Jackson Laboratory

Transgenic mouse platforms have enabled the identification of diverse, high-affinity and developable drug candidates leading to new marketed therapies. The Jackson Laboratory, in partnership with Abtherx, aims to improve access to these advanced tools, for both researchers and drug developers, with the introduction of novel transgenic mouse models expressing human antibody variable sequences – the Atlas mice – designed for traditional monoclonal and bispecific discovery campaigns.

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and

experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: The Promise of AI in Therapeutic Discovery - Has it Lived up to the Hype?

Timothy Riley, PhD, SVP, Discovery, 310.ai

BREAKOUT DISCUSSION: Navigating the Future of Cell & Gene Therapy: Overcoming Development, Manufacturing, and Commercialization Challenges

Michael D. Jacobson, PhD, Managing Partner, Cambridge Biostrategy Associates LLC

CELL THERAPIES FOR AUTOIMMUNE DISEASE

1:55 Chairperson's Remarks

Saad Kenderian, PhD, Assistant Professor, Medicine and Oncology, Mayo Clinic College of Medicine; Co-Leader, Cancer Immunotherapy, Mayo Clinic Cancer Center

2:00 Harnessing RNA to Enable Cell Therapy for Autoimmune Disease: From Concept to Clinic

Christopher M. Jewell, PhD, CSO, Cartesian Therapeutics

Autoimmunity, which impacts over 50 million people in the United States, occurs when the immune system mistakenly attacks host tissue. While cell therapies have been transformative for some cancers, application of cell therapies to autoimmune disease has been limited by safety risks, pretreatment chemotherapy, and lengthy inpatient stays. This presentation will share Cartesian's strategy to overcome these hurdles with RNA, enabling safe and effective treatment of patients with autoimmune disease.

2:30 Engineering Autologous CAR T Cells for the Treatment of Autoimmunity

Neal S. Van Hoeven, PhD, Vice President, Preclinical Research, Cabaletta Bio

B cell-depleting chimeric antigen receptor T cell (CAR T) therapy has shown remarkable and durable utility for the treatment of autoimmune diseases. The development of novel advanced CAR T products needs to account for the unique considerations that autoimmune patients have compared to oncology patients. The



role of preclinical studies to further evaluate and optimize these advanced CAR T candidates will be discussed.

3:00 CAR-MSC Technology for Autoimmune Disease

Saad Kenderian, PhD, Assistant Professor, Medicine and Oncology, Mayo Clinic College of Medicine; Co-Leader, Cancer Immunology Immunotherapy, Mayo Clinic Cancer Center

Allogeneic mesenchymal stromal cells (MSCs) show inconsistent efficacy in immune disorders due to insufficient immunosuppression. We enhanced their function by engineering MSCs with chimeric antigen receptors (CARs). We developed CAR-MSCs targeting E-cadherin to treat graft-versus-host disease and inflammatory bowel diseases. CAR-MSCs improved T cell suppression and targeted localization, significantly ameliorating symptoms and survival. This method promises a broadly applicable approach to boost immunosuppression in various conditions.

3:30 Comprehensive Solutions to Advance Cell Therapies for Autoimmune Diseases

Dr. An Ouyang, Product Manager, Product Development, ACROBiosystems

Autoimmune diseases are chronic, debilitating conditions characterized by dysfunction in the immune system's ability to distinguish self from non-self, triggering an aberrant immune response against the body's own cells and tissues. Chimeric antigen receptor (CAR) cell therapy has emerged as a promising solution for treating autoimmune diseases by engineering immune cells, such as T cells or natural killer (NK) cells, to express specialized receptors that can target and eliminate specific cells driving the autoimmune responses. At ACROBiosystems, we are committed to providing comprehensive products and solutions to accelerate your autoimmune disease drug discovery and development.

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

TARGETING SOLID TUMORS

4:40 Targeting Solid Tumors with Integrated Circuit T Cells

Sarah Lensch, PhD, Senior Scientist, Arsenal Bio

ArsenalBio is leveraging synthetic biology to enhance both the specificity and potency of CAR T cells. ArsenalBio's logic-gated technology enables CAR T cells to selectively respond based on the presence of two tumor antigens, and avoid when those antigens appear individually on healthy cells. CAR T cells are also engineered to contain Synthetic Pathway Activators (SPA) and shRNAs that improve persistence and survival in the immunosuppressive tumor microenvironment.

5:10 Armoring TIL with Regulated Immune Mediators for Enhanced Potency in Challenging Tumor Microenvironments

Michelle Ols, PhD, Senior Director & Head, Cell Therapy, Obsidian Therapeutics, Inc.

Obsidian's cytoDRIVE platform enables pharmacologic regulation of protein expression using drug-responsive domains (DRD). Our lead clinical candidate, OBX-115, in Phase 1/2 clinical development (NCT06060613), is an IL2-free tumor infiltrating lymphocyte (TIL) cell therapy product using regulatable membrane-bound IL15 to drive IL2-independent TIL persistence and efficacy. Preclinically, we are coregulating two cytokines, evaluating novel DRDs, and pairing DRD regulation with inducible promoters to enable spatiotemporal control of protein expression.

5:40 Generation of a Triple Antigen Targeting CAR T Cell Therapy for AML; Why Use VHHs?

Alexander W. Kinna, PhD, Associate Director, Binder Discovery, Autolus Therapeutics

CAR T cells traditionally employ scFv-derived binding domains for antigen recognition. However, alternative antibody formats—notably Camelid-derived single-domain antibodies—differ in biophysical properties such as stability and aggregation propensity, and exhibit distinct interactions with target cells. We evaluated the functional differences between VHH- and scFv-based CARs targeting CD123 and built on these findings with a triple OR gate VHH-CAR targeting CD123, CLL-1, and CD33 to address challenges in treatment of AML.

6:10 New Methods for Targeting Intracellular Oncoproteins Using CAR T Cells

Mark Yarmarkovich, PhD, Principal Investigator, Assistant Professor, NYU School of Medicine

CAR T cells have transformed cancer treatment, yet only a small fraction of cancer patients benefit from these therapies. The knowledge of tumor-specific targets is the rate-limiting step in developing new CAR therapies. Conventional CARs target membrane proteins, few of which are specific to tumors. We will discuss new methods for uncovering tumor drivers presented by HLA and novel methods for overcoming the challenges of targeting pHLA using CARs.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Engineering Cell Therapies Conference



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: Challenges and Opportunities in Solid Tumor and Autoimmune Disease Therapeutic Innovations

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

TUESDAY, MAY 13

6:30 pm Recommended Dinner Short Course

SC5: Targeting the Target: Aligning Target and Biologic Format Biology to Achieve Desired Outcomes

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

IN VIVO CAR T ENGINEERING: MOVING INTO THE CLINIC

8:25 Chairperson's Remarks

Adrian Bot, MD, PhD, CSO, Executive Vice President, R&D, Capstan Therapeutics

8:30 *In vivo* Engineering of Immune Cells: Update from Umoja BioPharma

David J. Fontana, PhD, Chief Business and Strategy Officer, Umoja BioPharma



9:00 *In vivo* mRNA-Based CAR T Cell Engineering for Treatment of B Cell Disorders

John Rossi, PhD, Vice President, Translational Medicine, Capstan Therapeutics

We developed a novel *in vivo* anti-CD19 CAR mRNA product (CPTX2309), delivered through CD8-targeted lipid nanoparticles (tLNP). Evaluation in non-human primates speaks to the potential of this platform to achieving immune reset, key to effectively treating B cell-autoimmunity. This sets up the stage for clinical development of CPTX2309 and opens an avenue for development of similar products for broad indications, overcoming the challenges of *ex vivo* viral-engineered CAR T cells.



9:30 KEYNOTE PRESENTATION: *In vivo* and *ex vivo* Use of LNP-Mediated Technology to Treat Hematological Disorders

Stefano B. Rivella, PhD, Professor, Pediatrics, Children's Hospital of Philadelphia

Current therapies allow the replacement of diseased hematopoietic stem progenitor cells (HSPC) with gene-engineered or healthy HSPC through bone marrow transplantation. However, current protocols have major side effects and limited access. Starting from conventional *ex vivo* technologies, we will discuss how the use of targeted lipid nanoparticles (tLNP) carrying messenger RNA (mRNA) can target HSPC and revolutionize the way we perform bone marrow transplantation or directly cure HSPC *in vivo*.

10:00 Advancing Bispecific Antibody Development: Overcoming Challenges with Innovative Solutions for Target Binding and Functional Assessment

SARTORIUS

Speaker to be Announced, Sartorius

Bispecific antibodies (BsAbs) are therapeutic antibodies targeting different antigens or epitopes, enhancing potency and therapeutic effects. Various constructs, like scFv, DARTs, Triomabs, and BiTEs, are being developed for diseases like cancer. Their diverse designs may face structural constraints affecting binding and performance. A major challenge is the lack of technologies for quantitative functional assessment of BsAbs' dual targets, necessitating innovative approaches beyond traditional monoclonal antibodies. This talk will present solutions for efficient biophysical and functional characterization of BsAbs in development.

10:15 Presentation to be Announced

KACATUS

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

NEXT-GENERATION IMMUNOTHERAPIES: IN VIVO APPROACHES

1:55 Chairperson's Remarks

Hamideh Parhiz, PharmD, PhD, Research Assistant Professor, Infectious Diseases, University of Pennsylvania

2:00 Increasing the Availability of CAR T Cells

Frederic B. Thalheimer, PhD, Molecular Biotechnology & Gene Therapy, Paul Ehrlich Institut

This presentation focusses on two upcoming strategies facilitating CAR T cell generation. Short-term CAR T cells accelerate production times but may bear an increased risk for severe cytokine release syndrome. *In vivo* CAR T generation relies on T cell-specific vectors as off-the-shelf product while proof for clinical benefit remains to be provided.

2:30 Talk Title to be Announced

Jagesh V. Shah, PhD, SVP, Head of Platform, Stealth Biotech, Flagship Pioneering

3:00 mRNA Delivered *In Vivo* CAR for Myeloid Cells to Combat Solid Tumors

Yuxiao Wang, PhD, Co-Founder & Vice President, Discovery Research, Myeloid Therapeutics



we introduce a novel class of innate immune receptor-based CARs designed to program myeloid cells *in vivo* using mRNA/LNP, overcoming limitations of current CAR therapies in solid tumors. Preclinical data demonstrate robust anti-tumor efficacy, leading to the initiation of first-in-human clinical trials for TROP2 and GPC3-targeting CARs, highlighting significant potential for advancing cancer immunotherapy.

3:30 Sponsored Presentation (Opportunity Available)

4:00 Networking Refreshment Break

4:30 Engineering Chimeric Antigen Receptor for mRNA CAR T

Huan Yang, PhD, Associate Principal Scientist, Discovery Biologics, Merck & Co. Inc.

Tonic signaling from CAR expression is proposed to be associated with CAR T exhaustion. Our study describes an *in vitro* model for investigating tonic signaling in mRNA CAR T cells, which has not been fully characterized. Among approximately 80 tested permutations of structural elements, a few optimal CAR designs showed improved antigen-dependent T cell immune responses *in vitro*. Additionally, several formats of mRNA were also evaluated for CAR expression persistence.

5:00 Targeted Fusogens Enable Potent *in vivo* CAR T Generation with High Cell-Specificity

Kyle M. Trudeau, PhD, Executive Director, Innovation, Sana Biotechnology, Inc.

5:15 Adaptive Protein Evolution X-attention (APEX) Model for Augmented CAR Discovery

Jenny Wei, PhD, Senior Director, R&D Informatics and Technology, Kite Pharma

To improve the efficiency of design and development of CAR constructs, we built the APEX model by fine tuning protein-language model ESM2 with a dataset comprised of binder (scFv, Fab, and VHH) and antigen pairs curated from the Structural Antibody Database. The model achieved robust performance on affinity prediction and can be expanded for other property prediction. Model adoption into CAR campaign facilitates binder prioritization to reduce discovery cycle time.

5:30 Presentation to be Announced

6:00 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: ML to Optimize Immune Cell Engagers

Winston Haynes, PhD, Head, Data Science & Machine Learning, LabGenius Ltd.

COMPUTATIONAL AND ML APPROACHES TO T CELL ENGAGERS

8:25 Chairperson's Remarks

Caleb A. Lareau, PhD, Assistant Professor, Memorial Sloan Kettering Cancer Center

8:30 Next-Generation Immunotherapies Unlocked via Petabyte-Scale Analyses

Caleb A. Lareau, PhD, Assistant Professor, Memorial Sloan Kettering Cancer Center

The accumulation of biological data, including DNA sequencing data in the Sequence Read Archive (SRA) and protein structures in the Protein Data Base (PDB) are the primary substrates underlying recent advances in the use of artificial intelligence in biological systems. Here, we present our lab's recent work on both mining and extrapolating from these repositories of petabyte-scale data, including our identification of potential new modalities for immunotherapy.

9:00 FEATURED PRESENTATION: Leveraging Single-Cell Sequencing to Identify Highly Precise T-Cell Engager Targets

Alexander J Martinko, PhD, Senior Director, Antibody Engineering & Design, Cartography Biosciences Inc.

T-cell engagers (TCEs) are a promising approach for solid tumors; however, progress is limited by a lack of tumor-selective targets that maximize efficacy while minimizing toxicity. We developed the ATLAS platform, a single-cell RNA sequencing resource that

leverages both healthy and tumor-derived datasets to identify highly precise TCE targets. Using ATLAS, we discovered LY6G6D as a tumor-specific colorectal cancer (CRC) target, guiding the engineering of a LY6G6D TCE for CRC.

9:30 Bispecific T Cell Engager Targeting a Novel pHLA Target

Ryan L. Stafford, PhD, Executive Director, Protein Engineering, 3T Biosciences Inc.

T cells recognize intracellular targets presented by HLA to enable potent anti-tumor immune responses, and these targets can be leveraged to generate off-the-shelf therapeutics using T cell-bispecific engagers to treat a broad patient population. We've developed 3T-TRACE to rapidly identify the antigens of orphan T cells from patient tumors and 3T-PRIME, a TCR mimetic platform to rapidly generate potent and specific binders for therapeutic development.

10:00 Sponsored Presentation (Opportunity Available)

10:30 Networking Coffee Break

11:00 A Novel T Cell Engager Platform Empowering Innovative and Effective Immunotherapies

Ahmet S. Vakkasoglu, PhD, Associate Director, Biologics Discovery and Innovation, Cue Biopharma

Immuno-STATs represent a Fc fusion molecules capable of engaging, activating, and amplifying disease-specific T-cells. Our leading clinical candidate, CUE-101, specifically targets HPV E7-specific T cells and has shown remarkable efficacy in patients with advanced head and neck cancer. With this clinical success and our platform's proven safety, we introduce the Immuno-STAT platform. It enables the targeting of various tumor types in addition to AI applications.

11:30 Non-Pathogenic *E. coli* Displaying Decoy-Resistant IL18 Mutein Boosts Antitumor and CAR NK Cell Responses

Jiahe Li, PhD, Assistant Professor, Biomedical Engineering, University of Michigan

The tumor microenvironment can inhibit the efficacy of cancer therapies through mechanisms such as poor trafficking and exhaustion of immune cells. To address this challenge, we exploited the safety, tumor tropism, and ease of genetic manipulation of non-pathogenic *Escherichia coli* to deliver key immune-activating cytokines to tumors via surface display on the outer membrane of *E. coli* K-12 DH5a.

**12:00 pm Cancer-Specific Targeting of Vesicular Stomatitis Virus**

Kepeng Wang, PhD, Assistant Professor, Department of Immunology, University of Connecticut

Oncolytic viral therapies for cancers are frequently limited to intralesional injection due to non-specific localization of systemically injected viral particles. We developed a modified vesicular stomatitis virus (VSV) that harbors tumor-activating moiety. This novel virus preferentially distributes to tumor tissues and showed enhanced safety compared to wild-type VSV. When incorporated with a single chain, biologically active interleukin-12 (IL-12)—the novel virus mounts effective control against tumor growth.

12:30 Close of Summit



EXPRESSION STREAM

Enhancing Efficiency, Quality, and Cost-Effectiveness



Addressing the rising demand for recombinant proteins requires the integration of cutting-edge research and advanced techniques with the latest tools and technologies. The Expression Stream centers on 1) overcoming challenges in the expression, production, and purification of hard-to-express recombinant proteins, 2) assessing various expression hosts and platforms to identify the optimal system for producing your recombinant protein of interest, and 3) implementing management strategies for efficient protein production laboratories. These strategic back-to-back tracks explore the newest data, innovations, and methods to make the expression and production of valuable recombinant therapeutic proteins more streamlined, effective, and reliable.

EXPRESSION STREAM CONFERENCES

MAY 12-13

Difficult-to-Express Proteins

[AGENDA](#)

MAY 13-14

Optimizing Protein Expression

[AGENDA](#)

MAY 15-16

Maximizing Protein Production Workflows

[AGENDA](#)



MONDAY, MAY 12

7:00 am Registration and Morning Coffee

EXPRESSION AND PRODUCTION OF CHALLENGING BIOTHERAPEUTICS

8:20 Chairperson's Opening Remarks

Haruki Hasegawa, PhD, Scientific Director, Discovery Protein Science, Amgen

8:30 Optimizing the Assembly of an Asymmetric Antibody: Lessons Learned and Methods Implemented

Sulo Baskaran, PhD, Senior Director, Protein Science, Santa Ana Bio IgG-like asymmetric bispecific antibodies are one of the challenging biotherapeutics—and successful scalable production might demand engineering of both heavy and light chains to facilitate correct pairing. Multiple engineering possibilities have been developed to increase the quality, quantity, and stability of bispecifics. In this case study we will be presenting the challenges encountered and the analytical strategies implemented to check product quality during expression, purification and formulation.

9:00 Production and Characterization of AI-Engineered Proteins: From Antibodies to Soluble MPMP Proxies

Allison Sheen, PhD, Senior Scientist, Nabla Bio Inc.

AI protein design strategies show promise for drug design—from *de novo* binder discovery to redesign of antibodies and antigens with improved properties. Even with best-in-class computational design, high-throughput laboratory methods are required to identify successful designs at scale. Here, we describe our experience producing and characterizing AI-designed proteins, including antibodies and solubilized multi-pass membrane protein proxies ("solMPMPs"), highlighting benefits, challenges, and the integration of computational and experimental methods.

9:30 Understanding the Biosynthesis of Polymeric IgM to Explore Its Structure as a Multivalent Binder Modality

Haruki Hasegawa, PhD, Scientific Director, Discovery Protein Science, Amgen

Polymeric IgMs are abundantly secreted from plasma cells despite their structural complexity and intricate polymerization steps. To gain insights into IgM's assembly mechanics that underwrite high-level secretion, we characterized IgM's biosynthetic process by testing a series of mutant subunits that differentially disrupt secretion, folding, and specific inter-chain disulfide bond formation. Insights obtained from this study provide a foundation for designing IgM-like multivalent binders.

10:00 Application of BacMam in Difficult Protein Expression and Purification

Nian Huang, Senior Research Scientist I, R&D-Small Molecule, Curia

10:30 Networking Coffee Break

11:00 Greasing Protein Wheels: Unlocking Lipidation Strategies for Next-Generation Biomaterials and Therapeutics

Davoud Mozhdzhi, PhD, Associate Professor, Chemistry, Syracuse University

Protein lipidation remains a largely untapped resource in therapeutic development, despite its prevalence regulating cell biology. Traditional semi-synthetic methods for protein lipidation often suffer from low yields, harsh reaction conditions, and can induce protein misfolding, complicating purification processes and limiting therapeutic potential. Our work addresses these challenges by genetically engineering prokaryotes to rapidly produce diverse libraries of lipidated proteins, enabling systematic investigation of lipid-driven protein behavior.

11:30 Developing mRNA Therapeutics for Cardiovascular Diseases

Ajit Magadum, PhD, Assistant Professor, Center for Regenerative Medicine, Department of Internal Medicine, Heart Institute, University of South Florida

mRNA therapeutics is rapidly emerging as a groundbreaking strategy for treating cardiovascular diseases (CVD), which affects 650 million people. Despite advances in medicine, the need for curative therapies remains urgent. I will share our decade of work on mRNA therapies that promote cardiac regeneration, and combat fibrosis, cell death, and hypertrophy in CVD animal models. Additionally, we introduce novel cell-specific mRNA expression platforms, advancing the field of CVD therapeutics.

12:00 pm Session Break

12:10 Luncheon Presentation to be Announced 

12:40 Luncheon Presentation to be Announced 

1:10 Session Break

EXPLORING PROTEIN ENGINEERING STRATEGIES

1:15 Chairperson's Remarks

Athéna Patterson-Orazem, PhD, Senior Scientist II, RNAimmune Inc.



1:20 A Genetic Encoding for Glycans: Platform Agnostic and Site-Specific Glycan Design, Selection, and Homogenization

Benjamin Kellman, PhD, Research Fellow, Pathology, Ragon Institute of MGH MIT & Harvard

Unlike other biopolymers, dogma describes glycosylation as non-template biosynthesis. Without a genetic encoding, glycan impact on biology is opaque. Here, we challenge template-free glycosylation and describe protein-encoded rules for glycan biosynthesis. We quantify glycan-protein associations and reformulate these associations as an engineering strategy. With this genetic encoding for glycans, we can integrate the siloed practices of glycan and protein engineering into a unified process of glycoprotein engineering.

1:50 Overcoming Expression Challenges to Antigen Engineering through Iterative *in silico* Design with Limited *in vitro* Screening

Athéna Patterson-Orazem, PhD, Senior Scientist II, RNAimmune Inc.

We applied AI-assisted, iterative *in silico* approaches to stabilize RSV and influenza antigens for mRNA vaccines. Abrogated protein expression and secretion in early design motivated adaptations to *in silico* design methodology. Within two iterations and twenty variants, four sets of unique mutations demonstrated RSV expression/stability enhancement comparable to established stabilizing mutations. Similar success with influenza B optimization supports broader applicability of iterative *in silico* design methods to streamline antigen engineering.



2:20 KEYNOTE PRESENTATION: Introns: From Nature to Design

Kart Tomberg, PhD, Co-Founder & CEO, ExpressionEdits Ltd.

If you compare a typical human gene to the transgenes used to manufacture proteins, they have markedly different structures despite both being foundational to the biotechnology industry. At ExpressionEdits, we have revised the paradigm for how a mammalian transgene should look by reintroducing introns back into the cDNA sequence. We have trained an AI model of "genetic syntax" to learn how to combine coding and non-coding DNA to improve protein expression.



2:50 GPEX® Lightning Technology: Overcoming Catalent® Challenges to Deliver Difficult to Express Proteins

Rachel Kravitz, Principal Scientist, R&D, Catalent Pharma Solutions

The GPEX® Lightning platform accelerates high-titer production of next-generation multi-specific antibodies and complex protein biologics with unmatched speed, flexibility, and scalability. Utilizing over 100 dock sites for stable integration, Catalent's GPEX® Lightning technology achieves unique genetic tunability ensuring balanced expression of complex and hard-to-express proteins. This presentation will provide case studies leveraging GPEX® Lightning's flexibility to deliver complex molecules such as multi-chain bi-specifics, virus-like particles, and unusual fusion protein combinations.

3:20 Networking Refreshment Break

4:05 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:15 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research and Macovski Professor of Bioengineering, Stanford University



4:25 The Role of Protein Engineering in Developing New Innovative Modalities

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE



5:10 Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade

Jessica C. Stark, PhD, Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

5:55 Welcome Reception in the Exhibit Hall with Poster Viewing



YOUNG SCIENTIST MEET-UP

Co-Moderators:



Iris Goldman, Production, Cambridge Innovation Institute
Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab
Julie Sullivan, Production, Cambridge Innovation Institute

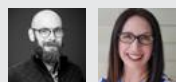
7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC
Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists:
IN-PERSON ONLY

TOOLS AND PROTOCOLS FOR IMPROVING FUNCTIONAL PROTEIN PRODUCTION

8:30 Chairperson's Remarks

Sunhee Hwang, PhD, Scientist 4, Peptide Therapeutics, Genentech Inc.

8:35 Unprecedented GPCR Expression for Conformational Dynamics Study of GPCR Using 19F-NMR

Libin Ye, PhD, Associate Professor, Molecular Biosciences, University of South Florida

Despite minimal sample preparation of cryo-EM results in thousands of GPCR structures resolved, we still face challenges to conduct conformational transitions and dynamics study using 19F-qNMR, a super tool in quantifying conformational states because of its ultra-sensitivity to the microenvironmental changes compared to other nuclei. To address this, my lab developed two protocols driving the field forward, allowing us to produce 5-10 mg of functional receptors/1L cell culture.

9:05 High-Throughput Protein Expression Screening and Production of Cell-Surface Protein Ectodomains

Rob Meijers, PhD, Head, Biological Discovery, Institute for Protein Innovation

Mammalian cell-surface receptors pose challenges in expression and purification due to low levels, misfolding, and instability. We introduce a high-throughput ELISA fluorescence approach to rapidly assess multiple recombinant constructs. Utilizing small-scale expression, enzymatic biotinylation, and C-terminal His-tag capture, this approach efficiently prioritizes constructs for large-scale production. Testing truncation constructs across various protein families demonstrated its effectiveness, significantly saving time in identifying optimal candidates for downstream applications.

9:35 Capabilities of KIWI-Biolab's Robotic Ecosystem for Process Development and Optimization of Difficult-to-Express Proteins

Peter Neubauer, PhD, Lab Head, Bioprocess Engineering, TU Berlin

Based on fully-automated, well-controlled, parallel fed-batch cultivations with integrated analytics and model-based DoEs/ Machine learning, the KIWI biolab allows a fast selection of best clones and optimization of process parameters in a single



experiment. The power of the established self-driven lab is demonstrated with difficult-to-express protein processes, including hydrogenase, Fabs and elastin like proteins.

10:05 Presentation to be Announced**10:20 Innovative Cell Line Development Approaches for the Next Generation of mAb Formats and Non-Antibody Products**

Lena Tholen, Director, Cell Line & Bioprocess Development, FyoniBio

We will illustrate the relevance of host cell selection in early development with its effect on product quality and process feasibility. We will show how seamless and full-blown CLD approaches can impact final results in complex antibody format production. Finally, case studies for complex bispecific antibody project developed in FyoniBio's CHOnamite and difficult-to-express protein in human GlycoExpress cells will be presented.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing**11:15 EZ Tag: A New Solution for Difficult-to-Express Proteins**

Sangyong Jon, PhD, Professor, Biological Sciences, KAIST

In this talk, I will share with the audience a new protein tag, designated EZ-tag, as a solution for difficult-to-express proteins. Our EZ-tag demonstrates a notable increase in the expression and solubility of various recombinant proteins compared with other conventional protein tags. Our EZ-tag will benefit researchers in related industry and academia who are seeking an efficient protein tag for expression and purification of difficult-to-express proteins of interest.

**11:45 Bioproduction Platform to Generate Functionalized Disulfide-Constrained Peptide Analogues**

Sunhee Hwang, PhD, Scientist 4, Peptide Therapeutics, Genentech Inc.

A versatile and highly-efficient bioproduction platform to generate various forms of disulfide-constrained peptides (DCPs) has been developed as an environmentally sustainable alternative to SPPS. This platform can be used to generate: (1) multivalent DCPs with different geometries, (2) DCPs with functional chemical groups such as biotin, (3) DCPs with unnatural amino acids through amber codon suppression, and (4) isotope-labeled DCPs.

12:15 pm Presentation to be Announced**12:45 Session Break****12:50 Luncheon Presentation to be Announced**

1:20 Luncheon Presentation (*Sponsorship Opportunity Available*) **or Enjoy Lunch on Your Own**

1:50 Close of Difficult-to-Express Proteins Conference



TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with
Poster Viewing

EXPANDING THE EXPRESSION TOOLBOX

2:20 Chairperson's Opening Remarks

Ernst Weber, PhD, Head, Molecular Design & Engineering & Science
Fellow, Bayer AG



2:30 FEATURED PRESENTATION: Optimizing
Codon Bias for Improved Productivity in
Cellular Stress

Susan Sharfstein, PhD, Professor of Nanoscale Science and
Engineering, University at Albany

Mammalian cell cultures undergo a variety of stresses under bioprocess conditions, including nutrient limitations, waste product accumulation, and increased osmolarity. In response to these stress conditions, cells alter their gene expression, tRNA prevalence, and tRNA synthetase enzymes—and exhibit epitranscriptomic modifications to their tRNAs. By analyzing these changes, we can recode both the gene sequence for our therapeutic protein and transcription factors to improve productivity.

3:00 Bioinformatics and AI Approaches in Construct Design
towards Soluble (and Crystallizable) Proteins

Christopher Cooper, PhD, Director and Head of Protein Sciences,
CHARM Therapeutics

Construct design towards soluble protein fragments for biochemical, biophysical, and structural analyses has been greatly facilitated by algorithms predicting features such as domains, disorder, and secondary elements. The recent advent of AI tools such as AlphaFold2, however, has transformed *in silico* structural biology. Here we present practical tips for using bioinformatics and AI tools in construct design to help users improve the likelihood of obtaining functional proteins for their needs.

3:30 Unleashing the Power of Cell-Free:
PUREfrex for Protein Engineering and Discovery

Takashi Ebihara, COO, GeneFrontier Corporation

PUREfrex is a revolutionary, fully reconstituted cell-free protein-expression system designed to redefine protein production. Its unparalleled flexibility suits a wide range of applications, including the production of difficult-to-express/therapeutic proteins and high-throughput screening. PUREfrex enables efficient *in vitro* display,



facilitating the discovery of novel antibodies and cyclic peptides, and combined with AI/ML, PUREfrex accelerates the development of next-generation biologics.

3:45 Signal Peptide Engineering Unlocks the
Cellular Secretory Pathway for Protein
Engineering Excellence



Tero-Pekka Alastalo, CEO, Avenue Biosciences Inc

Signal peptides play a pivotal role in protein synthesis, facilitating protein secretion, folding, post translational modifications, and yield. We showcase a high-throughput strategy for simultaneous analysis of thousands of naturally occurring and synthetic signal peptides, leveraging their diverse impact on protein biogenesis to boost expression and quality for a wide array of applications requiring a mammalian protein production system: from mRNA therapies to antibody engineering, and more. Our latest data reveal how our high throughput strategy outperforms the current industry standard, reshaping biologics development with precision and scalability.

4:00 Refreshment Break in the Exhibit Hall with
Poster Viewing

SPEED NETWORKING



How Many New Contacts Can You Make?

Kevin Brawley, Project Manager, Production Operations
& Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

4:40 Targeted Dual Selection to Optimize Transposon
Stable Pool Generation of Multispecifics in Large
Molecules Research

Julie Johnston, Scientist, Large Molecule Research, Sanofi

Targeted Dual Selection (TDS) with transposon-guided semi-targeted gene integration can be used to optimize stably expressed pools to enhance protein titers and pairing of multispecific molecules, thus improving molecule quality immediately off capture purification. We demonstrate that transient data can effectively predict vector combinations of larger-scale TDS stable pools. Utilizing this technology early in research can simplify purification strategies and increase production yields, facilitating successful project progression.

5:10 Phase-Separating Synthetic Organelles to
"Eukaryotize" *E. coli* Protein Expression

Haotian Guo, PhD, Founder & CEO, Ailurus Bio

Bacterial hosts enable rapid, cost-effective protein production but face challenges such as misfolding, aggregation, toxicity, disulfide bond formation, and complex purification processes. Here we show synthetic organelles driven by liquid-liquid phase separation "eukaryotize" *E. coli*, streamlining expression, and purification. This approach simplifies workflows, producing high-purity proteins through simple extraction with improved success rates. Bridging bacterial and eukaryotic systems, it offers a scalable, transformative solution for efficient protein production.

5:40 Setup and Applications of Modular Protein Expression
Toolboxes (MoPET) for Mammalian Systems

Ernst Weber, PhD, Head, Molecular Design & Engineering & Science
Fellow, Bayer AG

The Modular Protein Expression Toolbox (MoPET) empowers protein engineers with a flexible and efficient approach to generate both single-expression constructs and combinatorial libraries. The system utilizes standardized, reusable DNA modules, enabling rapid and reliable assembly of constructs tailored to diverse experimental needs. This presentation highlights MoPET's capabilities, offering practical insights and real-world use cases to demonstrate its potential to transform protein expression workflows and accelerate discovery.

6:10 Close of Day

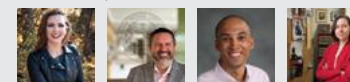
6:10 Dinner Short Course Registration

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce
Transformation: An Evolving Approach to
Achieve Innovation (*Continental Breakfast
Provided*) Co-Organized with Thinkubator Media



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and



transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University
College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer,
Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of
Immunology, University of Toronto



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences,
University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stromal microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP

Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics

Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

DEVELOPING EXPRESSION AND PRODUCTION PLATFORMS

10:20 Chairperson's Remarks

Lauren T. Cordova, PhD, Senior Scientist, Merck & Co. Inc.

10:25 Enhancing the Secretion-Antigen-Specific Miniproteins with High Valency in *Pichia pastoris*

Arturo Vera-Rodriguez, PhD, Head, Bioprocess Development, AI Proteins

Pichia pastoris is a low-cost expression host used to produce protein-based therapeutics. Two major drawbacks of this system are low-protein secretion levels and proteolysis of the product during fermentation. We overcame these shortcomings by formulating a new chemically defined growth medium and using site saturation mutagenesis. These changes increased the secretion of intact multivalent miniproteins, containing multiple target specificities codified within a single gene, by more than 20-fold.

10:55 Pool-Based Screening in *Pichia pastoris* for Rapid Evaluation of Secreted Protein Production

Lauren T. Cordova, PhD, Senior Scientist, Merck & Co. Inc.

Pichia pastoris is known for secreted protein production. To enhance the development workflow, a pool-based screening method was developed following strategies utilized in CHO cell line development. Expression of multiple protein and signal sequences were evaluated to identify optimal conditions for protein secretion. Individual strains from high, medium, and low-producing pools demonstrated comparable titer to their corresponding pool. This approach enabled a wide experimental design space with minimal resources.

11:25 Unleashing the Power of Automation for High-Throughput Antibody Synthesis

ThermoFisher
SCIENTIFIC

Claudia Chiochini, Manager, Protein Research & Development, R&D,
Thermo Fisher Scientific

The discovery and optimization of antibodies, whether through traditional methods or with the assistance of artificial intelligence, necessitates rapid and reliable data generation. Here we introduce a high-throughput platform for synthesizing microgram amounts of monoclonal antibodies. Our platform integrates DNA normalization, transfection, antibody purification, and buffer exchange within our Manufacturing Execution System (MES), ensuring traceability throughout the entire workflow.

11:55 Session Break

12:00 pm Luncheon Presentation to be Announced

12:30 LUNCHEON PRESENTATION: Tips and Tricks in speeding up Transient HEK293 and Transient/Stable CHO from 96 well, 24 well, 6 well, 125mL-7L Optimum Growth flasks

Speaker to be Announced, Thomson Instrument Co

The conditions for Plasmids, Transient HEK293 and Transient/Stable CHO from 96 well, 24 well, 6 well, 125mL-7L Optimum Growth flasks need to be maintained at small scale. Data will be presented on techniques and technology that allow for getting high amounts of protein in smaller volumes with fast techniques from 1mL-3L. This allows teams to get to IND molecules quickly. All of these techniques are proven technologies for protein production, structural biology, and can lead to successful clinical candidates.

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.





BREAKOUT DISCUSSION: Prokaryotic Expression Systems: Applications, Advancements, and Strategies for Optimization

Alex Kirkpatrick, PhD, Field Application Scientist, Protein Expression, Thermo Fisher Scientific

Prokaryotic expression systems, particularly *E. coli*, have long been the workhorse for protein expression, significantly contributing to the generation of recombinant proteins for various applications. Join us to explore the applications, strategies & practical solutions for improvement, and advancements in prokaryotic cell-based expression systems.

- Advantages of Different Prokaryotic Systems
- Optimization Strategies for Protein Production
- Current Challenges of Prokaryotic Hosts
- Innovative Approaches and Emerging Trends

BREAKOUT DISCUSSION: Getting the Math Right: Adding and Subtracting Post-Translational Modifications (PTMs) to Recombinant Proteins

Christopher Cooper, PhD, Director and Head of Protein Sciences, CHARM Therapeutics

- Choosing an appropriate QC method for your budget
- Moving on from biotinupcoming alternative protein labelling technologies
- Challenges in addition of site-specific PTMs (e.g. phosphorylation) and protein PTMs (e.g. ubiquitin, SUMO)
- Advances in (de)glycosylation and its analysis

ENHANCING CELL-FREE EXPRESSION

1:55 Chairperson's Remarks

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark



2:00 KEYNOTE PRESENTATION: Establishing High-Yielding Cell-Free Glycoprotein Synthesis Platforms for Therapeutic Production

Michael Jewett, PhD, Professor, Biogengineering, Stanford University

Protein medicines have revolutionized our ability to prevent and treat human diseases. However, the World Health Organization estimates that at least 30% of the world's population still lacks access to essential medicines. We are addressing this need by creating a portable, decentralized synthesis platform to make medicines when and where they are needed. Here, I describe work in advancing cell-free glycoprotein synthesis systems in support of this objective.

2:30 Pushing the Boundaries of Cell-Free Protein Synthesis: Engineering of the *E. coli*-Based XpressCF+ System for Clinical Manufacturing of Next-Generation Antibody-Drug Conjugates

Jacquelyn Blake-Hedges, PhD, Senior Scientist, Protein Biochemistry, Sutro Biopharma

Sutro Biopharma's cell-free protein synthesis system is a powerful platform to produce antibodies containing non-natural amino acids (nnAAs) that facilitates homogenous site-specific conjugation of antibody-drug conjugates (ADCs). This talk will highlight the cell-line engineering approaches used to enable the GMP manufacturing of IgGs containing nnAAs for clinical ADC production, including ADCs bearing two payloads with different mechanisms of action and ADCs with high drug-to-antibody ratios (>8).

3:00 Production and Characterization Pipeline of Therapeutic Proteins Using Cell-Free Synthesis

Takanori Kigawa, PhD, Senior Scientist, RIKEN Center for Biosystems Dynamics Research

We have developed a cell-free protein production pipeline that significantly accelerates the synthesis of therapeutic proteins, including cytokines, antibodies, and membrane proteins.

The automated system produces microgram-to-milligram quantities of multiple proteins simultaneously, enabling advanced characterization methods, including in-cell NMR. The presentation highlights key innovations that streamline protein production and interaction studies, offering substantial advancements for the design, development, and optimization of biotherapeutic candidates.

3:30 Rapidly Express Optimized Membrane Proteins in 48 hours

Michael Chen, CEO & Co Founder, Nuclera

Our CEO and co-founder, Michael Chen, will share exciting updates on how eProtein Discovery™ System offers rapid membrane protein expression and stabilization screening, delivering high-quality membrane proteins in under 48 hours ready for Cryo-EM structure determination or functional studies. Our integrated nanodisc and detergent screening technology streamlines stabilization condition identification, accelerating research in structural biology and drug discovery.

eProtein Discovery now delivers both soluble and membrane proteins - offering a comprehensive solution for diverse protein expression and purification needs.

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

ENHANCING CHO-CELL EXPRESSION



4:40 Collaboration between the innovative peptide and protein production platform CORYNEX® and the Site-specific antibody conjugation technology AJICAP®

Yumi Nagase, Lead Researcher, Biopharma Solutions, Ajinomoto Co., Inc
Tsubasa Aoki, Ph.D., Researcher, Biopharma Solutions, Ajinomoto Co., Inc

Ajinomoto Bio-Pharma Services as a fully integrated CDMO offers innovative platform technologies and end-to-end solutions for biopharmaceuticals. This presentation will introduce the Corynex® protein and peptide expression technology, highlighting its application towards the high-quality manufacture of GLP-1 related peptides and VHHs. Additionally, we will present the AJICAP® site-specific chemical conjugation technology for ADCs and antibody-VHH conjugates, and discuss how the synergy between Corynex® and AJICAP® enables innovative cancer therapies.

5:10 Eliminating Lactate Production in CHO Cells: Impacts on Protein Production and Cell Biology

Hooman Hefzi, PhD, Associate Professor, Advanced Mammalian Cell Engineering Group, Department of Biotechnology and Biomedicine, Technical University of Denmark

Lactate production is ubiquitous in proliferative mammalian cells and poses challenges for biopharmaceutical production as its accumulation inhibits cell growth and protein production. We have eliminated lactate production in CHO cells by knocking out multiple genes using CRISPR/Cas9. These cells remain amenable for the production of diverse biotherapeutic proteins, reaching industrially relevant titers and maintaining glycosylation. We will also share an initial assessment of the biological impact of this knockout.

5:40 Optimization of High-Density HD-CHO Transient Protein Production for a Robust Early-Stage Material Generation

Sultan Ciftci-Yilmaz, PhD, Senior Scientist II, Protein Design & Production, Merck Research Labs

Transient protein production in mammalian cells is vital for biopharmaceutical industry, enabling rapid molecule generation for early-stage biologics discovery. We present an optimized transfection protocol using high-density HD-CHO cell cultures enhanced by dimethylacetamide (DMA) and mild hypothermia. Our Design of Experiments (DOE) approach has doubled protein titers, streamlined the workflow, and minimized complexity. This presentation shares insights into our optimization method and its potential to accelerate protein production development.

**6:10 PANEL DISCUSSION: Speaking the Same Language—
Insights from Protein and Data Scientists**

Moderator: Christopher Cooper, PhD, Director and Head of Protein Sciences, CHARM Therapeutics

Data scientists view data in black and white while protein scientists consider the gray. Hear from both disciplines as they address:

- Can we enhance protein production using ML?
- How do we simplify data capture to encourage data entry and consistency?
- How do we reduce the need to curate and “clean-up” the data before applying ML?
- What is enough data to apply ML algorithms?
- The importance of including negative data

Panelists:

Kart Tomberg, PhD, Co-Founder & CEO, ExpressionEdits Ltd.

Yuan Wang, PhD, Head of Research Analytics, UCB Pharma

Ernst Weber, PhD, Head, Molecular Design & Engineering & Science Fellow, Bayer AG

**6:40 Networking Reception in the Exhibit Hall with
Poster Viewing****7:40 Close of Optimizing Protein Expression Conference**



THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

WORKFLOW MANAGEMENT: MEETING NEEDS BY INCREASING PRODUCTION EFFICIENCY**8:25 Chairperson's Remarks**

Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

8:30 FEATURED PANEL DISCUSSION: Higher-Throughput Protein Production Challenges: Methodologies, Strategies, and the Art of Managing Multiple Projects

Moderator: Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Protein-expression laboratories provide crucial support to drug discovery efforts. This panel discussion will focus on the concepts, technologies, and strategies necessary to meet the ever-increasing need for recombinant proteins.

- Know your protein
- Strategies on how to manage multiple "top priority" projects
- Total workflow efficiency
- The importance of tech development to long-term success
- Troubleshooting strategies or how much time should be spent before moving to the next option?

Panelists:

Ruth L. Saxl, PhD, Senior Manager, Protein Sciences, Scientific Services, Jackson Laboratory

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

Jessica Williamson, PhD, Head, US Protein Sciences, UCB

9:30 Balancing People, Priorities, and Proteins: Navigating Challenges and Innovating Solutions in Protein Science

Jessica Williamson, PhD, Head, US Protein Sciences, UCB

At UCB, our Protein Sciences team produces non-antibody proteins for global drug discovery. We navigate internal and external challenges, balance resources, ensure high-quality production, foster scientist growth, and innovate new methods and technologies. This talk explores our strategies and innovations to thrive in a dynamic industry.

10:00 Mitigate and Manage Risks with Our Comprehensive Raw Material Characterization Program

Jinlai Wei, Research Scientist, R&D Analytical and Data Science, FUJIFILM Irvine Scientific

The Raw Material Characterization Program (RMCP) at FUJIFILM Irvine Scientific was designed to establish a comprehensive understanding of the raw materials that are used in the manufacture of cell culture media. By identifying the degree and sources of variation, we can mitigate, manage risks, and maintain a supply of high-quality products that meet customer demands. Join us for a presentation to learn about, the rigorous raw material assessment methods that allow us to satisfy customer requirements and customer case studies that demonstrate the value and benefits of RMCP.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing**11:15 Transition to Plenary Fireside Chat****PLENARY FIRESIDE CHAT****11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As**

Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medicxi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing**STRATEGIES FOR OPTIMAL PURIFICATION, PERFORMANCE, AND YIELD****1:55 Chairperson's Remarks**

Jessica Williamson, PhD, Head, US Protein Sciences, UCB

2:00 Rapid Affinity-Based Purification of Multispecific Antibodies Using Kappa Select and Protein L

Brian E. Hall, PhD, Distinguished Scientist, Large Molecule Research, Sanofi

We report a versatile approach to remove product-related impurities of multispecific antibodies by altering the binding affinity of light chains to Kappa Select or Protein L resins. These purification-enabling mutations (PEMs) do not impact target binding or stability and we demonstrate the design and application of an entirely affinity-based purification scheme using bispecific and tri-specific antibodies. This purification approach should be adaptable across a range of production scales and workflows.

2:30 Accelerating High-Throughput Production through Functional Assessments of Bispecifics

Kristoff Homan, PhD, Senior Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb Company

Bispecific discovery can be accelerated through implementation of an efficient bispecific production platform. Through generating fit-for-purpose bispecifics ready for high-throughput functional assessments, timelines from target identification through lead optimization can be accelerated. Case studies from preclinical programs demonstrate the ability to rapidly identify preferred therapeutic formats and optimize bispecifics as well as efficiently interrogate large bispecific sequence spaces through leveraging sampling methods.

3:00 Novel High-Efficiency Protease Elution Enables High-Throughput, Automated Protein Production

Edson Carcamo Noriega, PhD, Investigator & Head, Biochemistry, AI Proteins

We developed a mag bead-based protease elution method for a high-throughput protein production platform, delivering over 1000 purified proteins weekly at >95% purity and yields of >200 µg/protein. Using *E. coli* and optimized automation, this workflow transitions from DNA to pure protein in 4 days. This scalable system is ideal for rapid protein evaluation, triaging, and generating datasets for machine-learning in protein engineering.

3:30 Sponsored Presentation (Opportunity Available)**4:00 Networking Refreshment Break**



THINK TANKS

IN-PERSON-ONLY: THINK TANKS

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

5:30 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: R&D with the End-in-Mind

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

- Determine what your end-product could look like
- Consider the full pipeline of your candidate as early as possible
- Select suitable expression systems early on
- Use regulatory acceptable hosts as soon as possible

DEVELOPING OPTIMIZED PROTEIN-PROCESS ROADMAPS

8:25 Chairperson's Remarks

Ruth L. Saxl, PhD, Senior Manager, Protein Sciences, Scientific Services, Jackson Laboratory

8:30 Strategies for High-Throughput Protein Production

Anita Ghosh, PhD, Senior Scientist, Antigen Production, Institute for Protein Innovation

The production and purification of recombinant native mammalian proteins in microgram to milligram quantities is a complex and time-consuming process, often presenting a significant bottleneck in protein-based applications. Despite these challenges, the Antigen Engineering and Production Group at IPI effectively supports both the high-throughput antibody discovery and validation platforms. This presentation highlights the key strategies we employ to overcome large-scale antigen production challenges while achieving "high-throughput-like" efficiency.

9:00 Optimization of Protein Secretion from B Cell Medicines: A Versatile B Cell Engineering Platform for Sustained Delivery of Therapeutic Biologics

Monika Musial-Siwiek, PhD, Director, Protein Sciences, Be Biopharma Inc.

We have developed B Cell Medicines (BCMs) using a CRISPR/Cas9-based precision B cell engineering platform to secrete diverse therapeutic proteins at sustained levels while serving as *in vivo* protein factories. BE-101 is a BCM therapy engineered to express human factor IX, offering a potential new therapeutic option for people with hemophilia B. US FDA cleared BE-101 IND. The FIH trial, BeCoMe-9 Phase 1/2 clinical trial, is open for enrollment (NCT06611436).

9:30 Developing an Antibody-Validation Pipeline

Ruth L. Saxl, PhD, Senior Manager, Protein Sciences, Scientific Services, Jackson Laboratory

Commercial antibodies are notoriously not completely validated making it difficult for investigators to discern if an antibody will work in their desired assay. At JAX, we have developed an antibody validation pipeline. Each antibody is screened by western blot, immuno-precipitation-mass spectrometry, immunohistochemistry, enzyme-linked-immunosorbent-assay, fluorescence-activated cell sorting, and Bio-Layer Interferometry. All collected data and the hybridoma sequence are supplied to our commercial distribution partner and any requesting JAX scientist.

10:00 Sponsored Presentation (Opportunity Available)

10:30 Networking Coffee Break

11:00 Leveraging Automation for Cell Culture and High-Throughput Protein Expression Screening

Andrea Partridge, PhD, Senior Scientist, Protein & Structural Chemistry, Merck & Co., Inc.

Structure-based drug design is an iterative process that requires the analysis of many DNA constructs along with optimization of expression conditions to yield high-quality target protein. For efficient screening of multivariate parameters, we developed high-throughput expression workflows utilizing Tecan Fluent and ambr15 robotic platforms. We successfully integrated these two systems, each optimized for different tasks, to express target proteins at various scales for downstream analytical needs.

11:30 Unlocking the Future of Protein Production in the Age of AI and Automation: The MARS Platform from Concept to Pipeline

Pramisha Adhikari, PhD, Senior Principal Scientist, Biologics Discovery, Johnson & Johnson Innovative Medicine

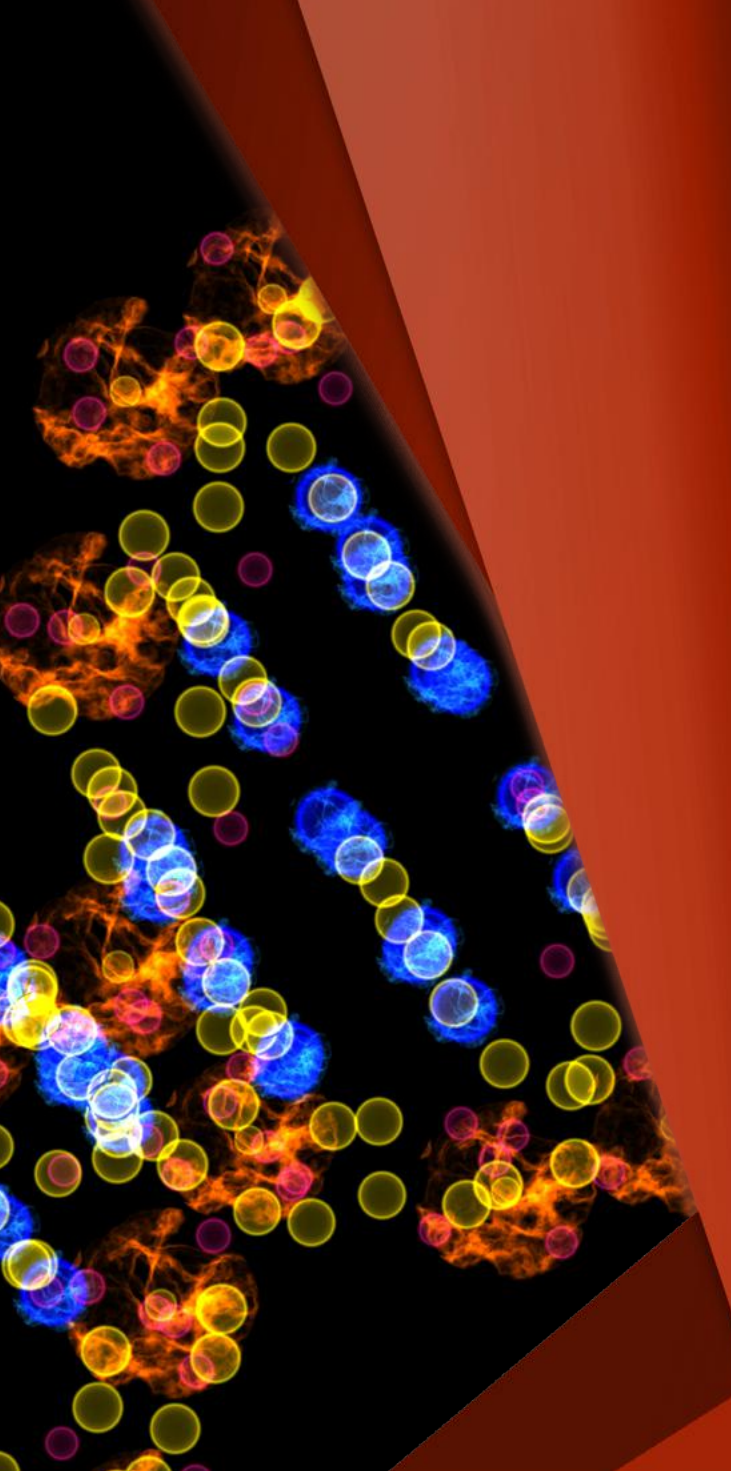
Production of high-quality biological molecules has historically been a major bottleneck in biologics discovery. While automation in this field has predominantly centered on protein production, labor-intensive tasks such as seed-culture production, workflow and data management, and high-volume bio-waste processing are often overlooked. Here, we present our redefined automation platform and highlight our journey going from a concept to a pipeline capable of generating large amounts of high-quality complex biologics.

12:00 pm From High-Throughput Discovery to Automating Small- to Mid-Scale Antibody Production to Support the Ever-Growing Needs of AI/ML

Christopher Wassif, PhD, Director, Molecular Engineering & Antibody Technologies, AstraZeneca

This presentation will focus on the convergence of a new high-throughput antibody discovery platform capable of screening 100s of millions of antibodies with machine learning to accelerate the full discovery process. This work is resulting in the identification of high affinity, developable modalities fit for therapeutic use in accelerated time frames, while generating significant amounts of data further refining our algorithms and models.

12:30 Close of Summit



ANALYTICAL STREAM

Transformative Advances in Biotherapeutic Analysis and Methods



In 2025, the PEGS Analytical Stream will showcase the latest advancements in biotherapeutic analysis across three dynamic tracks. ML and Digital Integration in Biotherapeutic Analytics will explore how digital tools and AI are transforming data integration, validation, and analysis across discovery, development, and clinical stages. Biophysical Methods will highlight innovations in automation, microfluidics, and emerging technologies, addressing challenges in characterizing novel modalities with legacy methods. Finally, Characterization for Novel Biotherapeutics will delve into the complexities of co-formulations, BBB-crossing therapies, and genetic medicines, alongside advancements in multispecifics, conjugations, and oligonucleotide therapeutics. Together, these tracks offer a comprehensive view of cutting-edge analytical methods shaping the future of biotherapeutic research and development.

ANALYTICAL STREAM CONFERENCES

MAY 12-13

ML and Digital Integration in Biotherapeutic Analytics

AGENDA

MAY 13-14

Biophysical Methods

AGENDA

MAY 15-16

Characterization for Novel Biotherapeutics

AGENDA

ML AND DIGITAL INTEGRATION IN BIOTHERAPEUTIC ANALYTICS

Best Practices for Implementing and Optimizing Big Data Tools in the Analytical Function

MAY 12-13, 2025



ANALYTICAL
STREAM

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: *In silico* and Machine Learning Tools for Antibody Design and Developability Predictions

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

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

TOOLS AND MODELS FOR ANALYTICAL SCIENTISTS

8:20 Chairperson's Remarks

Kadina Johnston, PhD, Senior Specialist, Discovery Biologics, Merck & Co., Inc.

8:30 Enhancing Laboratory Analysis with Generative AI-Based Chatbot

Michail Vlysidis, PhD, Senior Engineer, AbbVie

The integration of advanced technologies such as large language models (LLMs) and generative AI has the potential to revolutionize laboratory analysis. We present a novel approach to enhancing laboratory information management systems (LIMS) through the integration of a knowledge-driven chatbot powered by LLMs. The chatbot is designed to provide specialized and tailored assistance to scientists, streamlining their workflow and improving overall efficiency.

9:00 Democratizing Data Analysis through Automation

Sara Byers, PhD, Principal Scientist, Quantitative Sciences & Digital Transformation, Bristol-Myers Squibb

Substantial data analysis is routinely performed to support critical decisions and filings. The process from analysis to reporting results requires time-consuming and repetitive manual effort. We will share our insights on scripted add-ins developed to take this process from hours to seconds. These tools can be distributed to empower scientists, increase development speeds, reduce human error, and streamline workflows, allowing us to focus on more strategic and innovative activities.

9:30 An Introduction to Machine Learning Lifecycle Ontology and Its Applications

Milos Drobnjakovic, Research Associate, Systems Integration, NIST

Machine Learning (ML) shows promise in drug discovery and manufacturing, but its effective utilization faces hurdles including traceability, regulatory requirements, interoperability of related tools, model understanding, cross-organization collaborations, and dataset/model reuse. To address these, we introduce ML Lifecycle Ontology (MLLO) as a standard for capturing ML lifecycle metadata. A MLLO-based prototype tool, ML Lifecycle Explorer (MLLE), will be demonstrated. Finally, we discuss future work that integrates MLLO with domain knowledge.

10:00 From Data Capture to ML: Real-World Solutions to ML Integration Hurdles



Jana Hersch, Head of Corporate Scientific Engagement, Genedata

Integrating machine learning (ML) in biotherapeutic analytics is a transformative journey poised to revolutionize drug development. It requires high-quality data, technological advancements coupled with scalability, and interdisciplinary collaboration. This talk will showcase four real-world examples of biopharma companies tackling strategic challenges in ML integration: bridging digitalization gaps in chromatography, automating HT mass spectrometry workflows, validating automated NGS analysis, and using ML-derived developability data in discovery workflows.

10:30 Networking Coffee Break

11:00 Analytical Toolkit for Structural Characterization with Mass Spec

Simon Letarte, PhD, Director, Extended Structural Characterization, Gilead Sciences Inc.

Protein characterization with mass spectrometry involves a series of tools. Most labs will have some Orbitraps and QTOFs. Methods include reduced and non-reduced peptide maps, intact and subunit mass, and a few native MS methods such as native SEC and native CEX. Multidimensional chromatography to achieve complex separations and use salt-based methods on a mass spectrometer. It is desirable to have a cross-platform data processing suite and in-house software tools.

11:30 Predicting Subvisible Particle Formation of Monoclonal Antibodies Using Quartz Crystal Microbalance with Dissipation

Yibo Wang, PhD, Postdoctoral Fellow, Machine Learning, AstraZeneca

The occurrence of subvisible particles (SVPs) in monoclonal antibody (mAb) development presents challenges in assessing product stability. This study utilizes quartz crystal microbalance with dissipation (QCM-D) *in silico* and experimental physicochemical properties to investigate SVP formation risks associated with various containers and stress types. MAb adsorption kinetics were found to strongly correlate with SVP propensity in the stirring study, and *in silico* predictors significantly improved all model performance.

12:00 pm Session Break

12:10 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:10 Session Break

1:15 Chairperson's Remarks

Simon Letarte, PhD, Director, Extended Structural Characterization, Gilead Sciences Inc.



1:20 KEYNOTE PRESENTATION: AI in Biopharmaceutical Development: What Could Go Wrong?

Christopher P. Calderon, PhD, Associate Research Professor, Chemical and Biological Engineering, University of Colorado

This presentation presents an overview of recent practical challenges associated with designing and using data-driven algorithms in pharmaceutical development and process analysis.

USE CASES OF AI AND DIGITIZATION IN ANALYTICAL DEVELOPMENT

1:50 Leveraging Internal Datasets and Machine Learning to Design Better Biologics

Kadina Johnston, PhD, Senior Specialist, Discovery Biologics, Merck & Co., Inc.

High-quality datasets are key to successful biologics design and pre-developability prediction. Automated collection and curation of pre-developability data from electronic lab notebooks enables rapid

ML AND DIGITAL INTEGRATION IN BIOTHERAPEUTIC ANALYTICS

Best Practices for Implementing and Optimizing Big Data Tools in the Analytical Function

MAY 12-13, 2025


**ANALYTICAL
STREAM**

retraining and testing of predictors, and it has also been used to direct model-focused data-collection efforts. Furthermore, we use internal data to augment and validate models trained on publicly available datasets, increasing the impact of these models by improving their predictivity on internal assays.

2:20 Modular Multi-Objective Optimization Methods for Engineering Functional Proteases with High Therapeutic Potential

Jung-Eun (June) Shin, PhD, Machine Learning Scientist, Seismic Therapeutic

The development of biologic therapeutics is an exacting process, from discovery of a protein with desired function to optimizing for developability. To accelerate this process, we develop a modular multi-objective optimization method that synergistically harnesses deep learning and statistical models combined with structure-based and data-driven rational design. We apply this method to engineer immunoglobulin degrading proteases as potential therapeutics with desired target specificity and potency, low immunogenicity, and favorable manufacturability.

2:50 Maximize AI Potential in Biologics Discovery and Development: From Model Training to Consumption



Nicola Bonzanni, Founder & CEO, ENPICOM

We will discuss the key challenges in creating and deploying machine learning for biologics discovery. While creating complex models for discovery and development is becoming commonplace, managing the entire ML model lifecycle is essential for effective use in therapeutic research and maximizing AI investment returns. Discover how a unified platform can streamline AI use in biologics discovery, from model training to consumption.

3:20 Networking Refreshment Break

4:05 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:15 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research and Macovski Professor of Bioengineering, Stanford University



4:25 The Role of Protein Engineering in Developing New Innovative Modalities

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE



5:10 Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade

Jessica C. Stark, PhD, Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

5:55 Welcome Reception in the Exhibit Hall with Poster Viewing



YOUNG SCIENTIST MEET-UP

Co-Moderators:



Iris Goldman, Production, Cambridge Innovation Institute
Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab
Julie Sullivan, Production, Cambridge Innovation Institute

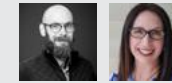
7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists: IN-PERSON ONLY

CHALLENGES AND SOLUTIONS

8:30 Chairperson's Remarks

Michail Vlysidis, PhD, Senior Engineer, AbbVie

8:35 Streamlining Science: The Role of the Digitally Enabled Scientist

Brett Rygelski, Scientist, Pharmaceutical Sciences, Pfizer

Explore the benefits of being a hybrid scientist in my journey from bench scientist to digital practitioner. Discover how digital skills empower the creation of quick, effective solutions, reducing reliance on external experts and manual processes. Learn about the future impact these tools have on portfolio progression through regulatory filings. Understand the importance of fostering digital development opportunities for future scientists.

ML AND DIGITAL INTEGRATION IN BIOTHERAPEUTIC ANALYTICS

Best Practices for Implementing and Optimizing Big Data Tools in the Analytical Function

MAY 12-13, 2025



ANALYTICAL
STREAM

9:05 Empowering Hybrid Scientists: Bridging Lab Expertise and Data Science, a Case Study of Developing an Automated ELN Data Quality Monitoring Tool

Dan (Cassie) Liu, Principal Statistician, Bristol Myers Squibb
Jason Parent, Scientist, Bioassay Development, Bristol Myers Squibb

This presentation explores the benefits of strategic partnership between the Quantitative Science & Digital Transformation team and the Bioassay Center of Excellence to foster skills of the future at Bristol Myers Squibb. We will share insights on the trainings, rotation experience, key learnings, and projects undertaken. The development of an automated ELN data-quality monitoring tool highlighting the importance of interdisciplinary collaboration in modern research will be presented.

9:35 Digital Transformation of Bioprocess Development Labs

Diana Bowley, PhD, Associate Director, CMC Data & Digital Strategy, Bioprocess Development, AbbVie, Inc.

Bioprocess development groups face challenges with complex modalities, faster development cycles, and more experimental data from HT and PAT technologies. Historically, lab experimental data is dispersed in many different instrument-software and unstructured-files formats requiring substantial manual data-manipulation efforts for experimental insights, decision-making, process-modeling, and tech transfer. Here we will share our journey to build and deploy a fit-for-science digital ecosystem within our bioprocess development labs.

10:05 Sponsored Presentation (Opportunity Available)

10:35 Coffee Break in the Exhibit Hall with Poster Viewing



11:15 Predicting Viscosity in Concentrated Antibody Solutions Using Machine Learning and Large-Scale Datasets

Pin-Kuang Lai, PhD, Assistant Professor, Chemical Engineering and Materials Science, Stevens Institute of Technology

We measured the viscosity of a large panel of 229 mAbs to develop predictive models for high-concentration screening. We developed DeepViscosity, consisting of 102 ensemble models to classify low-viscosity and high-viscosity mAbs at 150 mg/mL, using a sequence-based DeepSP model. Two independent test sets, comprising 16 and 38 mAbs, were used to assess DeepViscosity's generalizability. The model exhibited an accuracy of 87.5% and 89.5% on both test sets, respectively.

11:45 Elucidation of CHO Cell Metabolism Using Multi-Omics

J. Castro, PhD, Senior Scientist, Cell Engineering & Analytical Sciences, Johnson & Johnson Innovative Medicine

This study investigated the metabolism of Chinese Hamster Ovary (CHO) cells through a multi-omics approach, integrating proteomic and metabolomic datasets. By developing genome-scale models, metabolic patterns were successfully identified and analyzed, leading to new hypotheses about the regulatory mechanisms driving cellular behavior. These findings provided insights that enhance the understanding of CHO cell metabolism and may improve strategies for optimizing protein bioproduction.

12:15 pm Structure-Based Charge Calculations for Predicting Properties and Profiling Antibody Therapeutics

Nels Thorsteinson, Director of Biologics, Biologics, Chemical Computing Group

We present a method for modeling antibodies and performing pH-dependent conformational sampling, which can enhance property calculations. Structure-based charge descriptors are evaluated for their predictive performance on recently published antibody pI, viscosity, and clearance data. From this, we devised four rules for therapeutic antibody profiling which address developability issues arising from hydrophobicity and charged-based solution behavior, PK, and the ability to enrich for those that are approved by the FDA.

12:30 Sponsored Presentation (Opportunity Available)

12:45 Session Break

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:50 Close of ML and Digital Integration in Biopharmaceutical Analytics Conference

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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



Chemical
Computing
Group



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

EMERGING TECHNOLOGIES

2:20 Chairperson's Remarks

*Michael Dyson, PhD, Vice President, Antibody Discovery & Engineering, Ichnos Glenmark Innovation***2:30 Charge Detection MS and Mass Photometry Approaches to Characterize Protein- and mRNA-Based Therapeutics***Evolene Desligniere, PhD, CNRS Researcher, ICSN, Paris-Saclay University*

The increasing complexity and heterogeneity of advanced therapeutic products is a growing challenge. Currently, very few analytical methods are available to characterize heterogeneous biotherapeutics at the intact level. We show how charge detection mass spectrometry and mass photometry allow to tackle even extremely large and polydisperse samples, including adeno-associated viruses, glycoproteins, and messenger RNAs. These innovative approaches hold great promises to support the development and quality assessment of next-generation biotherapeutics.

3:00 Building a Roadmap to Enable Broader Adoption of MAM*Diane McCarthy, PhD, Senior Scientific Director, Global Biologics, US Pharmacopeia*

While the multi-attribute method (MAM) has potential to improve the efficiency and specificity of analytical testing, comparison to conventional methods is critical for implementation in QC. Through a cooperative agreement with US FDA, we have evaluated the performance of MAM versus conventional methods in detecting differences between thermally degraded therapeutic proteins from multiple sources. This presentation will share results and an implementation roadmap to facilitate broader adoption of MAM.

3:30 Meet Aunty, the New Benchmark for High Throughput, Total Protein Stability Characterization*Andre Mueller, Product Manager, Aunty & Honeybun, Marketing, Unchained Labs*

Stability screening of piles of proteins and formulations calls for the fastest and highest throughput characterization tool on the planet. Meet Aunty: load up to 96 of your samples into its quartz plate and let it power through all your stability experiments - reading fluorescence, SLS and DLS of the whole plate every minute of a Tm & Tagg thermal ramp or during an isothermal storage test. Join my talk to see Aunty and its unmatched resolution data of proteins, biosimilars and conjugates.

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

**How Many New Contacts Can You Make?***Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute*

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

AUTOMATION AND MINIATURIZATION

4:40 Exploring Mass Spectrometry Sample Preparation Strategies beyond Trypsin Digestion*Malika Godamudunage, PhD, Senior Scientist, AbbVie*

Peptide mapping is a critical component of our analytical toolbox used for characterization of biological assets. Trypsin/Lys-C digestion has been successfully used for many monoclonal antibodies. However, using this method for complex biological entities has been met with challenges such as lack of necessary sequence coverage and generating peptides that are too lengthy for unambiguous detection of modifications. This study focuses on alternative enzymatic digestion strategies to overcome these challenges.

5:10 Automated Ultradilute Measurements of Self-Association for the Identification of Antibodies with Favorable High-Concentration Solution Properties*Marissa V. Labreck, PhD, Senior Scientist, Sanofi*

One of the key challenges in antibody engineering is the development of analytical screening methods to ensure biologics are suitable for administration. Charge-stabilized self-interaction nanoparticle spectroscopy (CS-SINS), a modified version of the traditionally performed affinity-capture self-interaction nanoparticle spectroscopy (AC-SINS), has been adapted for predicting high-concentration solution behavior at Sanofi. Here, we demonstrate that the assay is compatible with high-throughput screening of therapeutic antibody candidates in early research.

5:40 Enhancing Complex Molecule Quantification Using Digitalized and Automated Platforms*Andreas Hald, PhD, Manager, Research Bioanalysis, Novo Nordisk*

The increasing complexity of next-generation therapeutic drug modalities presents a significant challenge for bioanalytical scientists responsible for quantifying drug exposure during early drug research. In response, we have engineered generic ligand binding assays, computational tools, and fully automated analytical platforms, which increase our analytical capacity and provide data applicable for training ML/AI models. Moreover, we are actively exploring AI-designed protein binders as an alternative to traditional assay antibodies.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee



WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (*Continental Breakfast Provided*) Co-Organized with Thinkubator Media



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stromal microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics
Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

BIOPHYSICAL CHARACTERIZATION FOR NEW MODALITIES

10:20 Chairperson's Remarks

Malika Godamudunage, PhD, Senior Scientist, AbbVie

10:25 A Developability Screening Cascade to Advance Multispecific Therapeutic Antibodies to the Clinic

Michael Dyson, PhD, Vice President, Antibody Discovery & Engineering, Ichnos Glenmark Innovation

The BEAT platform enables 5 or more functional modules to be combined into a single molecule. The biophysical and functional properties of a complex multispecific immune cell engager antibody can be different to the sum of its parts. Therefore, a screening cascade was developed, from Fab to lead candidate selection, to identify ISB 2001, a first-in-class tri-specific BCMA and CD38 T cell engager advancing in the clinic to treat Multiple Myeloma.

10:55 Evaluation of Orthogonal Technologies for AAV Empty/Full Capsid Analysis

Dana Tribby, Scientist, Analytical Development & Gene Therapy Chemistry, Biogen

AAV-based gene therapy has become an important therapeutic modality, and one of the key product quality attributes of AAV is the percentage of "empty" vs. "full" particles. Orthogonal technologies have been developed for empty/full capsid measurement and comparing analytical data from various AAV empty/full methods is critical. This presentation reviews data from several empty/full

techniques collected for different serotypes and products. Our strategy, correlations, and conclusions will be presented.

11:25 Presentation to be Announced



11:55 Session Break

12:00 pm Luncheon Presentation to be Announced



12:30 Luncheon Presentation to be Announced



INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Characterization of Protein Therapeutics Using Mass Spectrometry

Chris M. Chumsae, PhD, Director, Analytical Development, Bristol-Myers Squibb

BREAKOUT DISCUSSION: Developability Screening for Multispecific Antibodies

Michael Dyson, PhD, Vice President, Antibody Discovery & Engineering, Ichnos Glenmark Innovation

MASS SPECTROMETRY APPLICATIONS

1:55 Chairperson's Remarks

Linda Yi, Associate Director, Analytical Development, Biogen

2:00 Antibody Profiling with AI-Guided *de novo* Peptide Sequencing

Konstantinos Kalogeropoulos, PhD, Assistant Professor, Biotechnology and Biomedicine, DTU

Antibody sequencing is essential for therapeutic discovery and recombinant production, but current methods have significant limitations. We present a novel pipeline utilizing bottom-up proteomics with optimized protease digestion and AI-guided *de novo* peptide sequencing. This approach includes high-



throughput MS analysis, precise peptide sequence prediction, effective PSM filtering, and a robust protein assembly algorithm. Our work advances *de novo* protein sequencing for monoclonal and polyclonal antibodies, facilitating efficient therapeutic antibody development.



2:30 KEYNOTE PRESENTATION: Complete Sequencing of Large Modified Peptide-Nucleic Acids Using MALDI TOF MS/MS

Igor A. Kaltashov, PhD, Professor, Chemistry, University of Massachusetts, Amherst

Peptide nucleic acids (PNAs) are synthetic polymers that consist of a peptide-like backbone with nucleobases-like side chains. Their therapeutic potential was previously limited due to the manufacturability properties and poor biodistribution. A new generation of PNAs addresses these challenges by incorporating cationic "delivery shuttles," but their successful utilization critically depends on the availability of structural characterization methods. We demonstrate the complete coverage of large intact (>5kDa) PNA-based therapeutics.

3:00 Technology for Rapid Peptide Mapping with Direct Infusion Mass Spectrometry

Joshua J. Coon, PhD, Professor, Biomolecular Chemistry, University of Wisconsin Madison

We have developed a direct-infusion mass-spectrometry method that enables analysis of therapeutic antibodies in just 30–60 seconds. Here, we describe the method and software for accelerated data analysis. With this method we have generated several thousand peptide maps with the largest experiment so far being a collection of 1152 antibodies analyzed in only 35 hours and providing results comparable to the conventional LC-MS/MS methodology.

3:30 Presentation to be Announced



3:45 Sponsored Presentation

(Opportunity Available)

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

4:40 LC-MS Characterization of Polysorbates and Their Degradants

Linda Yi, Associate Director, Analytical Development, Biogen

Polysorbates (PS) are chemically diverse mixtures and may degrade through oxidation and hydrolysis pathways, and negatively impact product quality and stability. Comprehensive characterization of PS and its degradants are essential to enable effective PS analytical control strategies to assure product quality, stability and safety. Case studies describe utilization of LC-MS methods to characterize PS80 subspecies and its degradants, as well as fatty acid distribution.

PROBLEMS AND SOLUTIONS

5:10 Improvements in Throughput, Efficiency, and Precision of Size Variant Assessment in mAb Therapeutics by Analytical Ultracentrifugation

Zahid Khan, MS, Biopharmaceuticals Investigator, R&D Analytical Development, GSK

Sedimentation Velocity Analytical Ultracentrifugation (SV-AUC) is used to characterize and quantify size variants throughout mAb therapeutic development, either independently or in conjunction with methods such as SEC. Despite its unique advantages, such as analysis in native matrix and offering a broader dynamic range, SV-AUC is often considered a low-throughput technique. This session will illustrate how the incorporation of newer-generation AUC and data-processing software helps to improve efficiency and precision.

5:40 Streamlining and Accelerating Drug Discovery: Powering by Automated Sample Preparation through an Orchestrated Automation System

Jing Ke, PhD, Associate Principal Scientist, Discovery Biologics, Merck

We demonstrate a data-driven automation system that integrates wet-lab experimentation using standardized databases, robotics, and scheduling software. This system automates sample preparation from cell culture to bioassay plates, with real-time data acquisition, processing, and error-handling capabilities. It significantly impacts the pipeline by enabling quality control, developability assessments, and assay support for UP-SEC, CE-SDS, HIC, nanoDSF, etc. This enhances the interface between AI and multispecific protein screening, improving efficiency and reliability.

6:10 A Comprehensive and Holistic Characterization Strategy of Biotherapeutics to Enhance Product Quality and Process Control

Chris M. Chumsae, PhD, Director, Analytical Development, Bristol-Myers Squibb

With the increasing complexity of biologic therapeutics, more sophisticated analytical strategies are required to ensure proper assembly, primary structure, three-dimensional structure, and microheterogeneity. To address these challenges, application of high-resolution mass spectrometry is used to assess the molecular attributes of protein drugs in a holistic approach. In this talk, we will discuss a comprehensive analytical strategy and present case studies which highlight the unexpected challenges which may be encountered.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Biophysical Methods Conference

CHARACTERIZATION FOR NOVEL BIOTHERAPEUTICS

Analytical Best Practices for Emerging Modalities

MAY 15-16, 2025



ANALYTICAL
STREAM

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: Safety & Efficacy of Bispecifics and ADCs

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

TUESDAY, MAY 13

6:30 pm Recommended Dinner Short Course

SC5: Targeting the Target: Aligning Target and Biologic Format Biology to Achieve Desired Outcomes

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

NEXT-GENERATION CONJUGATES

8:25 Chairperson's Remarks

Maximilian Hartl, PhD, Scientist & Lab Manager, Pharma Research & Early Development, Roche Diagnostics GmbH

8:30 Characterization Issues for New Conjugation Chemistries and Platforms

Wendell P. Griffith, PhD, Lecturer II, Chemistry, University of Texas San Antonio

There has been much recent interest in protein-drug conjugates, especially antibody-drug conjugates, as an important pharmaceutical class of drugs in targeted therapies, which take advantage of the high specificity of antibodies and the potency of small molecule therapeutics. These, though, present several analytical challenges including determination of the drug-to-protein ratio and characterization of conjugation sites. Here we outline some of our experiences using various mass spectrometry-based tools and strategies.

9:00 Monitoring Degradation in ADCs by LC-MS

Mahalia Serrano, PhD, Principal Scientist, Biologics Development, Bristol-Myers Squibb

The talk will describe LC-MS methods used to characterize degradation products of ADCs. More specifically, mass spectrometry techniques were used to identify and quantify site-specific hydrolysis on the linker and payload. Furthermore, an LC-MS method for determination of the global payload hydrolysis levels was established to enable a more informed control strategy.

9:30 *In vitro* and *In vivo* Characterization Strategies for Novel Conjugations

Mei Han, Principal Scientist, Pharmacokinetics, Dynamics, Metabolism and Bioanalytical (PDMB), Merck & Co., Inc.

Antibody-drug conjugates (ADCs) have become an attractive modality for treating complex diseases. *In vivo*, ADCs could undergo biotransformation, leading to modifications of the linker-payload and/or changes in the drug-to-antibody ratio (DAR). These modifications could affect efficacy or introduce toxicity. Investigating the *in vitro/in vivo* stability/biotransformation could provide guidance to linker-payload and antibody selections. In this work, case studies of how biotransformation data informed lead candidate(s) selection or optimization are presented.

10:00 Dominate ADC Characterization with High-throughput, Low Volume analysis on Stunner



Speaker to be Announced, Unchained Labs

Antibody-drug conjugates (ADCs) are powerful but challenging – often in short supply and prone to aggregation. With the ever-increasing number and variety of ADCs under development, you need high-throughput, flexible tools to keep up the pace. Stunner gathers three key datapoints on up to 96 ADCs from 2 µL and in 2 minutes per sample: concentration, drug-antibody ratio (DAR), and an aggregation check. This means faster results, less waste, and more time to optimize your ADCs.

10:15 Presentation to be Announced

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

1:55 Chairperson's Remarks

Mahalia Serrano, PhD, Principal Scientist, Biologics Development, Bristol-Myers Squibb



2:00 Keynote Presentation: Analytical Development Challenges for a Diverse Product Portfolio

Ivan R. Correia, PhD, Senior Research Fellow & Head, Global Protein Sciences, AbbVie, Inc.

Analytical development with a diverse product portfolio poses unique challenges. Each product, whether it's a cutting-edge biotherapeutic or an innovative genetic medicine, demands customized methods to guarantee quality, efficacy, and safety. Balancing the standardization of processes with the flexibility to meet the specific demands of each product type is no small feat. Overcoming these challenges is where true innovation and teamwork shines, driving the possibility of new, life-changing therapies.

CHARACTERIZATION FOR NOVEL BIOTHERAPEUTICS

Analytical Best Practices for Emerging Modalities

MAY 15-16, 2025



ANALYTICAL
STREAM

CHARACTERIZATION OF VIRAL VECTORS

2:30 Assessment of Adeno-Associated Virus Purity by Capillary Electrophoresis-Based Western

Yiling Bi, PhD, Senior Scientist, Sangamo Therapeutics

Here we present two CE-western assays for quantifying the relative stoichiometry of VP, and residual levels of a baculovirus protein impurity, GP64. Various purified samples from diverse AAV serotypes were analyzed to determine their VP ratio or GP64 levels. The ratio of VP3/VP1 in rAAV samples was correlated with biological activity, and the clearance of GP64 from the manufacturing process was demonstrated. The results were further supported by LC-MS analyses.

3:00 Biophysical Characterization of Viral Vectors and Particulate Impurities in Gene Therapy Products

Andrea Hawe, PhD, CSO, Coriolis Pharma Research GmbH

There is a high demand to define analytical strategies for the characterization of adeno-associated virus (AAV)- and lentivirus (LV)-based drug products, because it is essential for ensuring safety and efficacy. In this context, both the characterization of the virus itself and the analysis of particulate impurities are crucial. While for AAV, already many biophysical methods to characterize the virus itself have been developed, fewer methods are available for LV.

3:30 Advances in Capillary Electrophoresis for Biotherapeutic Development

Peter Johnson, Field Application Scientist & Mgr, Field Applications, Bio Techne

Technical Talk Abstract:

In the presentation, Peter Johnson from Bio-Techne will illustrate a novel workflow that leverages icIEF-based fractionation, LC-MS characterization, and SPR analysis, offering a robust and efficient approach to evaluate the charge heterogeneity of biomolecules. The LC-MS characterization revealed similarities in main peaks and notable differences in acidic and basic variants between the innovator and biosimilar. The binding potency analysis showed notable differences in binding affinity, particularly between the biosimilar's acidic peak and ligand CD20.

4:00 Networking Refreshment Break

CHARACTERIZATION OF mRNA AND siRNA THERAPEUTICS

4:30 Characterization of Antibody siRNA Conjugates

Tun Liu, PhD, Senior Principal Scientist, Biophysics, Johnson & Johnson Innovative Medicine

Antibody-siRNA conjugate (AOC) has the potential to overcome the obstacles of systemic delivery of siRNAs. To cross the blood-brain barrier (BBB) for siRNA delivery, the antibody must have the affinity to the receptor to allow for brain uptake and subsequently be released for neuronal uptake. We have developed a set of tools to screen for antibodies with such an ideal range of affinity and to assess the stability of the AOCs.

5:00 From Structure to Function: Analytical Approaches in mRNA Therapeutics

Eva-Maria Schneeberger, PhD, Scientist, Analytical Development, Moderna

Ensuring the efficacy of mRNA therapeutics requires precise characterization and control of critical quality attributes at both the mRNA and lipid nanoparticle (LNP) levels. This talk explores advanced analytical methods, with a focus on mass spectrometry, to assess essential mRNA attributes—sequence fidelity, purity, cap/tail integrity, and process-related impurities—highlighting orthogonal approaches that support the structural and functional integrity of mRNA therapeutics.

5:30 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Particulate Impurity Analysis in Gene Therapy Products: Challenges & Opportunities

Andrea Hawe, PhD, CSO, Coriolis Pharma Research GmbH

OLIGONUCLEOTIDE THERAPEUTICS

8:25 Chairperson's Remarks

Tun Liu, PhD, Senior Principal Scientist, Biophysics, Johnson & Johnson Innovative Medicine

8:30 Comprehensive Insights into Antibody-Oligonucleotide Conjugates: Design, Developability, and *in vivo* Activity

Maximilian Hartl, PhD, Scientist & Lab Manager, Pharma Research & Early Development, Roche Diagnostics GmbH

This talk explores the multifaceted approach of combining antibody and oligonucleotide modalities, using Brainshuttle-ASO as a case study for delivering antisense oligonucleotides (ASOs) to the brain. We will discuss the design process, developability, and molecule stability. Closing with *in vivo* activity data, a holistic view of the journey from concept to practical application will be provided.

9:00 Lessons Learned during the Development of Maleimide-Conjugated ASO for Subsequent Functionalization

Zifan Li, PhD, Senior Scientist, Analytical Development, Biogen

Functionalization of therapeutic oligonucleotides by conjugating to multiple modalities may be beneficial for their efficacy or delivery. Maleimide-conjugated ASO can be easily functionalized by conjugating to thiol-bearing modalities. During the manufacturing development of such conjugates, we have encountered several difficulties, conquered them, and learned lessons. This presentation intends to share what we learned thus far.

9:30 Characterization and Reference Standards for Oligonucleotides

John P. Marino, PhD, Group Leader, Biomolecular Structure & Function Group, NIST

As emerging therapeutic and vaccine platforms, oligonucleotide-based modalities have shown great success in treating diseases and in COVID pandemic response. Defining and measuring the quality attributes of oligonucleotide-based modalities presents new analytical challenges. To this end, I will describe new measurement technologies and reference materials being developed at NIST to support analytical characterization and harmonization of methods for oligonucleotide therapeutics, from short siRNA and antisense drugs to mRNA vaccines.

CHARACTERIZATION FOR NOVEL BIOTHERAPEUTICS

Analytical Best Practices for Emerging Modalities

MAY 15-16, 2025



ANALYTICAL
STREAM

10:00 Sponsored Presentation (*Opportunity Available*)

10:30 Networking Coffee Break

OTHER NOVEL BIOLOGICS

11:00 An Effective Workflow for Assessing Domain-Specific Charge Heterogeneity in Bispecific Antibodies

Kai-Ti Chang, PhD, Scientist, Protein Biochemistry, Regeneron

Bispecific antibodies (bsAbs) have emerged as a novel therapeutic antibody format, leveraging two distinct Fab domains to directly bind multiple targets. Although this format enables bsAbs to address complex diseases, each Fab arm is differentially prone to modification, adding complexity to the charge profile. Here we present an effective workflow to characterize charge heterogeneity in bsAbs, using platform-based enrichment followed by domain-specific charge variant analysis, identity, and potency characterization.

11:30 A Cation Exchange-High Performance Liquid Chromatography (CEX-HPLC) Method for Identity and Population Characterization of Recombinant Polyclonal Antibody Therapeutics

Hongjun Yue, PhD, Director, CMC, GigaGen

Recombinant polyclonal antibodies (pAb) are a new class of therapeutics comprising over 1000 monoclonal species recognizing multiple epitopes or antigens. We developed a CEX-HPLC method to address a major hurdle in pAb manufacturing, the reliable characterization of pAb population diversity and identity. The

method generates a reproducible and unique profile for a pAb product, is sensitive to lot-to-lot variation in pAb population and can serve as a fingerprint identity assay.

12:00 pm Unlocking the Diagnostic and Therapeutic Potential of Ultrasensitive Extracellular Vesicle and Biomarker Detection using Single Molecule Detection Array (SiMoA)

Jennifer Pollock, Researcher, Biomedical Engineering, Brown University

A review of methods for isolating and characterizing EVs in order to address the challenges associated with the widespread heterogeneity in the size and composition of EVs. We will present a high-throughput single molecule detection array (SiMoA) for fast immune-phenotyping of extracellular vesicles from low-volume biofluids. The array has been used to observe changes in protein expression across different EV populations and identify key proteins associated with disease progression.

12:30 Close of Summit

IMMUNOGENICITY STREAM

Innovative Tools and Technologies for Safe and Efficacious Therapeutics



Immunogenicity assessment and management is a key consideration as drug developers seek to bring novel therapeutics through clinical testing and regulatory approvals to the market. This year's Immunogenicity Stream at PEGS Boston begins with an introductory training seminar providing a comprehensive overview of immunogenicity. New this year, the stream leads into a program wherein leading scientists will discuss the use of AI/ML for predicting immunogenicity. This program will highlight computational tools, antibody humanization, and predictive models. The stream concludes with an in-depth training seminar on bioassay design, development, analysis, validation, and monitoring. This stream gives drug developers a robust set of tools for immunogenicity management in clinical development.

IMMUNOGENICITY STREAM CONFERENCES

MAY 12-13

TRAINING SEMINAR:
**Introduction to
Immunogenicity**

[AGENDA](#)

MAY 13-14

**Predicting
Immunogenicity
with AI/ML Tools**

[AGENDA](#)

MAY 15-16

TRAINING SEMINAR:
**Bioassay
Development
and Analysis**

[AGENDA](#)



MONDAY, MAY 12, 2025 8:30 AM - 6:05 PM | TUESDAY, MAY 13, 2025 8:30 AM - 12:45 PM

Introduction to Immunogenicity

This 1.5-day training seminar provides a practical, comprehensive overview of immunogenicity—the causes, how to assess, predict, and prevent, and what to do if you observe immunogenicity during preclinical, clinical, and post-market approval. The seminar begins by detailing the science behind immunogenicity, the latest international guidance, followed by assay and bioanalytical assessment strategies for traditional and emerging biologics. Other topics include predictive models, the role of AI/ML, and reporting immunogenicity.

Instructors:



*Chloé Ackaert, PhD,
Senior Scientist,
Immunogenicity,
ImmunXperts, a Q2
Solutions Company*



*Sofie Pattijn, Founder
& CTO, ImmunXperts,
a Q2 Solutions
Company*



*Bonnie Rup, PhD,
Biotechnology Consultant,
Bonnie Rup Consulting*

Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered and solutions applied, and extensive coverage of the basic science underlying each topic. Experienced Training Seminar instructors offer a mix of formal lectures, interactive discussions, and activities to help attendees maximize their learning experiences. These immersive trainings will be of value to scientists from industry and academic research groups who are entering new fields—and to those working in supporting roles that will benefit from an in-depth briefing on a specific aspect of the industry.

Training Seminars will be held in person only. To ensure a cohesive and focused learning environment, moving between conference sessions and the training seminars is not allowed.

PREDICTING IMMUNOGENICITY WITH AI/ML TOOLS

Computational Tools Driving Drug Development Forward

MAY 13-14, 2025



IMMUNOGENICITY
STREAM

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: *In silico* and Machine Learning Tools for Antibody Design and Developability Predictions

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

TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

COMPUTATIONAL TOOLS FOR IMMUNOGENICITY ASSESSMENT AND PREDICTION

2:20 Chairperson's Remarks

Sivan Cohen, PhD, Senior Principal Scientist, Genentech



2:30 KEYNOTE PRESENTATION: Advancing Antibody and Nanobody Humanization through Computational Design

Pietro Sormanni, PhD, Group Leader, Royal Society University Research Fellow, Chemistry of Health, Yusuf Hamied Department of Chemistry, University of Cambridge

Novel approaches to antibody discovery, including computational design, require humanization methods agnostic of the antibody's source. Besides low immunogenicity, immune-system-derived antibodies have favorable *in vivo* properties like long half-life and low self-reactivity. Designing nanobodies indistinguishable from human ones is therefore important. In this talk, I will present deep learning strategies for designing and humanizing antibodies and nanobodies indistinguishable from immune-system-derived ones, using tools like AbNatiV.

3:00 Humanness and Humanization of Antibodies and **De Novo** Designed Proteins

David Prihoda, Bioinformatics Lead, MSD Czech Republic

Humanness evaluation and humanization of antibodies are well established, ranging from CDR grafting to deep learning methods. Here we present our contributions: OASis, a granular antibody humanness score, and Sapiens, a language model for antibody humanization, integrated into the open-source BioPhi web platform.

Finally, we explore whether similar principles can be applied to *de novo* designed proteins, highlighting challenges stemming from computational complexity and fundamental biological constraints.

3:30 Identifying tumor-specific antigens derived from protein translation errors

Kyle Hoffman, Applications Mgr, Applications & Service, Bioinformatics Solutions Inc



Hyperactivation of oncogenic pathways is associated with aberrant protein production. Peptides derived from cancer-specific aberrant protein production play a role in immune recognition and represent excellent therapeutic candidates. Here we identify tumor-specific antigens derived from protein translation errors that are unique to cancer cells using a mass spectrometry-based immunopeptidomics pipeline, called DeepImmu.

3:45 Sponsored presentation (*Opportunity Available*)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING



How Many New Contacts Can You Make?

Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

4:40 Antibody Immunogenicity Risk Assessment with Pep2Vec

Will Thrift, PhD, Principal Artificial Intelligence Scientist, Genentech

Epitope presentation by MHC Class II (pMHC) is a necessary condition for an immunogenic response to antibody therapeutics. Thus, high-performance pMHC models are a cornerstone for immunogenicity risk assessment. We have developed Pep2Vec, a modular, interpretable, pMHC model that achieves state-of-the-art performance on a variety of presentation and immunogenicity datasets. We will show how to use Pep2Vec to distinguish between high and low immunogenicity (human and humanized) antibody drugs.

5:10 A Library-Based Approach for Mapping and Engineering HLA-II Epitope Landscapes

Erik Procko, PhD, CSO, Cyrus Biotechnology; Adjunct Professor, University of Illinois, Urbana

Using a library-based method, HLA-II allele/epitope peptide interactions are measured at scale, and epitope landscapes are mapped to protein sequences. To engineer reduced immunogenicity, thousands of single substitutions were tested to comprehensively identify transitional mutations that switch an epitope from HLA-II binding to non-binding. While existing AI/ML algorithms are poor predictors of transitional epitopes, these data are expected to improve ML models for engineering proteins with reduced immunogenicity.

5:40 Improved Antibody-Antigen Interaction Prediction Using Inverse Folding Latent Representations

Paolo Marcatili, PhD, Head, Antibody Design, Novo Nordisk

Inverse folding (IF) and protein large language models (pLLMs) have become useful tools for antibody variant generation, with generally good performance, but limited ability to find mutations that enhance the binding to the antigen. Here, we show how IF models can be used to predict B cell epitopes, and how to extend this approach to estimate antibody-antigen interaction energy and to find mutations that increase affinity.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

PREDICTING IMMUNOGENICITY WITH AI/ML TOOLS

Computational Tools Driving Drug Development Forward

MAY 13-14, 2025



IMMUNOGENICITY
STREAM

WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (*Continental Breakfast Provided*) **Co-Organized with Thinkubator Media**



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARTs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

ENTREPRENEUR MEET-UP

Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics

Catharine Smith, Executive Director, Termeer Foundation

Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet-up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

IMMUNOGENICITY PREDICTION IN EARLY-STAGE DISCOVERY

10:20 Chairperson's Remarks

Jochem Gokemeijer, PhD, Distinguished Scientist Biologics, Biologics Discovery, Johnson & Johnson

10:25 Incorporating *in silico* Developability and Immunogenicity Assessments during Early Stage Discovery

Tony Pham, Scientist, Biologics Engineering & Developability, AstraZeneca

During early-stage discovery of antibody therapeutics it is important to consider not only target affinity but also developability attributes before selecting a lead candidate for further development. To facilitate this we have developed two tools ImmunoScreen and the InSiDe (*in silico* developability) pipeline for biologics discovery. These tools provide the ability to assess immunogenicity along with other interdependent risks such as aggregation and post-translation modification to guide lead selection.

10:55 Integrating Comprehensive *in silico* Immunogenicity Predictions into Bispecific Antibody Discovery

Stewart New, PhD, Associate Director, Antibody Discovery, Incyte

Accurate *in silico* immunogenicity predictions and effective deimmunization strategies have the potential to significantly enhance the clinical success of therapeutic large molecules. This analysis presents an integrated *in silico* examination of the immunogenicity of two bispecific antibodies, alongside clinical data on the specificity of their respective anti-drug antibody responses. It offers insights into how these tools can be effectively utilized within drug discovery pipelines.

11:25 Presentation to be Announced

11:55 Session Break

12:00 pm Luncheon Presentation (*Sponsorship Opportunity Available*) or Enjoy Lunch on Your Own

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: HLA Class II Peptide Presentation and Immunogenicity Screening of Therapeutic Antibodies with HLAIIIPred

Mojtaba Haghighatlari, PhD, Senior Machine Learning Scientist, Pfizer Inc.

- Best practices in data preparation for machine learning of peptidomics datasets
- Novel deep-learning approaches for predicting MHC antigen presentation and the modeling challenges
- Interpretability and explainability of the available deep-learning models
- New screening strategies for predicting immunogenic hotspots in therapeutic antibodies

BREAKOUT DISCUSSION: Predicting Immunogenicity with AI/ML Tools

Sivan Cohen, PhD, Senior Principal Scientist, Genentech

IN SILICO STRATEGIES FOR NEW MODALITIES

1:55 Chairperson's Remarks

Michael Gutknecht, PhD, Principal Scientist II, Novartis Pharma AG



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9:35 Coffee Break in the Exhibit Hall with Poster Viewing

PREDICTING IMMUNOGENICITY WITH AI/ML TOOLS

Computational Tools Driving Drug Development Forward

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IMMUNOGENICITY
STREAM

2:00 Computational Prediction and Experimental Verification of Human Immunogenicity in Vaccine Design and Evaluation

Alessandro Sette, PhD, Professor, Co-Director, Center for Vaccine Innovation, La Jolla Institute for Allergy & Immunology

Our group has been at the forefront of studying adaptive immune responses associated with vaccination and microbial outbreaks of new and old pathogens. Examples include SARS, pertussis, Mpox, and avian influenza. Our work is also currently directed at preparation for potential new pandemics by combining computational and experimental methods to predict immune responses to viral and bacterial families of cancer. The technology developed in these contexts is of general applicability.

2:30 Immunogenicity of Novel Modalities: *In silico* Methods and Strategies to Mitigate Immunogenicity Risk

Jochem Gokemeijer, PhD, Distinguished Scientist Biologics, Biologics Discovery, Johnson & Johnson

Novel modalities such as CAR T and gene therapy have progressed into the clinic and like other biologics, these therapies have the potential to be recognized by the human immune system, resulting in various immune responses that can compromise patient safety and the efficacy of the therapeutic. Here we will discuss the particular challenges associated with immunogenicity and these modalities and methods and strategies to assess and minimize potential immunogenic elements.

3:00 Immunogenicity Assessment in New Modality Development: T and B Epitope Prediction

Xiaobin Zhang, PhD, Associate Director, Takeda Pharmaceuticals

Biotherapeutics activate the immune system by the interactions with antigen presenting cells (APC), T cells and B cells. Identifying the immune hotspot is a critical step to deimmunize the drug candidates. In this presentation, we will introduce the factors that impact the immune response pathways, summarize the *in silico* prediction tools in immunogenicity risk assessment, and discuss multiple approaches to predict T cell and B cell epitope in drug candidate screening.

3:30 Optimizing development-ability of Antibody Therapeutics



Jesper Sorensen, Head of Scientific Development, OpenEye, Cadence Molecular Sciences

Developing an antibody from a hit or lead into a clinical candidate involves substantial optimization of the biophysical properties that affect large-scale production and long-term stability. We have developed a suite of antibody design tools in our modeling platform Orion® that assist in biophysical characterization and property optimization using a combination of physics-based simulation and AI. This talk will present some solutions to key problems in antibody design and development.

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

4:40 Machine Learning Methods for Antibody Design and Development

Philip M. Kim, PhD, Professor, Molecular Genetics & Computer Science, University of Toronto

I will cover our work on machine learning methods for antibody and protein design from both an academic and biotech perspective. Notably, I will cover our methods for *de novo* design as well as for optimization. I will cover some use-specific use cases, including optimizing developability characteristics using ML methods.

5:10 Incorporating Molecular Mimicry Features to Identify Immunogenic Hotspots in Antibody Therapeutic Sequences

Patrick Wu, MD, PhD, Senior Scientist, Genentech

In silico prediction of CD4+ T cell epitopes frequently results in numerous candidates, yet ranking these epitopes by their potential to activate naive CD4+ T cells and induce anti-drug antibodies remains challenging. Our research suggests that epitopes resembling bacterial sequences increase immunogenicity risk in antibody therapeutics. By integrating molecular mimicry characteristics into predictive models, we can better identify immunogenic hotspots, thereby enhancing the safety and efficacy of biotherapeutic development.

5:40 Analyzing and Decreasing the Immunogenicity Potential of Biotherapeutics Using *In Silico* Approaches

Michael Gutknecht, PhD, Principal Scientist II, Novartis Pharma AG

Immunogenicity potential assessment should be started as early as possible in the biotherapeutic development process to inform de-immunization approaches and to avoid resources spending on candidates with a high inherent immunogenicity potential. Oftentimes, this is only possible using *in silico* tools. In my presentation, I would like to introduce the audience to the *in*

silico-based workflow we implemented to analyze and decrease the immunogenicity potential of biotherapeutics in early development.

6:10 Prediction and Mitigation of Immunogenicity of Proteins Given via SC Route

Sathy Balu-Iyer, PhD, Professor, Pharmaceutical Sciences, SUNY Buffalo

The safety and efficacy of therapeutic proteins are undermined by immunogenicity driven by anti-drug antibodies (ADA). Proteins administered subcutaneously can suffer from enhanced immunogenic potential compared to intravenous administration. The talk will cover mechanistic insight into the subcutaneous immune response and our efforts to develop novel preclinical tools as well as a database to predict clinical immunogenicity as a human biology-based animal trial alternative.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Predicting Immunogenicity with AI/ML Tools Conference



THURSDAY, MAY 15, 2025 8:30 AM - 5:30 PM | FRIDAY, MAY 16, 2025 8:30 AM - 12:30 PM

Bioassay Development and Analysis

This course will focus on factors to be considered in the design, development, and validation of bioassays. The course introduces terminology and important statistical tools and best practices. Examples and case studies will be provided to help solidify understanding on the topics of design and development, robustness, validation, and post-validation. Relevant pharmacopeial and EUA regulations will be highlighted.



Instructor:
Steven Walfish, Owner, Statistical
Outsourcing Services

Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered and solutions applied, and extensive coverage of the basic science underlying each topic. Experienced Training Seminar instructors offer a mix of formal lectures, interactive discussions, and activities to help attendees maximize their learning experiences. These immersive trainings will be of value to scientists from industry and academic research groups who are entering new fields—and to those working in supporting roles that will benefit from an in-depth briefing on a specific aspect of the industry.

Training Seminars will be held in person only. To ensure a cohesive and focused learning environment, moving between conference sessions and the training seminars is not allowed.

EMERGING THERAPEUTICS STREAM

Innovative Solutions in Immunology, Radioligands, and Immunotherapies



The Emerging Therapeutics Stream at PEGS 2025 offers an in-depth exploration of cutting-edge advancements across three pivotal tracks. The **Biologics for Immunology Indications** track focuses on preclinical research and innovative strategies for complex immunological conditions, from autoimmunity to rare diseases, emphasizing novel therapeutic approaches and early-stage research. The **Radiopharmaceuticals Therapies** track investigates the forefront of radionuclide therapy, combining targeted molecules with radioisotopes for precise cancer treatment, addressing advancements, challenges, and clinical considerations. Lastly, the **Next Generation Immunotherapies** track covers the latest in target discovery and validation, including emerging technologies and novel targets for cancer and other diseases. Together, these tracks provide a comprehensive view of therapeutic innovations driving the future of biologic and targeted treatments.

EMERGING THERAPEUTICS STREAM CONFERENCES

MAY 12-13

Biologics for Immunology Indications

[AGENDA](#)

MAY 13-14

Radiopharmaceutical Therapies

[AGENDA](#)

MAY 15-16

Next-Generation Immunotherapies

[AGENDA](#)



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: Safety & Efficacy of Bispecifics and ADCs

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

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

MODULATING IMMUNE CHECKPOINTS AND
EFFECTOR CELLS

8:20 Chairperson's Remarks

Michael Leney-Greene, PhD, Investigator, Biology, AI Proteins

8:30 Disrupting B and T Cell Collaboration in Autoimmune Disease: T Cell Engagers versus CAR T Cell Therapy?

Venkat Reddy, PhD, Associate Professor, Rheumatology, University College London

B and T cells collaborate to drive autoimmune disease (AID). Anti-CD20 antibodies provide targeted B cell depletion (BCD), but some patients have refractory AID due to incomplete BCD. Novel therapies using T cells as effectors may disrupt B-T cell collaboration and overcome rituximab-resistant AID.

9:00 SAB03, a Highly Potent Multi-MOA mAb for the Depletion of Pathogenic T Cells in Autoimmune Diseases

Peter Emtage, PhD, CEO, Santa Ana Bio

T cell activation, essential for adaptive immunity, is tightly regulated since excessive activation can drive autoimmune diseases. Co-stimulatory molecules, such as CD28, enhance TCR signals to support immune responses, while inhibitory receptors like CTLA-4 and PD-1 limit TCR activation, preventing tissue damage. SAB03, an anti-PD-1 agonistic monoclonal antibody, features an enabled Fc domain to suppress and deplete pathogenic PD-1+ T cells, mitigating autoimmune effects.

9:30 Molecular Engineering of Interleukin-2 for Enhanced Therapeutic Activity in Autoimmune Diseases

Jamie B. Spangler, PhD, Associate Professor, Biomedical and Chemical & Biomolecular Engineering, Johns Hopkins University

The interleukin-2 (IL-2) cytokine plays an essential role in preventing the development of autoimmune disorders by supporting growth and activity of regulatory T cells (Tregs). IL-2 has great potential for autoimmune disease mitigation; however, its simultaneous stimulation of effector immune cells and short half-life limit clinical

promise. We developed cytokine/antibody fusion proteins that bias IL-2 towards Tregs while also extending half-life, leading to clinically promising therapies to treat autoimmune diseases.

10:00 Sponsored Presentation (*Opportunity Available*)

10:30 Networking Coffee Break

FcRn INHIBITION

11:00 Nipocalimab: A High-Affinity, Immunoselective FcRn Blocker as an Investigational Therapy for IgG-Driven Autoimmune and Alloimmune Diseases

Nilufer Seth, PhD, Senior Scientific Director and Head, Discovery, Autoantibody Portfolio and Maternal Fetal Disease Area, Johnson & Johnson Innovative Medicine

Nipocalimab is an immunoselective investigational therapy that lowers IgG, including pathogenic IgG which is implicated in various IgG-driven auto- and allo- antibody diseases. This investigational therapy is being evaluated across three critical disease segments: rare autoantibody—ranging from neurologic to hematologic diseases, maternal fetal immunology, and prevalent rheumatological autoantibody-driven diseases, in multiple potential indications, each with high unmet need.

11:30 Stepwise Design of a Next Generation FcRn Inhibitor Fused to an Albumin-Binder Results in Potent IgG Reduction

Vladimir Bobkov, PhD, Principal Scientist, Preclinical Product Development, argenx BVBA

Neonatal Fc receptor is a popular target for treatment of autoimmune disorders due to its role in maintaining IgG levels. Fc-ABDEG and albumin-binding VHH were combined to develop next-generation FcRn blockers with improved IgG clearance. Step-wise engineering was applied to optimize position and number of VHHs, their affinity to albumin, and the linker connecting it to Fc-ABDEG. Novel FcRn-based cellular assays and human FcRn transgenic mice will also be addressed.

12:00 pm Session Break

12:10 Luncheon Presentation to be Announced

12:40 Luncheon Presentation (*Sponsorship Opportunity Available*) or Enjoy Lunch on Your Own

1:10 Session Break

EMERGING TARGETING STRATEGIES

1:15 Chairperson's Remarks

*Joel Goldstein, PhD, Executive Director R&D, Celldex Therapeutics*1:20 Characterization of the First *de novo* Miniprotein Inhibitors of TNFR1 for the Treatment of Inflammatory Disease*Michael Leney-Greene, PhD, Investigator, Biology, AI Proteins*

Specific inhibition of TNF receptor 1 has been challenging using conventional antibody-based therapeutics, due to potentially dangerous agonistic activity. We have successfully generated *de novo* miniproteins that specifically inhibit TNFR1 but not TNFR2 with picomolar affinity *in vitro* and *in vivo*, blocking pathogenic TNF- α signaling. This work reveals a novel mechanism of action for alleviating autoimmune disease by blocking TNFR1 activity while regulatory beneficial signaling through TNFR2 remains intact.

1:50 KnotBodies: Creating Ion Channel-Modulating Antibodies by Fusing Knottins into Antibody Loops

John D. McCafferty, PhD, CTO and Founder, Maxion Therapeutics

Ion channels are an important target class which are underserved by biologics. Maxion has shown that small cysteine-rich peptides with ion-channel modulating activity can be inserted into antibody CDR loops while retaining their function. The resulting molecules modulate ion channel activity while benefitting from the optimal drug-like properties of antibodies. This presentation will illustrate the generation and optimization of KnotBody inhibitors to therapeutically relevant ion-channel targets.

2:20 Dual Inhibition of Mast Cells and TSLP for Inflammatory Disorders Using a Novel Bispecific Antibody, CDX-622

Joel Goldstein, PhD, Executive Director R&D, Celldex Therapeutics

Mast cells (MCs) play a significant role in various immune-related disorders. Their survival depends on KIT receptor activation by Stem Cell Factor (SCF). TSLP neutralization has demonstrated activity in asthma. CDX-622, a bispecific antibody, neutralized both SCF and TSLP in functional assays and resulted in MC depletion in a non-human primate study. CDX-622 offers potential benefits by targeting complementary pathways in chronic inflammation. A phase 1 clinical study is underway.

2:50 Sponsored Presentation (*Opportunity Available*)

3:20 Networking Refreshment Break

4:05 Transition to Plenary Keynote Session



PLENARY KEYNOTE SESSION

4:15 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research and Macovski Professor of Bioengineering, Stanford University



4:25 The Role of Protein Engineering in Developing New Innovative Modalities

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE



5:10 Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade

Jessica C. Stark, PhD, Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

5:55 Welcome Reception in the Exhibit Hall with Poster Viewing



YOUNG SCIENTIST MEET-UP

Co-Moderators:



Iris Goldman, Production, Cambridge Innovation Institute
Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC
Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists: IN-PERSON ONLY

8:30 Chairperson's Remarks

Nilufer Seth, PhD, Senior Scientific Director and Head, Discovery, Autoantibody Portfolio and Maternal Fetal Disease Area, Johnson & Johnson Innovative Medicine



8:35 KEYNOTE PRESENTATION: Modulating Inflammation through Cytokine Engineering

Jeffrey A. Hubbell, PhD, Professor, Chemical and Biomolecular Engineering, New York University

The immune system exists in a delicate balance of mounting effector responses to pathogens while existing in an active state of tolerance to self. We are developing approaches for targeting inflammatory cytokines as well as chemokines to the tumor microenvironment and for targeting anti-

inflammatory cytokines to the lymph nodes that drain sites of inflammation. These, respectively, show promise in mouse models of solid tumors and of autoimmune conditions.

BIO-THERAPEUTICS FOR UNMET AND UNDERSERVED MEDICAL NEEDS

9:05 An Oral Antibody for Inflammatory Bowel Disease

James T. Koerber, PhD, Distinguished Scientist and Director, Antibody Engineering, Genentech, Inc.

Existing IBD therapeutics exhibit high costs, systemic safety risks, and require injections. Here, we present a workflow to develop oral VHHs via simultaneous optimization of the affinity and protease stability. This oral VHH matches the efficacy of an injected antibody in a murine colitis model and exerts a strong pharmacodynamic effect in non-human primates. With high potency, gut stability, and favorable developability, oral VHHs offer a promising approach for IBD.

9:35 DONQ52 Multispecific Antibody against HLA-DQ2.5/ Gluten Peptide Complex for Celiac Disease

Noriyuki Takahashi, Director, Lead Identification, Chugai Pharmabody Research Pte Ltd.

Complex of HLA-DQ2.5/gluten peptides elicits gluten-specific CD4+ T cells activation in celiac disease patients. DONQ52 is a novel multispecific antibody aimed to bind cross-reactively to multiple gluten peptide-loaded HLA-DQ2.5. DONQ52 has potential to neutralize immune response to gluten. Here we introduce antibody engineering strategy, including lead identification and lead optimization as well as broad reactive characteristics of DONQ52.

10:05 Sponsored Presentation (Opportunity Available)

10:35 Coffee Break in the Exhibit Hall with Poster Viewing



11:15 Post-Translational Modified Insulin Neopeptides—Potential New Precision Targets in Type 1 Diabetes Diagnosis and Treatment

Ahuva Nissim, PhD, Professor, Antibody and Therapeutic Engineering, William Harvey Research Institute, Queen Mary University of London

Antibodies specific to oxidative post-translational modifications (oxPTM) of insulin (oxPTM-INS) are present in most individuals with Type 1 diabetes (T1D), even before the clinical onset. We then observed antibody response to three oxPTM-INS neopeptide peptides (oxPTM-INSP) and evaluated their ability to stimulate both



humoral and T cell responses in T1D. oxPTM-INS neo-antigenic epitopes, may be involved in the immunopathogenesis of Type 1 diabetes and potentially become targets for precision medicine.

11:45 Targeting the Undruggable: Identification and Early Development of Succinate-Modulating Therapies

Isabel Huber-Ruano, PhD, Scientific CEO and Co-Founder, Succipro SL

Our company is pioneering a first-in-class therapy targeting succinate, a metabolite elevated in many metabolic and inflammatory disorders. Traditionally considered undruggable, we are developing a diversified pipeline to block or degrade succinate. This talk will highlight our progress, from initial identification using specialized *in silico* approaches, to promising *in vivo* efficacy results, demonstrating potential therapeutic benefits for addressing these chronic conditions.

12:15 pm Sponsored Presentation (*Opportunity Available*)

12:45 Session Break

12:50 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Enjoy Lunch on Your Own**

1:50 Close of Biologics for Immunology Indications Conference

6:30 Recommended Dinner Short Course

SC5: Targeting the Target: Aligning Target and Biologic Format Biology to Achieve Desired Outcomes

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



TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

THE OUTLOOK AND PROMISE OF RADIOPHARMACEUTICAL THERAPIES

2:20 Chairperson's Remarks

Joseph Vacca, Vice President Solutions, RLT, Perceptive Imaging



2:30 KEYNOTE PRESENTATION: Can Radiopharmaceuticals Overcome Cancer Evasiveness?

Elcin Zan, MD, Chair, Nuclear Medicine, Imaging Institute, Cleveland Clinic

Radiopharmaceuticals offer a promising approach in cancer treatment by emitting a range of particle radiation that targets cancer cell DNA while minimizing damage to healthy cells. Utilizing the Theranostics approach for real-time imaging, radiopharmaceuticals can be truly personalized and adjusted based on the cancer's response. Combination therapies for immune response augmentation are under development and aim to overcome cancer's adaptive evasiveness and resistance mechanisms.

3:00 PANEL DISCUSSION: State-of-the-Industry Panel Discussion: The Coming-of-Age of Radiopharmaceutical Therapies

Moderator: Frank Comer, PhD, Director, Tumor Targeted Delivery, Early Oncology R&D, AstraZeneca

- Investment trends and M&As
- Beyond PSMA, NETS and thyroid cancer
- Dosing and sequencing considerations
- Production and supply chain challenges
- Regulatory guidance reimbursement

Panelists:

Elcin Zan, MD, Chair, Nuclear Medicine, Imaging Institute, Cleveland Clinic

Daniel Yokell, Vice President, Theranostic NeuroOncology, Telix Pharmaceuticals Ltd.

Phillip Kuo, M.D., Ph.D., F.A.C.R., Division Chief, Nuclear Medicine, Department of Diagnostic Radiology, City of Hope Cancer Center

3:30 Sponsored Presentation (Opportunity Available)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING



How Many New Contacts Can You Make?

Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

BENCH-TO-BEDSIDE TRANSLATION

4:40 Presentation to be Announced

5:10 Targeting Strategies and Isotope Selection in Cancer Therapy

John Babich, PhD, Co-Founder, Ratio Therapeutics

Radioligand therapy (RLT) is experiencing a dramatic renaissance in modern medicine. The recent approvals of Xofigo, Lutathera, and Pluvicto have transformed this once-niche field into an area of intense scientific and commercial interest. Successful RLT with an optimal therapeutic index requires the careful application of several key principles. This presentation will explore the fundamental elements necessary for developing effective and safe radioligand therapies.

5:40 From DNA-Encoded Chemistry to ACP3-Targeted Radioligand Therapeutics against Prostate Cancer

Sebastian Oehler, Research Scientist, Small Molecule Therapeutics, Philochem AG

In contrast to Prostate-Specific Membrane Antigen (PSMA), Prostatic Acid Phosphatase (ACP3) is virtually absent in healthy organs but highly expressed in prostate cancer. We used DNA-encoded chemical libraries to identify highly potent ACP3 ligands which selectively accumulated in ACP3-positive tumor lesions in mice—with curative effects at low and well-tolerated 177Lu doses. Our clinical candidate, OncoACP3, may overcome current limits of PSMA-based ligands for pharmacodelivery applications in prostate cancer patients.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC7: Nuts and Bolts of Building a Radiopharmaceutical Therapy Agent

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

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (Continental Breakfast Provided) Co-Organized with Thinkubator Media



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto



8:50 Ex vivo and in situ Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARTs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely



resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP
Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics
Catharine Smith, Executive Director, Termeer Foundation
Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet up. Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

10:20 Chairperson's Remarks

Sean Carlin, PhD, Principal Scientist, Scientific & Medical Services, Perceptive Inc.



10:25 KEYNOTE PRESENTATION: Keys to the Success of Radiopharmaceutical Therapy

George Sgouros, PhD, Professor & Director, Radiological Physics Division, Department of Radiology, Johns Hopkins University School of Medicine

Radiopharmaceutical Therapy (RPT) is generally defined as "The delivery of radioactive atoms to tumor associated targets." (Sgouros, Nat Rev Drug Discov. 2020). Use of radioactive atoms as the cytotoxins is key to the success of RPT. The presentation will expand on the idea that, although logistically burdensome, optimization via imaging, dosimetry and pharmacokinetics in humans holds the key to success of this treatment modality.

10:55 Challenges and Pitfalls in Design of Next-Generation Radiopharmaceutical Therapies

Daniel Stevens, CMO, Blue Earth Therapeutics Ltd

Creation of another "me-too" agent is no longer good enough, nor is a development program that does not directly address positive differentiation early on. Radiopharmaceuticals offer unique opportunities to address these issues. The talk will explore strategies to address both structured design of better agents, and on options for development programs to de-risk new agents

11:25 PANEL DISCUSSION: Isotope Selection, Acquisition, and Production—Challenges and Opportunities

Moderator: Sean Carlin, PhD, Principal Scientist, Scientific & Medical Services, Perceptive Inc.

Panelists:

Shaemus Gleason, Executive Vice President, Clarity Pharmaceuticals
Kevin Haehl, Chief Product Officer, Nusano

11:55 Session Break

12:00 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

CLINICAL ADVANCES

1:55 Chairperson's Remarks

Shaemus Gleason, Executive Vice President, Clarity Pharmaceuticals

2:00 Clinical Update on CONV01-Alpha—An Ac-225 Containing Radioantibody Targeting PSMA

Philip W. Kantoff, MD, Co-Founder & CEO, Convergent Therapeutics

PSMA is a validated cancer target in metastatic CRPC. Use of an alpha emitter as a radionuclide and a high affinity monoclonal antibody offers the promise of improved potency and accuracy of PSMA-targeted therapy. 225Ac-J591 has been evaluated for safety and efficacy in academic investigator-initiated trials with promising results. CONVERGE-01 is an industry-sponsored study of CONV01-alpha (225Ac-J591) in patients with progressive PSMA PET-positive CRPC. Enrollment began in August 2024.

2:30 Redefining Radiopharmaceuticals: An Innovative Pipeline

Pamela Habib, MD, CMO, Therapeutics, Telix Pharmaceuticals Ltd.

Telix is a therapeutic radiopharmaceutical company, committed to precision oncology. Our theranostic pipeline focuses on critical unmet medical need in urologic oncology, neuro-oncology, musculoskeletal oncology, and hematology. For each target we develop a radiodiagnostic imaging agent, along with a therapeutic candidate, including beta and alpha therapies. Our objective is to bring to market first-in-class or best-in-class theranostics by selecting isotopes and targeting agents that are tailored to each clinical application.

3:00 [18F]FAPI-74 PET in Gastrointestinal Cancers—Addressing an Unmet Need

Sherly Mosessian, PhD, CSO, SOFIE

Fibroblast Activation Protein has emerged as a promising target of radiopharmaceuticals in imaging and therapy. Here we discuss the current state of FAP targeting for imaging in gastrointestinal cancers. In addition, we will highlight the latest clinical development and regulatory efforts with [18F]FAPI-74 in the United States.

3:30 Developing a Radiopharmaceutical Clinical Operations Strategy - Trials and Tribulations

Lauren Creeden, Head of Clinical CMC Execution, Clarity Pharmaceuticals

Developing a radiopharmaceutical clinical operations strategy presents unique challenges and opportunities. This talk explores the intricacies of designing and executing clinical trials in this complex field, highlighting common obstacles such as regulatory hurdles, logistical constraints, and patient recruitment in specialized populations. It also discusses innovative approaches and best practices to streamline operations and enhance collaboration across multidisciplinary teams.



4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

TARGETING MECHANISMS— ANTIBODIES & BEYOND

4:40 Self-Assembling and Disassembling Bispecific Fusion Proteins for Pretargeted Radioimmunotherapy: Preclinical Perspectives and Trials in Progress

Norman D. LaFrance, MD, Chief Development Officer, Y mAbs Therapeutics Inc.

Investigational approaches to pretargeted radioimmunotherapy (PRIT) are designed to optimize the delivery of cytotoxic radiation to tumors, whilst limiting exposure to normal “off-target” tissues. Here, we’ll present the scientific rationale and preclinical evidence supporting the clinical development of self-assembling and disassembling bispecific fusion proteins used in two-step PRIT for the treatment of solid and hematological malignancies.

5:10 Bicycle-Radionuclide Conjugates

Monika Maciuszek, PhD, Sr Scientist, Peptide Medicinal Chemistry, Bicycle Therapeutics

Bicycle molecules are novel molecules formed by constraining short linear peptides into a stabilized bi-cyclic structure using a central chemical scaffold. Using Bicycle’s proprietary phage platform, *de novo* binders to important targets can be identified with ideal properties for radioisotope delivery. Bicycle Radionuclide Conjugates (BRCs) contain a Bicycle molecule targeted to a specific tumor antigen and a highly potent radioisotope, making BRC molecules potentially suited to cancer imaging and therapy.

5:40 Affibody Molecules as Engineered Carriers in Molecular Radiotherapy with Tezatabep Matraxetan for PET Patient Selection & ABY-271 for Beta Radioligand Therapy

Fredrik Frejd, PhD, CSO, Affibody AB

Affibody molecules are minimized protein domains with very high tumor-targeting capacity as demonstrated in recent trials with HER2 targeting tezatabep matraxetan in patients with metastatic breast cancer. This HER2 binder has in recent development been engineered for reduced kidney uptake and improved tumor load resulting in a radiotherapeutic drug which is currently in late IND-enabling studies. Preclinical development and theranostic patient selection will be discussed.

6:10 Utilizing the Potential of CXCR4-Targeting Radiotheranostics in Oncology and Beyond

Lisa Kalfhues, PhD, Scientific Program Manager, Pentixapharm

Increased expression of CXCR4 has been observed in benign adrenal tumors and in over 20 malignant cancers. Our clinical pipeline includes PentixaTher, a Yttrium-90 based therapeutic, and PentixaFor, a Gallium-68 based companion diagnostic. We will present how we are using both as a theranostic pair in oncology and highlight the potential of PentixaFor outside of oncology as a diagnostic tool for primary aldosteronism (PA), an important cause of hypertension.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Radiopharmaceutical Therapies Conference



SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: Solid Tumors: Challenges and Therapeutic Innovations

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

TUESDAY, MAY 13

6:30 pm Recommended Dinner Short Course

SC5: Targeting the Target: Aligning Target and Biologic Format Biology to Achieve Desired Outcomes

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

IN VIVO CAR T ENGINEERING: MOVING INTO THE CLINIC

8:25 Chairperson's Remarks

Adrian Bot, MD, PhD, CSO, Executive Vice President, R&D, Capstan Therapeutics

8:30 *In vivo* Generation of CAR T and NK Cells Utilizing an Engineered Lentiviral Vector

Philip R. Johnson, MD, CEO, Interius Biotherapeutics

Current CAR T cell therapy often involves extracting and engineering T cells outside the body. This study explores *in vivo* generation of CAR T cells. This approach aims to create CAR T cells directly within a patient, potentially leading to improved therapeutic outcomes in immuno-oncology (IO) by overcoming limitations associated with *ex vivo* manipulation.

9:00 *In vivo* Engineering of Immune Cells: Update from Umoja Biopharma

David J. Fontana, PhD, Chief Business and Strategy Officer, Umoja BioPharma

9:30 KEYNOTE PRESENTATION: *In vivo* and *ex vivo* Use of LNP-Mediated Technology to Treat Hematological Disorders

Stefano B. Rivella, PhD, Professor, Pediatrics, Children's Hospital of Philadelphia

Current therapies allow the replacement of diseased hematopoietic stem progenitor cells (HSPC) with gene-engineered or healthy HSPC through bone marrow transplantation. However, current protocols have major side effects and limited access. Starting from conventional *ex vivo* technologies, we will discuss how the use of targeted lipid nanoparticles (tLNP) carrying messenger RNA (mRNA) can target HSPC and revolutionize the way we perform bone marrow transplantation or directly cure HSPC *in vivo*.

10:00 Advancing Bispecific Antibody Development: Overcoming Challenges with Innovative Solutions for Target Binding and Functional Assessment

Speaker to be Announced, Sartorius

Bispecific antibodies (BsAbs) are therapeutic antibodies targeting different antigens or epitopes, enhancing potency and therapeutic effects. Various constructs, like scFv, DARTs, Triomabs, and BiTEs, are being developed for diseases like cancer. Their diverse designs may face structural constraints affecting binding and performance. A major challenge is the lack of technologies for quantitative functional assessment of BsAbs' dual targets, necessitating innovative approaches beyond traditional monoclonal antibodies. This talk will present solutions for efficient biophysical and functional characterization of BsAbs in development.

10:15 Presentation to be Announced

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

SARTORIUS

KACATUS

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BiolImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

NEXT-GENERATION IMMUNOTHERAPIES: IN VIVO APPROACHES

1:55 Chairperson's Remarks

Hamideh Parhiz, PharmD, PhD, Research Assistant Professor, Infectious Diseases, University of Pennsylvania

2:00 *In vivo* mRNA-Based CAR T Cell Engineering for Treatment of B Cell Disorders

Adrian Bot, MD, PhD, CSO, Executive Vice President, R&D, Capstan Therapeutics

We developed a novel *in vivo* anti-CD19 CAR mRNA product (CPTX2309), delivered through CD8-targeted lipid nanoparticles (tLNP). Evaluation in non-human primates speaks to the potential of this platform to achieving immune reset, key to effectively treating B cell-autoimmunity. This sets up the stage for clinical development of CPTX2309 and opens an avenue for development of similar products for broad indications, overcoming the challenges of *ex vivo* viral-engineered CAR T cells.

2:30 Engineering Macrophages for Cancer and Fibrosis: Cell Therapy and Direct *In vivo* Reprogramming

Michael Klichinsky, PharmD, PhD, Co-Founder & CSO, Carisma Therapeutics

Current cancer immunotherapy struggles to harness the full potential of macrophages. This study explores innovative methods



to engineer macrophages for tumor destruction and fibrosis. Investigating CAR M (Chimeric Antigen Receptor Macrophages) and *in vivo* reprogramming, the research proposes a revolutionary approach to rewire macrophages, leveraging their abilities to fight cancer.

3:00 mRNA Delivered *In Vivo* CAR for Myeloid Cells to Combat Solid Tumors

Yuxiao Wang, PhD, Co-Founder & Vice President, Discovery Research, Myeloid Therapeutics

We introduce a novel class of innate immune receptor-based CARs designed to program myeloid cells *in vivo* using mRNA/LNP, overcoming limitations of current CAR therapies in solid tumors. Preclinical data demonstrate robust anti-tumor efficacy, leading to the initiation of first-in-human clinical trials for TROP2 and GPC3-targeting CARs, highlighting significant potential for advancing cancer immunotherapy.

3:30 Sponsored Presentation (*Opportunity Available*)

4:00 Networking Refreshment Break

4:30 Increasing the Availability of CAR T Cells

Frederic B. Thalheimer, PhD, Molecular Biotechnology & Gene Therapy, Paul Ehrlich Institut

This presentation focusses on two upcoming strategies facilitating CAR T cell generation. Short-term CAR T cells accelerate production times but may bear an increased risk for severe cytokine release syndrome. *In vivo* CAR T generation relies on T cell-specific vectors as off-the-shelf product while proof for clinical benefit remains to be provided.

5:00 Engineering Chimeric Antigen Receptor for mRNA CAR T

Huan Yang, PhD, Associate Principal Scientist, Discovery Biologics, Merck & Co. Inc.

Tonic signaling from CAR expression is proposed to be associated with CAR T exhaustion. Our study describes an *in vitro* model for investigating tonic signaling in mRNA CAR T cells, which has not been fully characterized. Among approximately 80 tested permutations of structural elements, a few optimal CAR designs

showed improved antigen-dependent T cell immune responses *in vitro*. Additionally, several formats of mRNA were also evaluated for CAR expression persistence.

5:30 Adaptive Protein Evolution X-attention (APEX) Model for Augmented CAR Discovery

Jenny Wei, PhD, Senior Director, R&D Informatics and Technology, Kite Pharma

To improve the efficiency of design and development of CAR constructs, we built the APEX model by fine tuning protein-language model ESM2 with a dataset comprised of binder (scFv, Fab, and VHH) and antigen pairs curated from the Structural Antibody Database. The model achieved robust performance on affinity prediction and can be expanded for other property prediction. Model adoption into CAR campaign facilitates binder prioritization to reduce discovery cycle time.

6:00 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: ML to Optimize Immune Cell Engagers

Winston Haynes, PhD, Head, Data Science & Machine Learning, LabGenius Ltd.

COMPUTATIONAL AND ML APPROACHES TO T CELL ENGAGERS

8:25 Chairperson's Remarks

Caleb A. Lareau, PhD, Assistant Professor, Memorial Sloan Kettering Cancer Center

8:30 Next-Generation Immunotherapies Unlocked via

Petabyte-Scale Analyses

Caleb A. Lareau, PhD, Assistant Professor, Memorial Sloan Kettering Cancer Center

The accumulation of biological data, including DNA sequencing data in the Sequence Read Archive (SRA) and protein structures in the Protein Data Base (PDB) are the primary substrates underlying recent advances in the use of artificial intelligence in biological systems. Here, we present our lab's recent work on both mining and extrapolating from these repositories of petabyte-scale data, including our identification of potential new modalities for immunotherapy.

9:00 FEATURED PRESENTATION: AI Approaches for Developing New Immunotherapies

Alexander J Martinko, PhD, Director, Antibody Engineering & Design, Cartography Biosciences Inc

T cell engagers (TCEs) have emerged as a promising therapeutic approach for solid tumors. Clinical data with TCE show T cell infiltration into "cold" CRC tumors. Highly specific tumor targets will enable efficacy. Using our ATLAS platform, we identified LY6G6D as the most promising CRC target: high tumor specificity, surface stability, and persistence in both primary and metastatic CRC. Accordingly, we engineered a best-in-class TCE-targeting LY6G6D.

9:30 Bispecific T Cell Engager Targeting a Novel pHLA Target

Ryan L. Stafford, PhD, Executive Director, Protein Engineering, 3T Biosciences Inc.

T cells recognize intracellular targets presented by HLA to enable potent anti-tumor immune responses, and these targets can be leveraged to generate off-the-shelf therapeutics using T cell-bispecific engagers to treat a broad patient population. We've developed 3T-TRACE to rapidly identify the antigens of orphan T cells from patient tumors and 3T-PRIME, a TCR mimetic platform to rapidly generate potent and specific binders for therapeutic development.

10:00 Sponsored Presentation (*Opportunity Available*)

10:30 Networking Coffee Break

11:00 A Novel T Cell Engager Platform Empowering Innovative and Effective Immunotherapies

Ahmet S. Vakkasoglu, PhD, Associate Director, Biologics Discovery and Innovation, Cue Biopharma

Immuno-STATs represent a Fc fusion molecules capable of engaging, activating, and amplifying disease-specific T-cells. Our leading clinical candidate, CUE-101, specifically targets HPV E7-specific T cells and has shown remarkable efficacy in patients



with advanced head and neck cancer. With this clinical success and our platform's proven safety, we introduce the Immuno-STAT platform. It enables the targeting of various tumor types in addition to AI applications.

11:30 Non-Pathogenic *E. coli* Displaying Decoy-Resistant IL18 Mutein Boosts Antitumor and CAR NK Cell Responses

Jiahe Li, PhD, Assistant Professor, Biomedical Engineering, University of Michigan

The tumor microenvironment can inhibit the efficacy of cancer therapies through mechanisms such as poor trafficking and exhaustion of immune cells. To address this challenge, we exploited the safety, tumor tropism, and ease of genetic manipulation of non-pathogenic *Escherichia coli* to deliver key immune-activating cytokines to tumors via surface display on the outer membrane of *E. coli* K-12 DH5a.

12:00 pm Cancer-Specific Targeting of Vesicular Stomatitis Virus

Kepeng Wang, PhD, Assistant Professor, Department of Immunology, University of Connecticut

Oncolytic viral therapies for cancers are frequently limited to intralesional injection due to non-specific localization of systemically injected viral particles. We developed a modified vesicular stomatitis virus (VSV) that harbors tumor-activating moiety. This novel virus preferentially distributes to tumor tissues and showed enhanced safety compared to wild-type VSV. When incorporated with a single chain, biologically active interleukin-12 (IL-12)—the novel virus mounts effective control against tumor growth.

12:30 Close of Summit

MACHINE LEARNING STREAM

Technological Advancements Driving Drug Development Forward



The Machine Learning stream at PEGS Boston in 2025 brings together scientists at the intersection of technology, data, and biotherapeutics. This stream will feature cutting-edge research across three key areas of drug development. The stream's opening program will highlight machine learning approaches for protein engineering, including prediction, discovery, design, and optimization. The stream will then hone in on computational tools and AI/ML for immunogenicity prediction. Finally, the stream will move to the ML and Digital Integration in Biotherapeutic Analytics program to explore how digital tools and AI are transforming data integration, validation, and analysis across discovery, development, and clinical stages. The stream as a whole offers a walkthrough of how ML/AI, simulation, and computational tools are being leveraged to drive drug development forward.

MACHINE LEARNING STREAM CONFERENCES

MAY 12-13

**ML and Digital
Integration in
Biotherapeutic
Analytics**

[AGENDA](#)

MAY 13-14

**Predicting
Immunogenicity
with AI/ML Tools**

[AGENDA](#)

MAY 15-16

**Machine Learning
Approaches
for Protein
Engineering**

[AGENDA](#)

ML AND DIGITAL INTEGRATION IN BIOTHERAPEUTIC ANALYTICS

Best Practices for Implementing and Optimizing Big Data Tools in the Analytical Function

MAY 12-13, 2025



MACHINE
LEARNING
STREAM

SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: *In silico* and Machine Learning Tools for Antibody Design and Developability Predictions

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

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

TOOLS AND MODELS FOR ANALYTICAL SCIENTISTS

8:20 Chairperson's Remarks

Kadina Johnston, PhD, Senior Specialist, Discovery Biologics, Merck & Co., Inc.

8:30 Enhancing Laboratory Analysis with Generative AI-Based Chatbot

Michail Vlysidis, PhD, Senior Engineer, AbbVie

The integration of advanced technologies such as large language models (LLMs) and generative AI has the potential to revolutionize laboratory analysis. We present a novel approach to enhancing laboratory information management systems (LIMS) through the integration of a knowledge-driven chatbot powered by LLMs. The chatbot is designed to provide specialized and tailored assistance to scientists, streamlining their workflow and improving overall efficiency.

9:00 Democratizing Data Analysis through Automation

Sara Byers, PhD, Principal Scientist, Quantitative Sciences & Digital Transformation, Bristol-Myers Squibb

Substantial data analysis is routinely performed to support critical decisions and filings. The process from analysis to reporting results requires time-consuming and repetitive manual effort. We will share our insights on scripted add-ins developed to take this process from hours to seconds. These tools can be distributed to empower scientists, increase development speeds, reduce human error, and streamline workflows, allowing us to focus on more strategic and innovative activities.

9:30 An Introduction to Machine Learning Lifecycle Ontology and Its Applications

Milos Drobnjakovic, Research Associate, Systems Integration, NIST

Machine Learning (ML) shows promise in drug discovery and manufacturing, but its effective utilization faces hurdles including traceability, regulatory requirements, interoperability of related tools, model understanding, cross-organization collaborations, and dataset/model reuse. To address these, we introduce ML Lifecycle Ontology (MLLO) as a standard for capturing ML lifecycle metadata. A MLLO-based prototype tool, ML Lifecycle Explorer (MLLE), will be demonstrated. Finally, we discuss future work that integrates MLLO with domain knowledge.

10:00 From Data Capture to ML: Real-World Solutions to ML Integration Hurdles



Jana Hersch, Head of Corporate Scientific Engagement, Genedata

Integrating machine learning (ML) in biotherapeutic analytics is a transformative journey poised to revolutionize drug development. It requires high-quality data, technological advancements coupled with scalability, and interdisciplinary collaboration. This talk will showcase four real-world examples of biopharma companies tackling strategic challenges in ML integration: bridging digitalization gaps in chromatography, automating HT mass spectrometry workflows, validating automated NGS analysis, and using ML-derived developability data in discovery workflows.

10:30 Networking Coffee Break

11:00 Analytical Toolkit for Structural Characterization with Mass Spec

Simon Letarte, PhD, Director, Extended Structural Characterization, Gilead Sciences Inc.

Protein characterization with mass spectrometry involves a series of tools. Most labs will have some Orbitraps and QTOFs. Methods include reduced and non-reduced peptide maps, intact and subunit mass, and a few native MS methods such as native SEC and native CEX. Multidimensional chromatography to achieve complex separations and use salt-based methods on a mass spectrometer. It is desirable to have a cross-platform data processing suite and in-house software tools.

11:30 Predicting Subvisible Particle Formation of Monoclonal Antibodies Using Quartz Crystal Microbalance with Dissipation

Yibo Wang, PhD, Postdoctoral Fellow, Machine Learning, AstraZeneca

The occurrence of subvisible particles (SVPs) in monoclonal antibody (mAb) development presents challenges in assessing product stability. This study utilizes quartz crystal microbalance with dissipation (QCM-D) *in silico* and experimental physicochemical properties to investigate SVP formation risks associated with various containers and stress types. MAb adsorption kinetics were found to strongly correlate with SVP propensity in the stirring study, and *in silico* predictors significantly improved all model performance.

12:00 pm Session Break

12:10 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:10 Session Break

1:15 Chairperson's Remarks

Simon Letarte, PhD, Director, Extended Structural Characterization, Gilead Sciences Inc.



1:20 KEYNOTE PRESENTATION: AI in Biopharmaceutical Development: What Could Go Wrong?

Christopher P. Calderon, PhD, Associate Research Professor, Chemical and Biological Engineering, University of Colorado

This presentation presents an overview of recent practical challenges associated with designing and using data-driven algorithms in pharmaceutical development and process analysis.

USE CASES OF AI AND DIGITIZATION IN ANALYTICAL DEVELOPMENT

1:50 Leveraging Internal Datasets and Machine Learning to Design Better Biologics

Kadina Johnston, PhD, Senior Specialist, Discovery Biologics, Merck & Co., Inc.

High-quality datasets are key to successful biologics design and pre-developability prediction. Automated collection and curation of pre-developability data from electronic lab notebooks enables rapid

ML AND DIGITAL INTEGRATION IN BIOTHERAPEUTIC ANALYTICS

Best Practices for Implementing and Optimizing Big Data Tools in the Analytical Function

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retraining and testing of predictors, and it has also been used to direct model-focused data-collection efforts. Furthermore, we use internal data to augment and validate models trained on publicly available datasets, increasing the impact of these models by improving their predictivity on internal assays.

2:20 Modular Multi-Objective Optimization Methods for Engineering Functional Proteases with High Therapeutic Potential

Jung-Eun (June) Shin, PhD, Machine Learning Scientist, Seismic Therapeutic

The development of biologic therapeutics is an exacting process, from discovery of a protein with desired function to optimizing for developability. To accelerate this process, we develop a modular multi-objective optimization method that synergistically harnesses deep learning and statistical models combined with structure-based and data-driven rational design. We apply this method to engineer immunoglobulin degrading proteases as potential therapeutics with desired target specificity and potency, low immunogenicity, and favorable manufacturability.

2:50 Maximize AI Potential in Biologics Discovery and Development: From Model Training to Consumption

Nicola Bonzanni, Founder & CEO, ENPICOM

We will discuss the key challenges in creating and deploying machine learning for biologics discovery. While creating complex models for discovery and development is becoming commonplace, managing the entire ML model lifecycle is essential for effective use in therapeutic research and maximizing AI investment returns. Discover how a unified platform can streamline AI use in biologics discovery, from model training to consumption.

3:20 Networking Refreshment Break

4:05 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:15 Plenary Keynote Introduction

Jennifer R. Cochran, PhD, Senior Associate Vice Provost for Research and Macovski Professor of Bioengineering, Stanford University



ENPICOM
DECODING THE BIOMOLECULAR SYSTEM



4:25 The Role of Protein Engineering in Developing New Innovative Modalities

Puja Sapra, PhD, Senior Vice President, Head R&D Biologics, Engineering and Oncology Targeted Discovery, AstraZeneca

Advances in protein engineering technologies have revolutionized biologics design, paving the way for new innovative drug modalities. This talk will highlight key advancements in the field of protein engineering that have enabled these new modalities to enter the clinic and provide benefit to patients. The talk will also explore the impact of machine learning-enabled deep screening technology on hit identification, lead optimization, and development of antibody-based therapies.

YOUNG SCIENTIST KEYNOTE



5:10 Antibody-Lectin Chimeras for Glyco-Immune Checkpoint Blockade

Jessica C. Stark, PhD, Underwood-Prescott Career Development Professor, MIT

Despite the curative potential of cancer immunotherapy, most patients do not benefit from treatment. Glyco-immune checkpoints—interactions of cancer glycans with inhibitory glycan-binding receptors called lectins—have emerged as prominent mechanisms of resistance to existing immunotherapies. I will describe development of antibody-lectin chimeras: a biologic framework for glyco-immune checkpoint blockade that is now moving toward the clinic.

5:55 Welcome Reception in the Exhibit Hall with Poster Viewing



YOUNG SCIENTIST MEET-UP

Co-Moderators:



*Iris Goldman, Production, Cambridge Innovation Institute
Garrett Rappazzo, PhD, Scientist, Platform Technologies, Adimab
Julie Sullivan, Production, Cambridge Innovation Institute*

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

MENTORING MEET-UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship



Carter A. Mitchell, PhD, CSO, Purification & Expression, Kemp Proteins, LLC

Deborah Moore-Lai, PhD, Vice President, Protein Sciences, ProFound Therapeutics

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists: IN-PERSON ONLY

CHALLENGES AND SOLUTIONS

8:30 Chairperson's Remarks

Michail Vlysidis, PhD, Senior Engineer, AbbVie

8:35 Streamlining Science: The Role of the Digitally Enabled Scientist

Brett Rygelski, Scientist, Pharmaceutical Sciences, Pfizer

Explore the benefits of being a hybrid scientist in my journey from bench scientist to digital practitioner. Discover how digital skills empower the creation of quick, effective solutions, reducing reliance on external experts and manual processes. Learn about the future impact these tools have on portfolio progression through regulatory filings. Understand the importance of fostering digital development opportunities for future scientists.

ML AND DIGITAL INTEGRATION IN BIOTHERAPEUTIC ANALYTICS

Best Practices for Implementing and Optimizing Big Data Tools in the Analytical Function

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9:05 Empowering Hybrid Scientists: Bridging Lab Expertise and Data Science, a Case Study of Developing an Automated ELN Data Quality Monitoring Tool

Dan (Cassie) Liu, Principal Statistician, Bristol Myers Squibb

Jason Parent, Scientist, Bioassay Development, Bristol Myers Squibb

This presentation explores the benefits of strategic partnership between the Quantitative Science & Digital Transformation team and the Bioassay Center of Excellence to foster skills of the future at Bristol Myers Squibb. We will share insights on the trainings, rotation experience, key learnings, and projects undertaken. The development of an automated ELN data-quality monitoring tool highlighting the importance of interdisciplinary collaboration in modern research will be presented.

9:35 Digital Transformation of Bioprocess Development Labs

Diana Bowley, PhD, Associate Director, CMC Data & Digital Strategy, Bioprocess Development, AbbVie, Inc.

Bioprocess development groups face challenges with complex modalities, faster development cycles, and more experimental data from HT and PAT technologies. Historically, lab experimental data is dispersed in many different instrument-software and unstructured-files formats requiring substantial manual data-manipulation efforts for experimental insights, decision-making, process-modeling, and tech transfer. Here we will share our journey to build and deploy a fit-for-science digital ecosystem within our bioprocess development labs.

10:05 Sponsored Presentation (Opportunity Available)

10:35 Coffee Break in the Exhibit Hall with Poster Viewing



11:15 Predicting Viscosity in Concentrated Antibody Solutions Using Machine Learning and Large-Scale Datasets

Pin-Kuang Lai, PhD, Assistant Professor, Chemical Engineering and Materials Science, Stevens Institute of Technology

We measured the viscosity of a large panel of 229 mAbs to develop predictive models for high-concentration screening. We developed DeepViscosity, consisting of 102 ensemble models to classify low-viscosity and high-viscosity mAbs at 150 mg/mL, using a sequence-based DeepSP model. Two independent test sets, comprising 16 and 38 mAbs, were used to assess DeepViscosity's generalizability. The model exhibited an accuracy of 87.5% and 89.5% on both test sets, respectively.

11:45 Elucidation of CHO Cell Metabolism Using Multi-Omics

J. Castro, PhD, Senior Scientist, Cell Engineering & Analytical Sciences, Johnson & Johnson Innovative Medicine

This study investigated the metabolism of Chinese Hamster Ovary (CHO) cells through a multi-omics approach, integrating proteomic and metabolomic datasets. By developing genome-scale models, metabolic patterns were successfully identified and analyzed, leading to new hypotheses about the regulatory mechanisms driving cellular behavior. These findings provided insights that enhance the understanding of CHO cell metabolism and may improve strategies for optimizing protein bioproduction.

12:15 pm Structure-Based Charge Calculations for Predicting Properties and Profiling Antibody Therapeutics



Nels Thorsteinson, Director of Biologics, Biologics, Chemical Computing Group

We present a method for modeling antibodies and performing pH-dependent conformational sampling, which can enhance property calculations. Structure-based charge descriptors are evaluated for their predictive performance on recently published antibody pI, viscosity, and clearance data. From this, we devised four rules for therapeutic antibody profiling which address developability issues arising from hydrophobicity and charged-based solution behavior, PK, and the ability to enrich for those that are approved by the FDA.

12:30 Sponsored Presentation (Opportunity Available)

12:45 Session Break

12:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:50 Close of ML and Digital Integration in Biotherapeutic Analytics Conference

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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

PREDICTING IMMUNOGENICITY WITH AI/ML TOOLS

Computational Tools Driving Drug Development Forward

MAY 13-14, 2025



MACHINE
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SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: *In silico* and Machine Learning Tools for Antibody Design and Developability Predictions

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

TUESDAY, MAY 13

1:50 pm Dessert Break in the Exhibit Hall with Poster Viewing

COMPUTATIONAL TOOLS FOR IMMUNOGENICITY ASSESSMENT AND PREDICTION

2:20 Chairperson's Remarks

Sivan Cohen, PhD, Senior Principal Scientist, Genentech



2:30 KEYNOTE PRESENTATION: Advancing Antibody and Nanobody Humanization through Computational Design

Pietro Sormanni, PhD, Group Leader, Royal Society University Research Fellow, Chemistry of Health, Yusuf Hamied Department of Chemistry, University of Cambridge

Novel approaches to antibody discovery, including computational design, require humanization methods agnostic of the antibody's source. Besides low immunogenicity, immune-system-derived antibodies have favorable *in vivo* properties like long half-life and low self-reactivity. Designing nanobodies indistinguishable from human ones is therefore important. In this talk, I will present deep learning strategies for designing and humanizing antibodies and nanobodies indistinguishable from immune-system-derived ones, using tools like AbNatiV.

3:00 Humanness and Humanization of Antibodies and **De Novo** Designed Proteins

David Prihoda, Bioinformatics Lead, MSD Czech Republic

Humanness evaluation and humanization of antibodies are well established, ranging from CDR grafting to deep learning methods. Here we present our contributions: OASis, a granular antibody humanness score, and Sapiens, a language model for antibody humanization, integrated into the open-source BioPhi web platform.

Finally, we explore whether similar principles can be applied to *de novo* designed proteins, highlighting challenges stemming from computational complexity and fundamental biological constraints.

3:30 Identifying tumor-specific antigens derived from protein translation errors

Kyle Hoffman, Applications Mgr, Applications & Service, Bioinformatics Solutions Inc



Hyperactivation of oncogenic pathways is associated with aberrant protein production. Peptides derived from cancer-specific aberrant protein production play a role in immune recognition and represent excellent therapeutic candidates. Here we identify tumor-specific antigens derived from protein translation errors that are unique to cancer cells using a mass spectrometry-based immunopeptidomics pipeline, called DeepImmu.

3:45 Sponsored presentation (*Opportunity Available*)

4:00 Refreshment Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING



How Many New Contacts Can You Make?

Kevin Brawley, Project Manager, Production Operations & Communications, Cambridge Innovation Institute

Bring yourself and your business cards or e-cards, and be prepared to share and summarize the key elements of your research in a minute. PEGS-Boston will provide a location, timer, and fellow attendees to facilitate the introductions.

4:40 Antibody Immunogenicity Risk Assessment with Pep2Vec

Will Thrift, PhD, Principal Artificial Intelligence Scientist, Genentech

Epitope presentation by MHC Class II (pMHC) is a necessary condition for an immunogenic response to antibody therapeutics. Thus, high-performance pMHC models are a cornerstone for immunogenicity risk assessment. We have developed Pep2Vec, a modular, interpretable, pMHC model that achieves state-of-the-art performance on a variety of presentation and immunogenicity datasets. We will show how to use Pep2Vec to distinguish between high and low immunogenicity (human and humanized) antibody drugs.

5:10 A Library-Based Approach for Mapping and Engineering HLA-II Epitope Landscapes

Erik Procko, PhD, CSO, Cyrus Biotechnology; Adjunct Professor, University of Illinois, Urbana

Using a library-based method, HLA-II allele/epitope peptide interactions are measured at scale, and epitope landscapes are mapped to protein sequences. To engineer reduced immunogenicity, thousands of single substitutions were tested to comprehensively identify transitional mutations that switch an epitope from HLA-II binding to non-binding. While existing AI/ML algorithms are poor predictors of transitional epitopes, these data are expected to improve ML models for engineering proteins with reduced immunogenicity.

5:40 Improved Antibody-Antigen Interaction Prediction Using Inverse Folding Latent Representations

Paolo Marcatili, PhD, Head, Antibody Design, Novo Nordisk

Inverse folding (IF) and protein large language models (pLLMs) have become useful tools for antibody variant generation, with generally good performance, but limited ability to find mutations that enhance the binding to the antigen. Here, we show how IF models can be used to predict B cell epitopes, and how to extend this approach to estimate antibody-antigen interaction energy and to find mutations that increase affinity.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC6: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 14

7:15 am Registration and Morning Coffee

PREDICTING IMMUNOGENICITY WITH AI/ML TOOLS

Computational Tools Driving Drug Development Forward

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MACHINE
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WORKFORCE INNOVATION BREAKFAST

7:30 PANEL DISCUSSION: Workforce Transformation: An Evolving Approach to Achieve Innovation (*Continental Breakfast Provided*) **Co-Organized with Thinkubator Media**



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

This panel will explore the pivotal decisions shaping our approach to DEI, focusing on workforce innovation and transformation. Panelists will discuss how these strategies are driving impactful change within organizations, fueling innovation, and redefining workplace culture.

Panelists:

Jared Auclair, PhD, Interim Dean, Northeastern University College of Professional Studies

Tom Browne, Founder & CEO, C to C Services

Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, Professor, Department of Immunology, University of Toronto



8:50 *Ex vivo* and *in situ* Engineered Stroma Targeted CAR T Cells for the Treatment of Solid Tumors and Fibrosis

Ellen Puré, PhD, Chair & Professor, Biomedical Sciences, University of Pennsylvania

Engineered chimeric antigen receptor expressing T cells (CARs) have had a major impact on the treatment of hematopoietic cancers. Solid tumors however, are largely resistant to malignant cell-targeted CAR Ts due to a stroma-rich microenvironment. This talk will provide proof-of-concept for therapeutic efficacy of *ex vivo* and *in situ* engineered stroma-targeted CAR Ts in solid tumors and tissue fibrosis, and their capacity to synergize with chemo- and other immune-based therapies.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

ENTREPRENEUR MEET-UP Fostering Entrepreneurship and Models for Start-Ups



Natalie Galant, PhD, CEO, Paradox Immunotherapeutics
Catharine Smith, Executive Director, Termeer Foundation
Natalie Galant, CEO of Paradox Immunotherapeutics and Termeer Fellow, and Catharine Smith, Executive Director of the Termeer Foundation, are co-hosting an entrepreneurship meet up.

Are you a founder or aspiring founder? Are you an academic entrepreneur? Join Natalie and Catharine and PEGS attendee founders and entrepreneurs for networking and discussion.

IMMUNOGENICITY PREDICTION IN EARLY-STAGE DISCOVERY

10:20 Chairperson's Remarks

Jochem Gokemeijer, PhD, Distinguished Scientist Biologics, Biologics Discovery, Johnson & Johnson

10:25 Incorporating *in silico* Developability and Immunogenicity Assessments during Early Stage Discovery

Tony Pham, Scientist, Biologics Engineering & Developability, AstraZeneca

During early-stage discovery of antibody therapeutics it is important to consider not only target affinity but also developability attributes before selecting a lead candidate for further development. To facilitate this we have developed two tools ImmunoScreen and the InSiDe (*in silico* developability) pipeline for biologics discovery. These tools provide the ability to assess immunogenicity along with other interdependent risks such as aggregation and post-translation modification to guide lead selection.

10:55 Integrating Comprehensive *in silico* Immunogenicity Predictions into Bispecific Antibody Discovery

Stewart New, PhD, Associate Director, Antibody Discovery, Incyte

Accurate *in silico* immunogenicity predictions and effective deimmunization strategies have the potential to significantly enhance the clinical success of therapeutic large molecules. This analysis presents an integrated *in silico* examination of the immunogenicity of two bispecific antibodies, alongside clinical data on the specificity of their respective anti-drug antibody responses. It

offers insights into how these tools can be effectively utilized within drug discovery pipelines.

11:25 Presentation to be Announced



11:55 Session Break

12:00 pm Luncheon Presentation (*Sponsorship Opportunity Available*) or **Enjoy Lunch on Your Own**

INTERACTIVE DISCUSSIONS

1:00 Find Your Table and Meet Your Discussion Moderator

1:10 Interactive Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: HLA Class II Peptide Presentation and Immunogenicity Screening of Therapeutic Antibodies with HLAIIPred

Mojtaba Haghighatlari, PhD, Senior Machine Learning Scientist, Pfizer Inc.

- Best practices in data preparation for machine learning of peptidomics datasets
- Novel deep-learning approaches for predicting MHC antigen presentation and the modeling challenges
- Interpretability and explainability of the available deep-learning models
- New screening strategies for predicting immunogenic hotspots in therapeutic antibodies

BREAKOUT DISCUSSION: Predicting Immunogenicity with AI/ML Tools

Sivan Cohen, PhD, Senior Principal Scientist, Genentech

IN SILICO STRATEGIES FOR NEW MODALITIES

1:55 Chairperson's Remarks

Michael Gutknecht, PhD, Principal Scientist II, Novartis Pharma AG

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2:00 Computational Prediction and Experimental Verification of Human Immunogenicity in Vaccine Design and Evaluation

Alessandro Sette, PhD, Professor, Co-Director, Center for Vaccine Innovation, La Jolla Institute for Allergy & Immunology

Our group has been at the forefront of studying adaptive immune responses associated with vaccination and microbial outbreaks of new and old pathogens. Examples include SARS, pertussis, Mpox, and avian influenza. Our work is also currently directed at preparation for potential new pandemics by combining computational and experimental methods to predict immune responses to viral and bacterial families of cancer. The technology developed in these contexts is of general applicability.

2:30 Immunogenicity of Novel Modalities: *In silico* Methods and Strategies to Mitigate Immunogenicity Risk

Jochem Gokemeijer, PhD, Distinguished Scientist Biologics, Biologics Discovery, Johnson & Johnson

Novel modalities such as CAR T and gene therapy have progressed into the clinic and like other biologics, these therapies have the potential to be recognized by the human immune system, resulting in various immune responses that can compromise patient safety and the efficacy of the therapeutic. Here we will discuss the particular challenges associated with immunogenicity and these modalities and methods and strategies to assess and minimize potential immunogenic elements.

3:00 Immunogenicity Assessment in New Modality Development: T and B Epitope Prediction

Xiaobin Zhang, PhD, Associate Director, Takeda Pharmaceuticals

Biotherapeutics activate the immune system by the interactions with antigen presenting cells (APC), T cells and B cells. Identifying the immune hotspot is a critical step to deimmunize the drug candidates. In this presentation, we will introduce the factors that impact the immune response pathways, summarize the *in silico* prediction tools in immunogenicity risk assessment, and discuss multiple approaches to predict T cell and B cell epitope in drug candidate screening.

3:30 Optimizing development-ability of Antibody Therapeutics

Jesper Sorensen, Head of Scientific Development, OpenEye, Cadence Molecular Sciences

Developing an antibody from a hit or lead into a clinical candidate involves substantial optimization of the biophysical properties that affect large-scale production and long-term stability. We have developed a suite of antibody design tools in our modeling platform Orion® that assist in biophysical characterization and property optimization using a combination of physics-based simulation and AI. This talk will present some solutions to key problems in antibody design and development.

4:00 Ice Cream Break in the Exhibit Hall with Poster Viewing

4:40 Machine Learning Methods for Antibody Design and Development

Phillip M. Kim, PhD, Professor, Molecular Genetics & Computer Science, University of Toronto

I will cover our work on machine learning methods for antibody and protein design from both an academic and biotech perspective. Notably, I will cover our methods for *de novo* design as well as for optimization. I will cover some use-specific use cases, including optimizing developability characteristics using ML methods.

5:10 Incorporating Molecular Mimicry Features to Identify Immunogenic Hotspots in Antibody Therapeutic Sequences

Patrick Wu, MD, PhD, Senior Scientist, Genentech

In silico prediction of CD4+ T cell epitopes frequently results in numerous candidates, yet ranking these epitopes by their potential to activate naive CD4+ T cells and induce anti-drug antibodies remains challenging. Our research suggests that epitopes resembling bacterial sequences increase immunogenicity risk in antibody therapeutics. By integrating molecular mimicry characteristics into predictive models, we can better identify immunogenic hotspots, thereby enhancing the safety and efficacy of biotherapeutic development.



5:40 Analyzing and Decreasing the Immunogenicity Potential of Biotherapeutics Using *in Silico* Approaches

Michael Gutknecht, PhD, Principal Scientist II, Novartis Pharma AG

Immunogenicity potential assessment should be started as early as possible in the biotherapeutic development process to inform de-immunization approaches and to avoid resources spending on candidates with a high inherent immunogenicity potential. Oftentimes, this is only possible using *in silico* tools. In my presentation, I would like to introduce the audience to the *in silico*-based workflow we implemented to analyze and decrease the immunogenicity potential of biotherapeutics in early development.

6:10 Prediction and Mitigation of Immunogenicity of Proteins Given via SC Route

Sathy Balu-Iyer, PhD, Professor, Pharmaceutical Sciences, SUNY Buffalo

The safety and efficacy of therapeutic proteins are undermined by immunogenicity driven by anti-drug antibodies (ADA). Proteins administered subcutaneously can suffer from enhanced immunogenic potential compared to intravenous administration. The talk will cover mechanistic insight into the subcutaneous immune response and our efforts to develop novel preclinical tools as well as a database to predict clinical immunogenicity as a human biology-based animal trial alternative.

6:40 Networking Reception in the Exhibit Hall with Poster Viewing

7:40 Close of Predicting Immunogenicity with AI/ML Tools Conference

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SUNDAY, MAY 11

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC1: *In silico* and Machine Learning Tools for Antibody Design and Developability Predictions

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

THURSDAY, MAY 15

7:45 am Registration and Morning Coffee

FURTHER ADVANCES ON ML/DL: NOVEL PLMs, CODON-BASED PLMs, INTERPRETABILITY, DIFFUSION

8:25 Chairperson's Remarks

Maria Wendt, PhD, Global Head, Preclinical Computational Innovation Strategy Research Platforms, R&D, Sanofi



8:30 KEYNOTE PRESENTATION: Generative AI to Accelerate Prediction and Design in Biomedicine and Sustainability

Debora S. Marks, PhD, Associate Professor, Systems Biology, Harvard Medical School

There's now an amazing opportunity to accelerate discovery across important 21st century challenges by using computation tightly coupled to biological experiments and clinical medicine. I will describe some recent approaches from my lab for these challenges where we have developed new machine learning methods that can exploit the enormous natural sequence diversity and our ability to sequence DNA at scale.

9:00 Large Language Models for mRNA Design

Sven Jager, PhD, Lead, Computational Science, Sanofi Germany GmbH
mRNA-based vaccines and therapeutics are increasingly popular and used for a variety of conditions. A key challenge in designing these mRNAs is sequence optimization. Even small proteins or peptides can be encoded by a vast number of mRNA sequences, each affecting properties such as expression, stability, and immunogenicity. To facilitate the selection of optimal sequences, we developed CodonBERT, a large language model (LLM) specifically for mRNAs.

9:30 Progress Report on AlphaFold and OpenFold-Driven Biomolecular Modeling

Nazim Bouatta, PhD, Senior Research Fellow, Lab of Systems Pharmacology and Systems Biology, Harvard Medical School

AlphaFold2 has transformed structural biology with groundbreaking advances in protein structure prediction. However, despite these advances, many challenges remain. In this talk, I will present a progress update on AlphaFold2 and share insights gained from OpenFold, an optimized and trainable variant of AlphaFold2. I'll also explore potential paths to address the limitations of AlphaFold-like systems.

10:00 *In silico*-Driven Strategies to Unlock the Therapeutic Potential of Rabbit-Derived Antibodies



Shuji Sato, Senior Director Client Relations, ImmunoPrecise Antibodies

This session will explore effective strategies for accelerating lead selection from a diverse panel of antibodies. Key techniques presented include proprietary methods for leveraging the unique immune system of rabbits, early epitope landscape profiling, and the use of IPA's *in silico*-driven diversification and optimization workflows, resulting in the rapid delivery of optimized antibodies ready for clinical development.

10:15 Sponsored Presentation (*Opportunity Available*)

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

11:25 Riding the Next Biotech Wave—Trends in Biotech Investments, Partnering, and M&As



Moderator: Jakob Dupont, MD, Executive Partner, Sofinnova Investments

- Emerging Biotherapeutic Modalities, Technologies and Innovations—ADCs, radiopharmaceuticals, GLP-1, AI, machine learning, and other exciting trends to watch
- Introduction to different strategies for investments, M&As, partnering, licensing etc.
- Investing in platforms versus assets
- Advice on funding options for start-ups, early- to late-stage clinical programs, etc.

Panelists:

Michal Preminger, PhD, MBA, Regional Head, East North America, Johnson & Johnson Innovation LLC

Shyam Masrani, Partner, Medixi

Uciane Scarlett, PhD, Former Principal, MPM BioImpact

Anthony B. Barry, PhD, Executive Director, ES&I Lead, Biotherapeutics, Technologies, and Digital, Pfizer Inc.

12:25 pm Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

DEVELOPABILITY AND OPTIMIZATION

1:55 Chairperson's Remarks

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, an IQVIA business

2:00 Biophysical Cartography of the Native and Human-Engineered Antibody Landscapes Quantifies the Plasticity of Antibody Developability

Victor Greiff, PhD, Associate Professor, University of Oslo and Director of Computational Immunology, IMPRINT

Developing effective monoclonal antibody (mAb) therapies requires optimizing multiple properties, known as 'developability,' to ensure they can progress through the development pipeline. We analyzed 86 DPs across two million antibody sequences, finding key differences in the predictability and sensitivity of sequence- and structure-based DPs. Our findings reveal that human-engineered antibodies occupy a narrower space within the natural antibody landscape, offering a foundation for more precise mAb design.

2:30 Machine Learning-Guided Selection and Design Optimization of Chemically Stable Antibodies

Saeed Izadi, PhD, Senior Principal Scientist & Group Leader, Pharmaceutical Development, Genentech, Inc.

Chemical degradation poses significant risks in the developability of antibodies, potentially leading to loss of binding or liabilities like aggregation and immunogenicity. Here, I will present a machine-learning-driven approach to identify structural features crucial for chemical stability. I will share experimental evidence showing that targeted point mutations can effectively mitigate chemical liabilities without compromising binding, and discuss how these insights can inform the multi-parameter optimization of antibodies for enhanced stability.

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3:00 Insights from the Alntibody Benchmarking Competition

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, an IQVIA business

This talk highlights the integration of strategic data collection and intelligent experimental design to advance AI-powered antibody discovery and optimization. We will share updates from the Alntibody competition, a benchmarking initiative engaging the biotech, pharma, academia, and AI communities. These efforts, alongside tailored discovery campaigns for individual collaborators, aim to accelerate innovation and drive progress in early-stage therapeutic discovery.

3:30 Revolutionizing Antibody Expression: Leap-In Transposase® for Stable, Scalable Biologics Manufacturing



Speaker to be Announced, ATUM

As the demand for high-quality biologics accelerates, biopharmaceutical developers face increasing pressure to optimize cell line development for speed, quality, stability, and scalability. ATUM's Leap-In Transposase® technology is transforming the landscape of protein expression by enabling rapid, predictable, and high-yield stable cell line generation. Unlike traditional random integration methods, the Leap-In Transposase® system facilitates highly efficient transgene integration at transcriptionally active loci, leading to enhanced expression, improved genetic stability, and accelerated development timelines. In this presentation, we will showcase how Leap-In Transposase® technology is empowering biopharma teams to achieve faster workflows while eliminating the need for labor-intensive single-cell cloning. We will present case studies demonstrating its impact across monoclonal antibodies, multispecifics, and novel therapeutic proteins, highlighting significant improvements in titers, scalability, and manufacturability. Furthermore, we will discuss its seamless integration with CHO and HEK cell systems, making it an ideal solution for both early-stage discovery and commercial-scale production.

4:00 Networking Refreshment Break

4:30 Generative AI-Guided Design of Vaccine Immunogens

Reda Rawi, PhD, Staff Scientist and Co-Head, Structural Bioinformatics Core, NIH NIAID

Structure-based vaccine design campaigns that aim to stabilize full-length proteins will not succeed when the virus is evading immune response by sequence diversity. In this work, we capitalized on the recent major advances that have been achieved in protein design using generative AI tools. We *in silico* designed *de novo*

proteins that scaffold sequence-conserved epitope regions of the antigens of interest.

5:00 AbGPT: De novo Antibody Design via Generative Language Modeling

Amir Barati Farimani, PhD, Associate Professor, Machine Learning, Carnegie Mellon University

The adaptive immune response relies on B-cell receptors (BCRs) for pathogen neutralization, yet designing BCRs *de novo* remains challenging due to structural complexity. Here, we introduce Antibody Generative Pretrained Transformer (AbGPT), a fine-tuned model from a foundational protein language model. Using a tailored generation and filtering pipeline, AbGPT generated 15,000 high-quality BCR sequences, effectively capturing the intrinsic variability and conserved regions critical to antibody design.

5:30 Scaling Foundation Models for Protein Generation

Ali Madani, PhD, Founder and CEO, Profluent Bio

Language models learn powerful representations of protein biology. We introduce a new foundation model suite that directly investigates scaling effects for protein generation. We then apply this for applications in antibody and gene editor design.

6:00 Close of Day

FRIDAY, MAY 16

7:15 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Delivering on the AI Antibody Promise: The Alntibody Benchmarking Competition

Andrew R.M. Bradbury, MD, PhD, CSO, Specifica, an IQVIA business
M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, an IQVIA business

- AI promises in antibody discovery and optimization: will they really revolutionize the field? or just another way of addressing solved problems?
- What can AI do now? And where are we seeing the greatest value relative to existing technologies?
- The Alntibody benchmarking competition: Did AI deliver on the Alntibody challenges?
- Ideas for future benchmarking competitions

BENCHMARKING AND AUTOMATION

8:25 Chairperson's Remarks

Victor Greiff, PhD, Associate Professor, University of Oslo and Director of Computational Immunology, IMPRINT

8:30 Closed-Form Test Functions for Biophysical Sequence Optimization Algorithms

Samuel Stanton, PhD, Machine Learning Scientist, Prescient Design, Computational Sciences, Genentech

Many researchers are trying to replicate the success of machine learning (ML) in computer vision and natural language processing in modeling biophysical systems. As a discipline, ML heavily relies on low-cost empirical benchmarks to guide algorithm development, but available benchmarks for biophysical applications have major shortcomings. Drawing inspiration from mutational landscape models, we propose Ehrlich functions, a new class of test functions for biophysical sequence optimization algorithms.

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9:00 Avoiding Pitfalls in ML Model Validation for Protein Design: The Importance of Data Splits

Norbert Furtmann, PhD, Head, Computational and High-Throughput Protein Engineering, Large Molecule Research, Sanofi

This presentation will explore the development of machine learning models for protein property prediction. Focusing on customized protein language models for the NANOBODY modality, it will demonstrate the implementation of a downstream thermostability predictor. Using this example, the talk will emphasize the critical importance of meaningful data splits in model training and validation.

9:30 Closing the Loop: Ultra-Fast Wet Lab Validation for AI-Guided Protein Design

Julian Englert, MS, Co-Founder and CEO, Adaptyv Biosystems

Adaptyv accelerates data generation for training and validating AI models with a high-throughput lab that companies can access via our software interface and API. We empower protein-design teams to validate their AI models many times faster than before, without the need to run in-house wet labs. We're partnering with dozens of companies—from techbio startups to major pharma—and generated lab data for thousands of novel proteins.

10:00 Presentation to be Announced

10:30 Networking Coffee Break

absci

11:00 End-to-End Antibody Discovery against 100s of Targets per Year: From Antigen to AI-Driven Insights

André A. R. Teixeira, PhD, Senior Director, Antibody Platform, Institution for Protein Innovation

At IPI, we perform 300 antibody and VHH discovery campaigns per year against human targets. Our end-to-end antibody discovery platform integrates antigen production, yeast display libraries (Fab and VHH), next-generation sequencing, antibody production, and biophysical characterization. With a success rate exceeding 85%, this platform generates antibodies that benefit the community. Also, the data sets offer powerful opportunities for AI and machine learning applications, driving innovation in antibody discovery and development.

11:30 The IMMREP TCR-Epitope Prediction Challenge: Lessons Learned and Future Directions

Justin Barton, PhD, AI Scientist, Xaira Therapeutics

The IMMREP23 competition evaluated TCR-pMHC interaction prediction methods from 53 participating teams submitting 398 sets of predictions. Results showed reasonable performance for "seen" pMHC targets but near-random performance for "unseen" peptides, highlighting an unsolved generalization challenge. Here we discuss what has been learned from detailed analysis of predictions and provide insights for improving future benchmarks by carefully addressing biases in dataset construction.

12:00 pm DALSA—DTU Arena for Life Science Automation

Timothy Patrick Jenkins, PhD, Assistant Professor and Head, Data Science, DTU Bioengineering

The DTU Arena for Life Science Automation (DALSA) is a pioneering initiative aimed at advancing the technologies and use of automation within Life Science R&D and manufacturing for academia as well as industry. Our mission is to establish a central and open access hub for technology development and educational advancement in life science automation, serving as a test bed for the full-scale implementation of DALSA.

12:30 Close of Summit

SPONSORSHIP & EXHIBIT OPPORTUNITIES

CII offers comprehensive packages that can be customized to your budget and objectives. Sponsorship allows you to achieve your goals before, during, and long after the event. Packages may include presentations, exhibit space and branding, as well as the use of delegate lists. Signing on early will maximize your exposure to qualified decision-makers and drive traffic to your website in the coming months.

PODIUM PRESENTATIONS

Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific program, lunch, or a pre-conference workshop. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CII. Lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly! Sign on early to secure your talk.

INVITATION-ONLY VIP DINNER/ HOSPITALITY SUITE

Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending the invitations, to venue suggestions, CII will deliver your prospects and help you make the most of this invaluable opportunity.

ONE-TO-ONE MEETINGS

CHI will set up 6-8 in-person meetings during the conference, based on your selections from the advance registration list. Our staff will handle invites, confirmations, and reminders, and walk the guest over to the meeting area. This package also includes a meeting space at the venue, complimentary main-conference registrations, branding, an 8'x10' exhibit space, and more.

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

ADDITIONAL BRANDING AND PROMOTIONAL OPPORTUNITIES ARE AVAILABLE, INCLUDING:

- Conference Tote Bags
- Literature Distribution (*Tote Bag Insert or Chair Drop*)
- Badge Lanyards
- Conference Materials Advertisement
- Padfolios and More...

FOR MORE INFORMATION, PLEASE CONTACT:

COMPANIES A-K:

Jason Gerardi

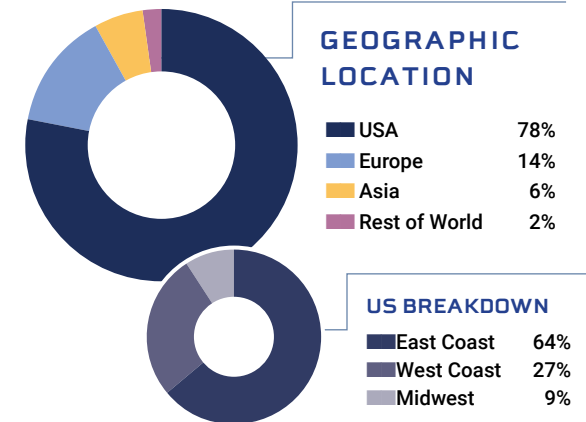
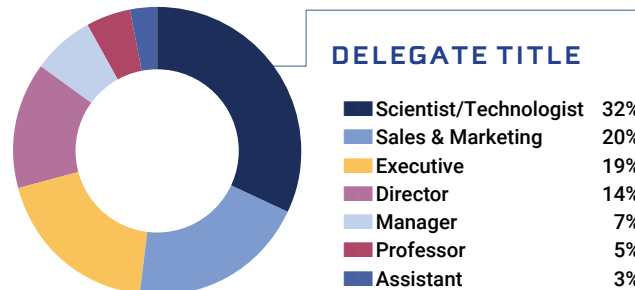
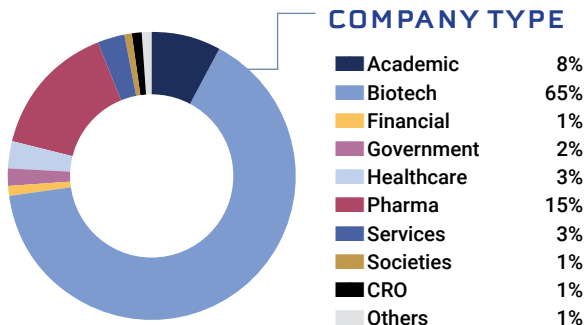
Senior Manager, Business Development
781-972-5452 | jgerardi@healthtech.com

COMPANIES L-Z:

Ashley Parsons

Manager, Business Development
781-972-1340 | ashleyparsons@healthtech.com

2024 ATTENDEE DEMOGRAPHICS



HOTEL & TRAVEL INFORMATION

CONFERENCE HOTEL AND VENUE:

Omni Boston Hotel at the Seaport
450 Summer Street
Boston, MA 02210

Discounted Room Rate:
\$365 Artist Tower s/d / \$395 s/d Patron Tower

** Includes Complimentary WiFi

Discounted Room Rate Cut-Off Date:
Friday, April 11, 2025

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