2025 CONFERENCE PROGRAMS

- ENGINEERING
- ONCOLOGY
- MULTISPECIFICS
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- EMERGING THERAPEUTICS
- MACHINE LEARNING
- SC SHORT COURSES
- TS Training SEMINARS

TABLE OF CONTENTS

PEGSummit.com

Organized by Cambridge Healthtech Institute

21ST ANNUAL PEGS BOSTON

MAY 12-16, 2025 BOSTON, MA

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The Essential Protein & Antibody Engineering Summit

2025 PLENARY KEYNOTE SPEAKERS

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

Ellen Puré, PhD
Professor & Chair
University of Pennsylvania

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Table of Contents

PEGS BOSTON

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.

2025 CONFERENCE PROGRAMS

ENGINEERING — VIEW

Display of Biologics

Engineering Antibodies

Machine Learning Approaches for Protein Engineering

ONCOLOGY — VIEW

Antibodies for Cancer Therapy

Emerging Targets for Oncology and Beyond

Antibody-Drug Conjugates

MULTISPECIFICS — VIEW

TRAINING SEMINAR:
Intro to Multispecific Antibodies

Advancing Multispecific Antibodies

Engineering Bispecific and Multifunctional Antibodies

IMMUNOTHERAPY — VIEW

Advances in Immunotherapy

Engineering Cell Therapies

Next-Generation Immunotherapies

EXPRESSION — VIEW

Difficult-to-Express Proteins

Optimizing Protein Expression

Maximizing Protein Production Workflows

ANALYTICAL — VIEW

ML and Digital Integration in Biotherapeutic Analytics

Biophysical Methods

Characterization for Novel Biotherapeutics

IMMUNOGENICITY — VIEW

TRAINING SEMINAR:
Introduction to Immunogenicity

Predicting Immunogenicity with AI/ML Tools

TRAINING SEMINAR:
Bioassay Development and Analysis

EMERGING THERAPEUTICS — VIEW

Biologics for Immunology Indications

Radiopharmaceutical Therapies

Next-Generation Immunotherapies

MACHINE LEARNING — VIEW

ML and Digital Integration in Biotherapeutic Analytics

Predicting Immunogenicity with AI/ML Tools

Machine Learning Approaches for Protein Engineering

SC SHORT COURSES

Training SEMINARS

TABLE OF CONTENTS

Conference at-a-Glance

PEGS BOSTON

2025 PROGRAMS	SUNDAY MAY 11	TUESDAY MAY 13	PART A MONDAY - TUESDAY AM (MAY 12-13)	PART B TUESDAY PM - WEDNESDAY (MAY 13-14)	PART C THURSDAY/FRIDAY MORNING (MAY 15-16)
ENGINEERING	AFTERNOON SHORT COURSES	DINNER SHORT COURSES	Display of Biologics	Engineering Antibodies	Machine Learning Approaches for Protein Engineering
ONCOLOGY			Antibodies for Cancer Therapy	Emerging Targets for Oncology & Beyond	Driving Clinical Success in Antibody Drug Conjugates
MULTISPECIFICS			TS: Introduction to Multispecifics	Advancing Multispecific Antibodies and Combination Therapy to the Clinic	Engineering Bispecific and Multifunctional Antibodies
IMMUNOTHERAPY			Advances in Immunotherapy	Engineering Cell Therapies	Next-Generation Immunotherapies
EXPRESSION			Difficult-to-Express Proteins	Optimizing Protein Expression	Maximizing Protein Production Workflows
ANALYTICAL			ML and Digital Integration in Biotherapeutic Analytics	Biophysical Methods	Characterization for Novel Biotherapeutics
IMMUNOGENICITY			TS: Introduction to Immunogenicity	Predicting Immunogenicity with AI/ML Tools	TS: Bioassay Development and Analysis
EMERGING THERAPEUTICS			Biologics for Immunology Indications	Radiopharmaceutical Therapies	Next-Generation Immunotherapies
MACHINE LEARNING			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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SinoBiological
StackWave
Syngene Putting Science to Work
Vazyme
ABclonal YUROGEN

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.

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.

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.

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.

SHORT COURSES*

IN-PERSON ONLY

*Separate registration required.

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, Senior Data Scientist, Machine Learning, AstraZeneca

Henriette Capel, PhD Student, University of Oxford

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

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: Solid Tumors: Challenges and Therapeutic Innovations

Instructor:

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

The tumor microenvironment (TME) can significantly impact the efficacy of cancer treatments, especially against solid tumors. Solid tumors are typically surrounded by a dense network of stromal cells, blood vessels, and extracellular matrix, which can create a barrier to the delivery of drugs and other therapies. This short course discusses the latest immunology, strategies and targets driving solid tumor cancer therapies.

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

SC4: Best Practices for Targeting GCPRs, 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, biologics-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.

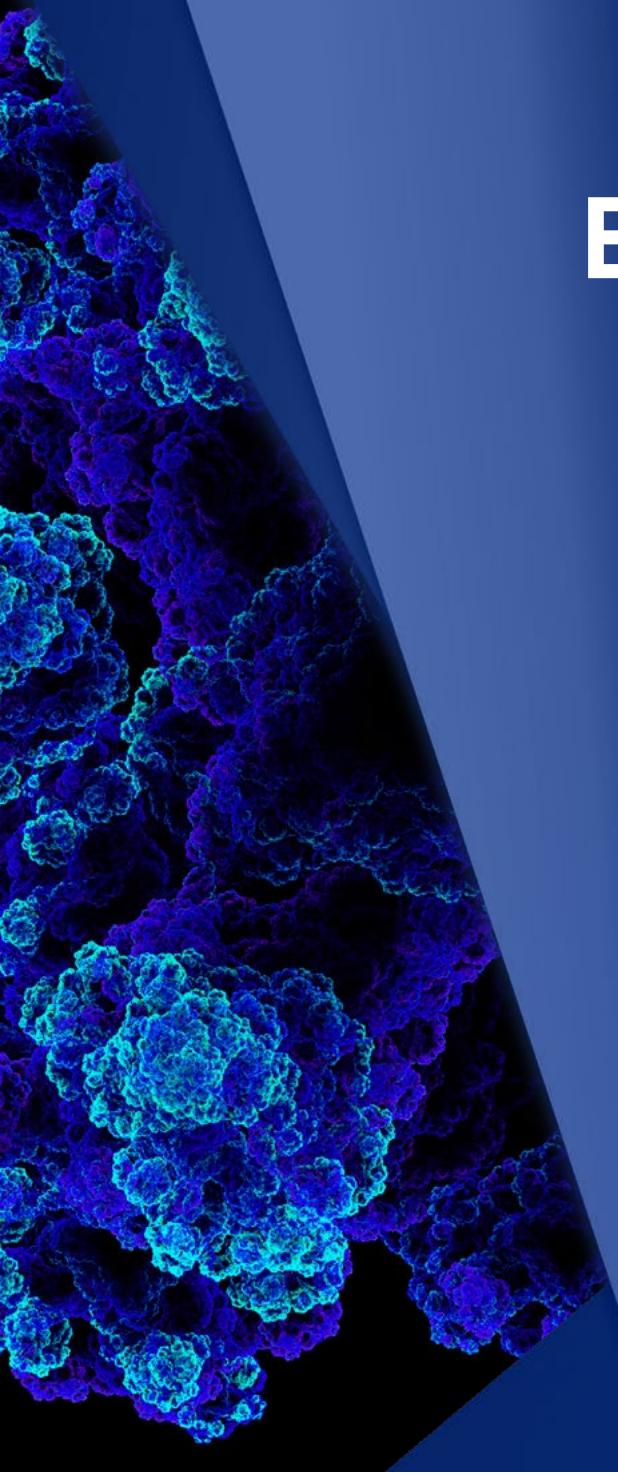
THURSDAY, MAY 15, 2025 8:30 AM - 5:30 PM
FRIDAY, MAY 16, 2025 8:30 AM - 12:30 PM

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, Assistant 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 IGSAGEN

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 integral molecular
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 Luncheon Presentation to be Announced Q² Solutions

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 transistor 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 Presentation to be Announced

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-Organizers:

Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

ALTERNATIVE SCAFFOLDS FOR RADIOPHARM AND CHEMOTHERAPY SESSIONS

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 DARPins for Radiotherapy

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

DARPins (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 to be Announced

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 Immuto Scientific

3:45 Presentation to be Announced Abterra bio

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 ß-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 GCPRs, Ion Channels, and Transporters with Monoclonal Antibodies

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

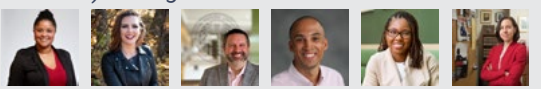
WEDNESDAY, MAY 14

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*

THINKUBATORMEDIA



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

TABLE OF CONTENTS

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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 evitria

11:55 Session Break

12:00 pm Luncheon Presentation to be Announced Antibody Solutions

12:30 Luncheon Presentation to be Announced rapid novor

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.

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

MENTORING MEET-UP

Organizer:
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

7:40 Close of Engineering Antibodies Conference

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 and Vice President, Digital and Biologics Strategy and Innovation, 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.

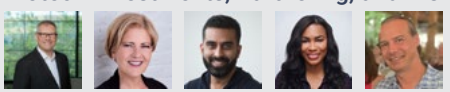
10:15 Sponsored Presentation *(Opportunity Available)*

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, 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

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 Plasticisity of Antibody Developability

Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

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, Scientist, Early-Stage 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.

3:00 Insights from the AIntibody 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 AIntibody 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 Sponsored Presentation *(Opportunity Available)*

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 advanced 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 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 AIntibody 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 AIntibody benchmarking competition: Did AI deliver on the AIntibody challenges?
- Ideas for future benchmarking competitions

BENCHMARKING AND AUTOMATION

8:25 Chairperson's Remarks

Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

8:30 The IMMREP TCR-Epitope Prediction Challenge: Lessons Learned and Future Directions

Justin Barton, PhD, Principal Machine Learning Scientist, University College London

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.

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 Sponsored Presentation *(Opportunity Available)*

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 Closed-Form Test Functions for Biophysical Sequence Optimization Algorithms

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

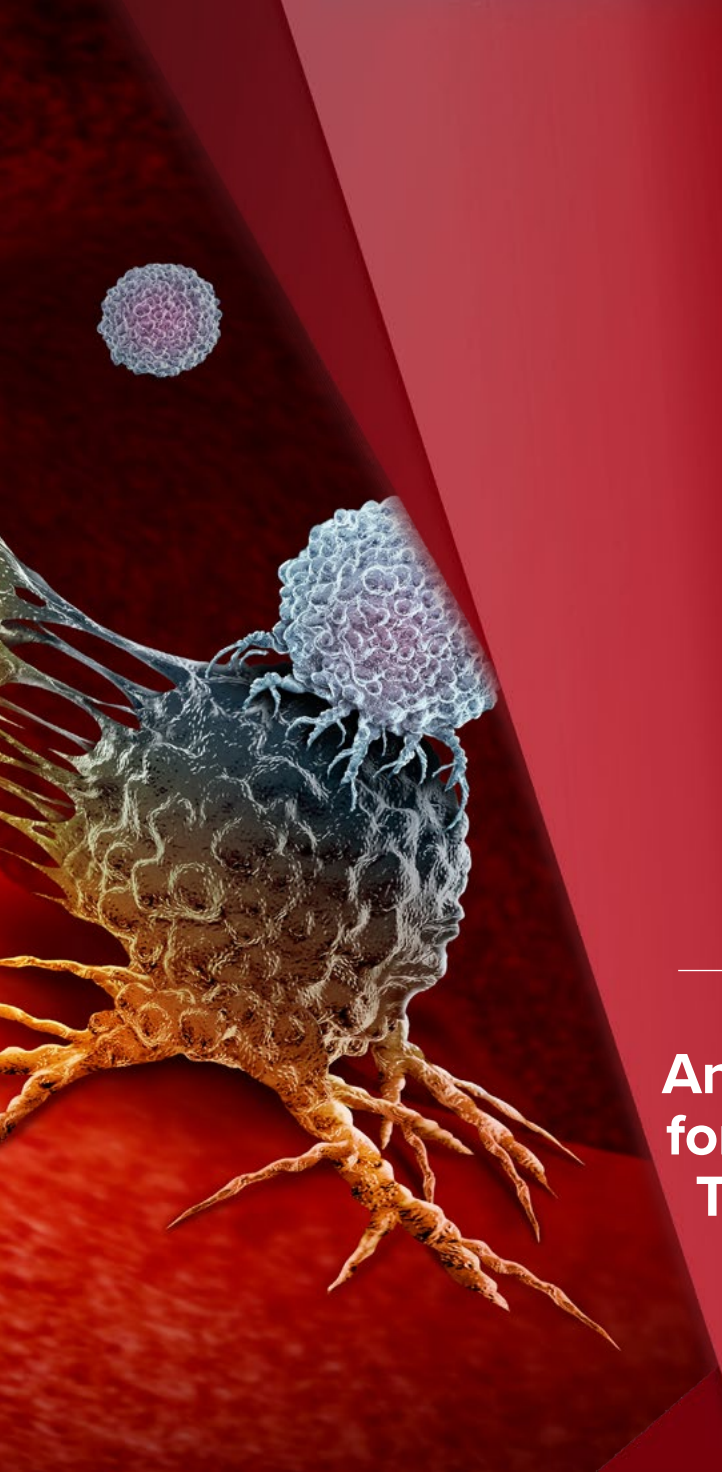
Many researchers are trying to replicate the success of machine learning (ML) in computer vision and natural language processing in modeling biophysical systems. As a discipline, ML heavily relies on low-cost empirical benchmarks to guide algorithm development, but available benchmarks for biophysical 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.

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. Nastri, 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 & Theranostics, 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

ORIGENE

Speaker to be Announced, OriGene Technologies Inc

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-Organizers:

Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

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, Vice President, Head of Oncology Research Department, Ichnos Sciences

Downregulation of targets limits the efficacy of monotargeted 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 Vγ9Vδ2-T Cell Engagers for Cancer Immunotherapy

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

Vγ9Vδ2-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 Vγ9Vδ2-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:

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 Sponsored Presentation *(Opportunity Available)*

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-Aß 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.

- Designing ARTEMIS (AbTCR) T cell engineering technology to improve solid tumor T cell infiltration and reduce CRS
- Targeting Glypican 3 (GPC3) in advanced hepatocellular carcinoma (HCC)
- Preclinical and clinical data of GPC3-targeting ARTEMIS T cell therapy for HCC patients

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

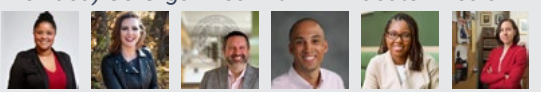
*Separate registration required. See short course page for details.

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*



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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.

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 Targeting mCALR in MPN Diseases

Horacio G. Nastri, 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 Presentation to be Announced

WuXi Biologics
Global Solution Provider

11:55 Session Break

12:00 pm Luncheon Presentation to be Announced

abcam
progress happens together

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.

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

MENTORING MEET-UP

Organizer:

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

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 Degrader-Antibody Conjugates (DACs) Unlock Heterobifunctional Degraders 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. Degrader-Antibody Conjugates (DACs) could significantly expand the number of druggable payload targets; however, conjugation and identification of suitable degraders remain challenging. Here, we report a new DAC platform ensuring excellent DAC stability antibody-mediated delivery of functional degraders enabling long-lasting responses even after single-dose injections in preclinical animal models.

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

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

Degrader Antibody Conjugates (DACs) represent a novel therapeutic approach that combines the specificity of antibodies with the potency of protein degraders. 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 Degrader 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 degraders. By enhancing pharmacokinetics and prolonging degrader 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*.

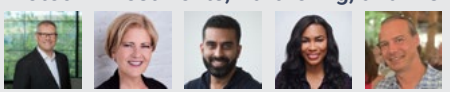
10:00 Sponsored Presentation *(Opportunity Available)*

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, 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

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.

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 FcgR 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 The Impact of Engineering Linker Stability on ADC Tolerability

Jamie R. Rich, PhD, Senior Director Technology, ADC Therapeutic Development, Zymeworks Inc.

Engineering antibody-drug conjugate linker stability significantly impacts payload disposition and thus affects both toxicity and anti-tumor activity. While improving ADC stability may result in better preclinical tolerability, the same advantage is not clear in the clinic. Nevertheless, engineering linker stability is a focus of considerable current attention. Data from clinical trials of antibody-drug conjugates suggest that more stable linkers impact the tolerability of ADCs in both expected and unexpected ways.

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

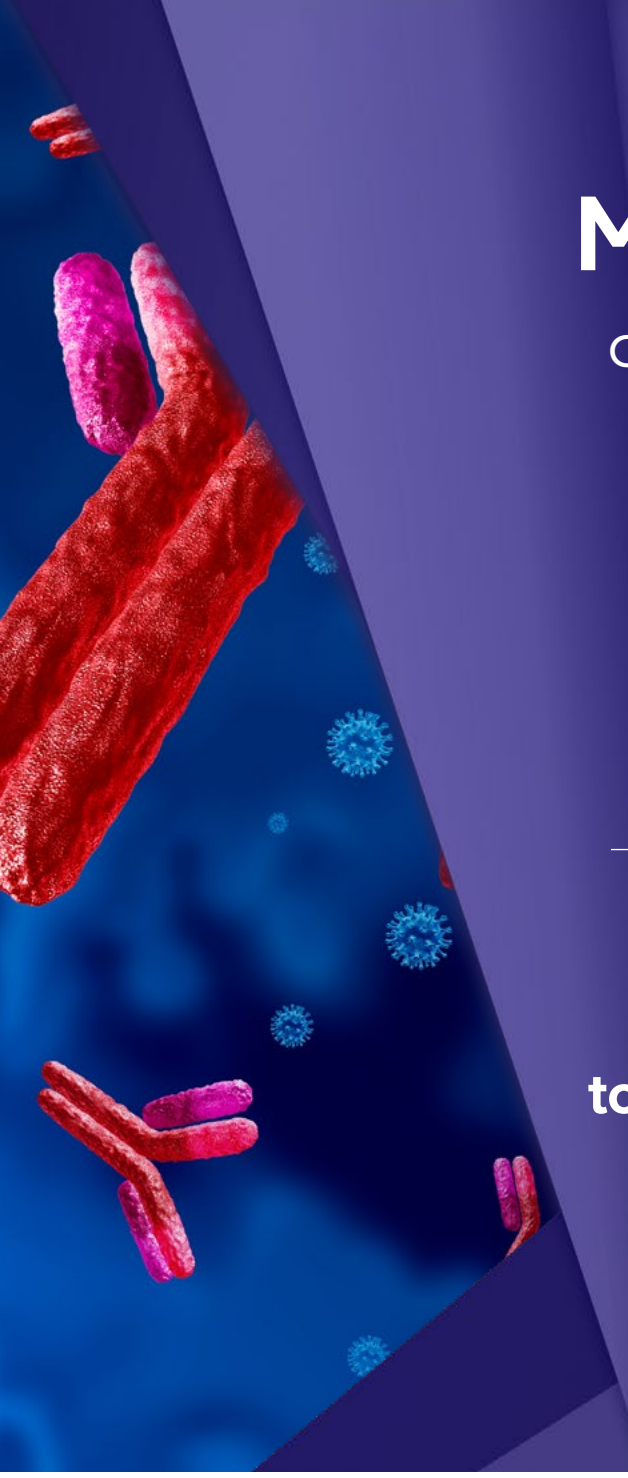
- Highlight stable bioconjugation approaches for increased ADC stability *in vitro* and *in vivo*
- Describe tumor-selective linker designs that are aimed to improve the therapeutic index of ADCs by altering the toxicity profile and increasing tolerability
- Introduce ProAlk as a novel ADC payload with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

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.

Please see website for more details. PEGSummit.com/Posters

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, RNDO-564, a CD28 x Nectin-4 bispecific antibody for treatment of metastatic bladder cancer.

3:30 Presentation to be Announced

DPBIO

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.

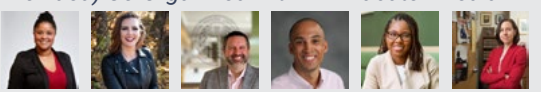
WEDNESDAY, MAY 14

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*

THINKUBATORMEDIA



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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

sphere FLUIDICS

11:55 Session Break

12:00 pm Luncheon Presentation to be Announced

OmniAb

12:30 LUNCHEON PRESENTATION: Sequence-Forward, Single B-Cell Solutions by LAMPIRE

LAMPIRE BIOLOGICAL LABORATORIES

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.

BISPECIFICS FOR NON-ONCOLOGY APPLICATIONS *(CONT.)*

1:55 Chairperson's Remarks

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

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 proviruses 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-DARPins 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 M. Alvarez-Vallina, PhD, Group Leader, Immuno Oncology and Immunotherapy Group, Unidad de Immunoterapia del Cancer UNICA

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

MENTORING MEET-UP

Organizer:

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

7:40 Close of Advancing Multispecific Antibodies Conference

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.

ABLEXIS
AlivaMab BIOLOGICS

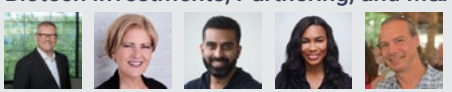
10:00 Presentation to be Announced

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, 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

NOVEL MECHANISMS OF ACTION

1:55 Chairperson's Remarks

Eugene A. Zhukovsky, PhD, CSO, Ichnos Sciences

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 evaluated for targeting efficiency, cellular uptake, and the loading of diverse drug cargoes (peptides, oligonucleotides, and particles). This approach facilitates early screening of drug conjugates as well as supports late-stage drug development.

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.

TABLE OF CONTENTS

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.

BISPECIFICS FOR ONCOLOGY

8:25 Chairperson's Remarks

Christian Klein, PhD, CXO in Residence and Drug Hunter, Curie.Bio

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

Ulrike Philippar, 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 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

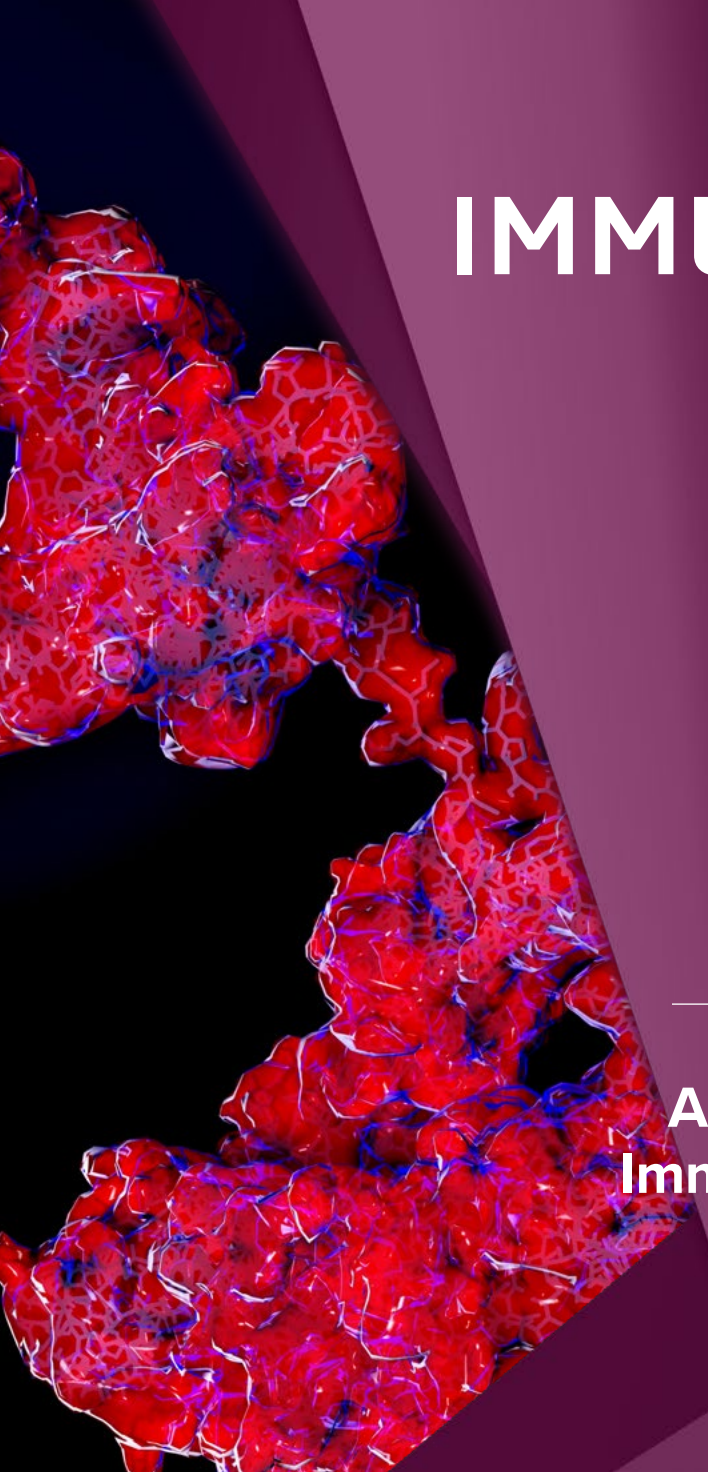
The development of therapeutic molecules is often limited by insufficient on-target efficacy and adverse effects related to on-target, off-tissue activity. Ampersand has developed a computationally powered drug-discovery approach that has identified tissue-specific addresses that in turn has enabled 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: Solid Tumors: Challenges and Therapeutic Innovations
*Separate registration required. See short course page for details.

MONDAY, MAY 12

7:00 am Registration and Morning Coffee

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 Equilabrative 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

Syntekabio

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/FcgR 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

charles river

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 Asstant 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
Jonas Schilz, PhD, Group Leader, Antibody Discovery & Protein Interactions, 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 approach for 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-Organizers:

Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

IMMUNOTHERAPIES FOR AUTOIMMUNE DISORDERS

8:30 Chairperson's Remarks

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

8:35 Leveraging the Advantages of Multivalent IgM Antibodies for Novel Immunotherapeutic Strategies

William Strohl, PhD, President & Owner, BiStro Biotech Consulting LLC, Board of Directors, IGM Biosciences

Most bispecific T-cell engager antibodies are potent enough to deplete target cells, but come with the adverse effects of significant cytokine release syndrome (CRS) and sometimes neurological sequelae. The audience will gain an appreciation for how safe and effective therapeutic IgM antibodies, exhibiting minimal CRS and other toxicities, can be engineered for use to treat severe autoimmune diseases.

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 *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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: Solid Tumors: Challenges and 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: Clinical Biomarkers of Response to Ciltacabtagene Autoleucel in Patients with Relapse or Refractory Multiple Myeloma

Vicki Plaks, PhD, Global Head, Cell Therapy, Translational Research, Johnson & Johnson

3:00 FEATURED 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.

3:30 Presentation to be Announced

WuXi Biologics Global Solution Provider

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*

THINKUBATORMEDIA






Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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.

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 evasins.

11:25 Sponsored Presentation *(Opportunity Available)*

11:55 Session Break

12:00 pm Luncheon Presentation to be Announced

The Jackson Laboratory

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.

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 Immunology 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 Sponsored Presentation *(Opportunity Available)*

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 Logic-Gated Cell Therapies

Timothy Riley, PhD, Senior Scientist, A2 Biotherapeutics

Engineered immune cells, such as CAR T cells, show promise for immuno-oncology but must overcome the obstacle of on-target/off-tumor toxicity. Novel logic-gated strategies, like the Tmod platform, offer promising avenues by recognizing combinatorial antigen profiles. The modular Tmod system integrates an activating CAR with an inhibitory receptor, providing a safety switch to spare normal tissues expressing inhibitory antigens.

5:40 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.

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

MENTORING MEET-UP

Organizer:

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

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: 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
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
KAGTUS

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

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 *In vivo* panCAR Therapy Using Circular RNA for the Treatment of B Cell Malignancies

Isin Dalkilic-Liddle, PhD, Director and Head, Rare Genetic Diseases Group, Orna Therapeutics

In vivo CAR therapy could eliminate the need for patient cell isolation and avoid risks associated with conditioning regimens of CAR T therapies. Orna Therapeutic's panCAR combines a synthetic, circular coding RNA platform (oRNA) and proprietary immunotropic lipid nanoparticle (LNP) to drive immune effector cell (e.g.; T cells, NK cells) CAR expression after *in vivo* administration, promising a transient, re-dosable, and scalable immune cell therapy without preconditioning lymphodepletion.

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 T-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 Presentation to be Announced

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

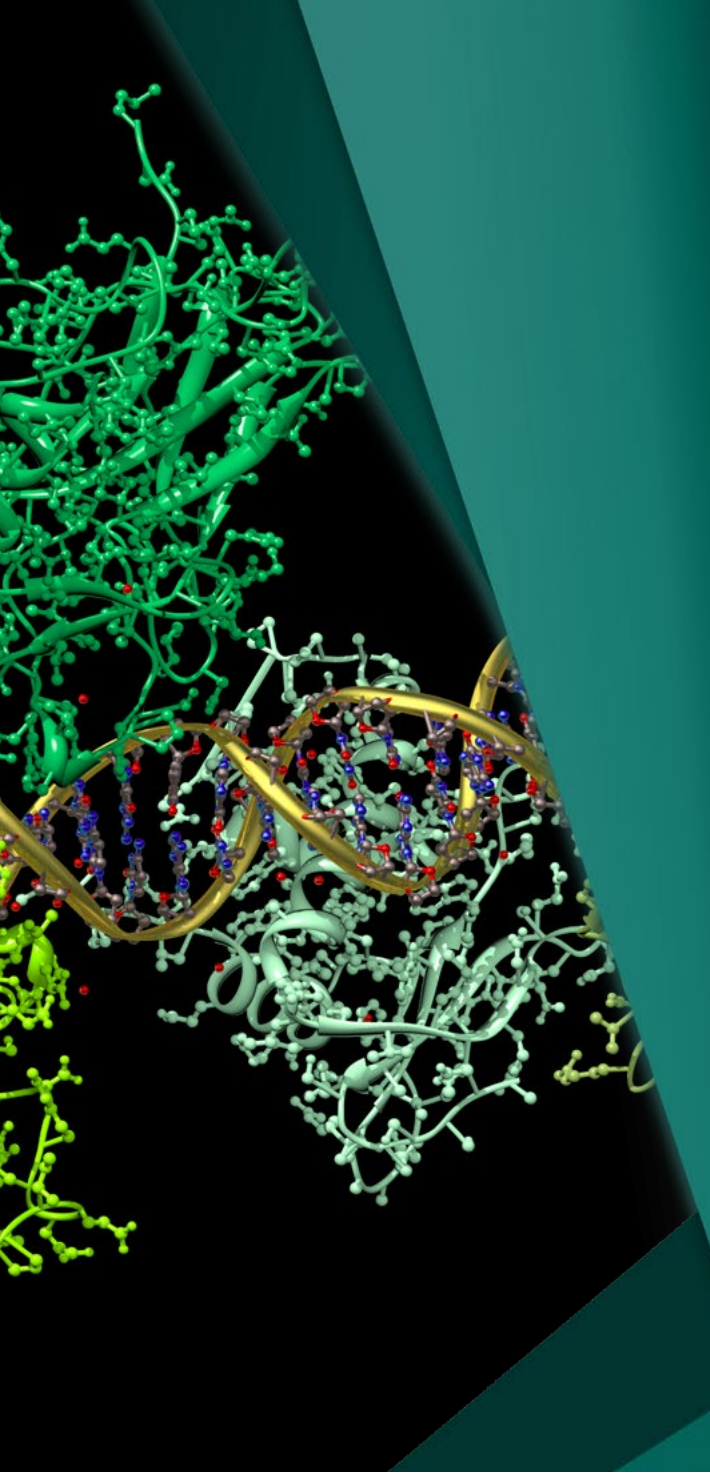
The tumor microenvironment can inhibit the efficacy of cancer therapies through mechanisms such as poor trafficking and exhaustion of immune cells. To address this challenge, we exploited the safety, tumor tropism, and ease of genetic manipulation of non-pathogenic *Escherichia coli* to deliver key immune-activating 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 Sceintist, 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 Presentation to be Announced

10:30 Networking Coffee Break

11:00 Greasing Protein Wheels: Unlocking Lipidation Strategies for Next-Generation Biomaterials and Therapeutics

Davoud Mozhdehi, 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, Department of Cardiovascular Diseases + ACDC, Lewis Katz School of Medicine, Temple University

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 Presentation to be Announced

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-Organizers:

Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

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 Sponsored Presentation *(Opportunity Available)*

12:45 Session Break

12:50 Luncheon Presentation to be Announced

GenScript
Make Research Easy

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

GeneFrontier

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 Presentation to be Announced

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

AVENUE BIOSCIENCES

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

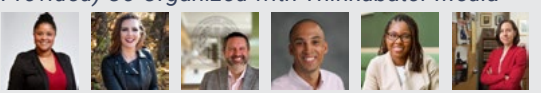
WEDNESDAY, MAY 14

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*

THINKUBATORMEDIA



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)

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

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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.

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

Claudia Chiocchini, 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 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.

EXPANDING THE EXPRESSION TOOLBOX: 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 Presentation to be Announced

nuclera

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

4:40 Presentation to be Announced

Ajinomoto

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

MENTORING MEET-UP

Organizer:

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

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

FUJIFILM Irvine Scientific

Hasmik Grigoryan, PharmD, PhD, R&D Sr. Manager of Analytical and Data Sciences, R&D, 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:

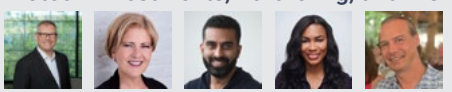
- The rigorous raw material assessment methods that allow us to satisfy customer requirements
- Customer case studies that demonstrate the value and benefits of RMCP

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 though 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.

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-Siwek, 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)*

10:15 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

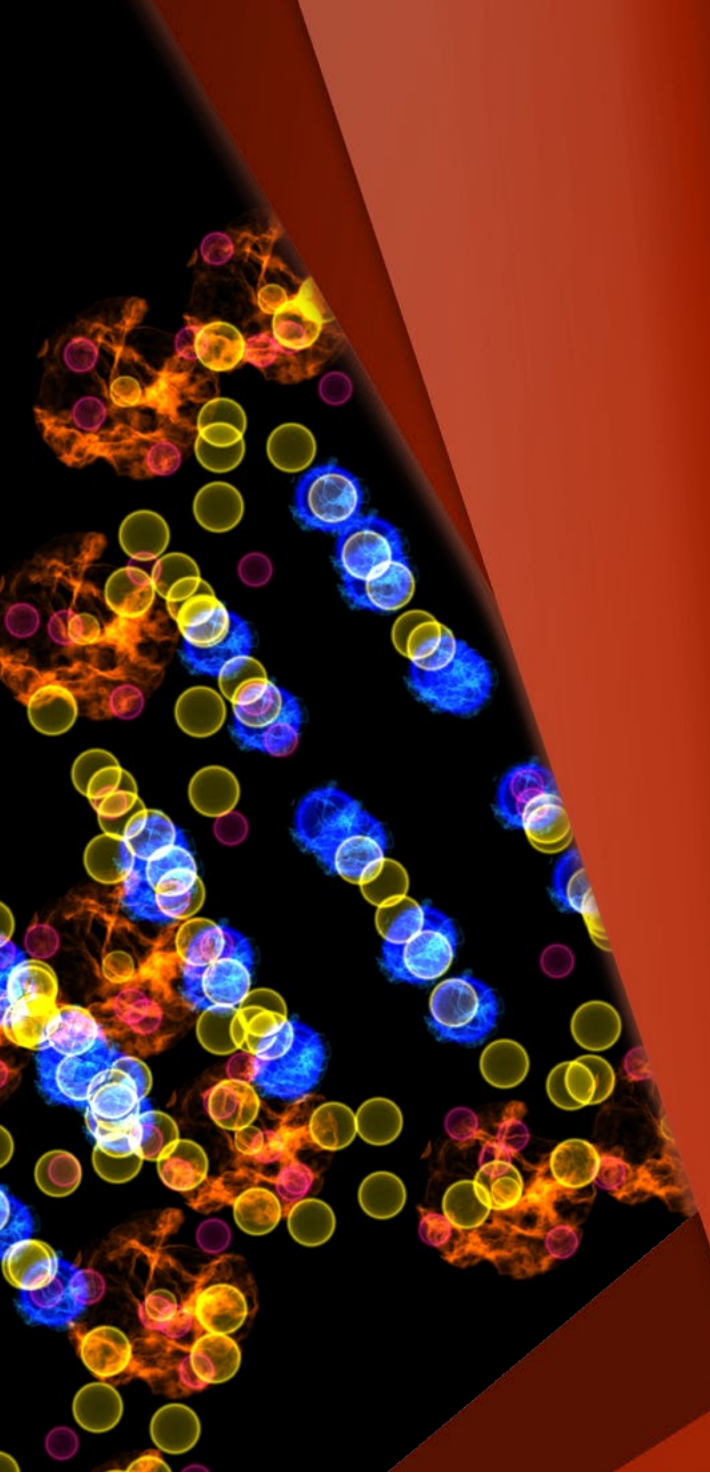
Production of high-quality biological molecules has historically been a major bottleneck in biologics discovery. While automation in this field has predominantly centered on protein production, labor-intensive tasks such as seed-culture production, workflow and data management, and high-volume bio-waste 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

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 Genedata
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 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-Organizers:

Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

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.

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 Presentation to be Announced

Chemical Computing Group

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.

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 Presentation to be Announced UNCHAINED LABS

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

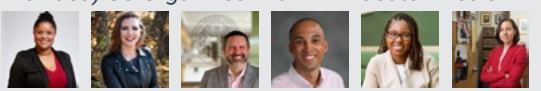
*Separate registration required. See short course page for details.

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* THINKUBATORMEDIA



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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

Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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.

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 *(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.

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 thecomplete 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

proteindynamic SOLUTIONS

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, Associate 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

MENTORING MEET-UP

Organizer:
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

7:40 Close of Biophysical Methods 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

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 Presentation to be Announced UNCHAINED LABS

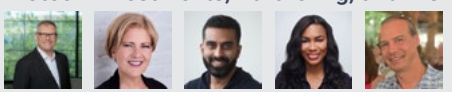
10:15 Presentation to be Announced REFEYN

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

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 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

Tim Menzen, PhD, CTO & Pharmacist, 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 Presentation to be Announced bio-techne

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.

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.

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

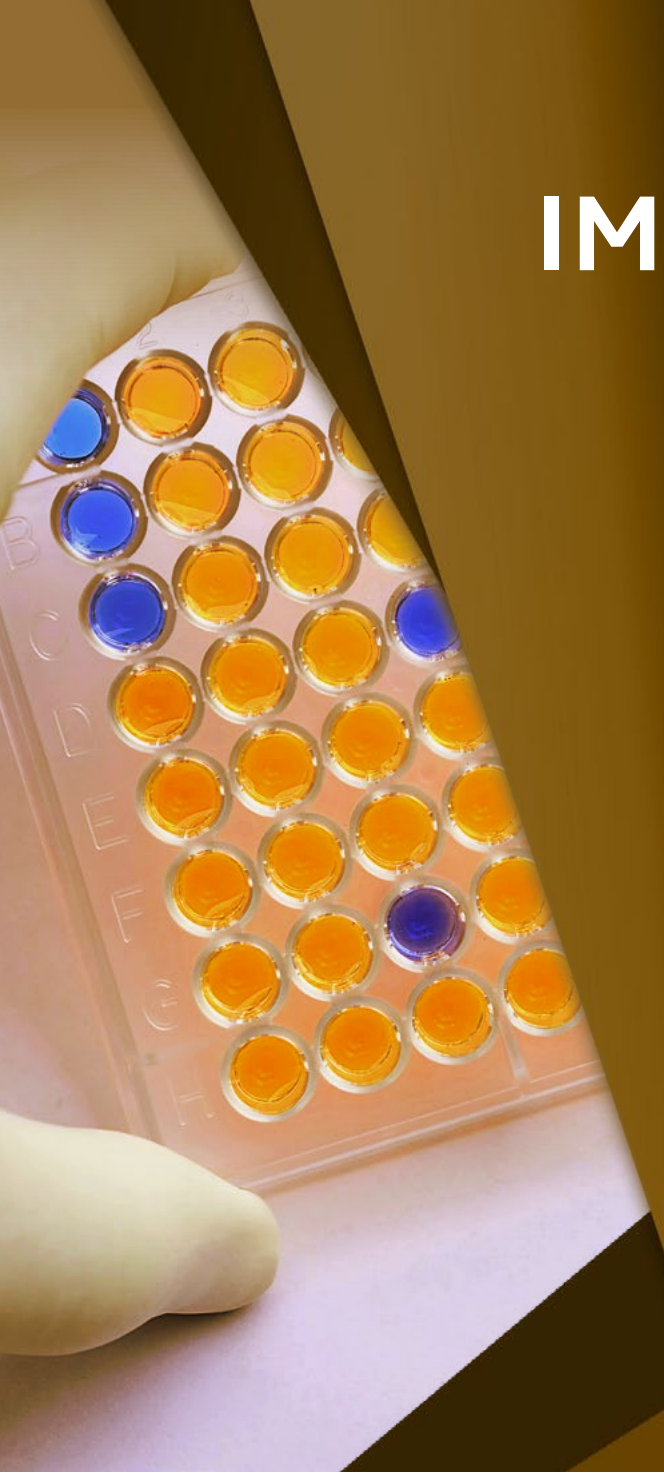
Recombinant polyclonal antibodies (pAb) are a new class of therapeutics comprising over 1000 monoclonal species recognizing multiple epitopes or antigens. We developed a CEX-HPLC method to address a major hurdle in pAb manufacturing, the reliable characterization of pAb population diversity and identity. 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.

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 Antibody Immunogenicity Risk Assessment with Pep2Vec
Will Thrift, PhD, Senior 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.

3:30 Presentation to be Announced

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 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.

5:10 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.

5:40 A Comprehensive Bioinformatics Pipeline for the Identification of Conserved Conformational Epitopes across the Viral Proteome
Cassie Bryan, PhD, Senior Scientist, Synthetic Biology, Charles Stark Draper Laboratory, Inc.

The C2PEP pipeline is a robust generalized framework for the identification of conserved conformational epitopes and is adaptable to applications in biosurveillance, diagnostics, vaccines, and therapeutic antibody development against known and emerging biological threats. It integrates a suite of AI/ML and biophysics-based software tools to model conformational epitope probability and structural similarity and output a conserved epitope database.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

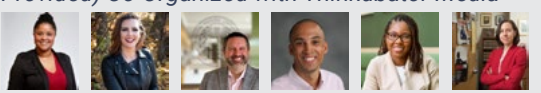
SC6: Developability of Bispecific Antibodies
*Separate registration required. See short course page for details.

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*



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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.

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 antibod?ies

IN SILICO STRATEGIES FOR NEW MODALITIES

1:55 Chairperson's Remarks

2:00 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.

2:30 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.

3:00 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.

3:30 Optimizing development-ability of Antibody Therapeutics

OpenEye | cadence

Speaker to be Announced, OpenEye Scientific

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

4:40 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.

5:10 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.

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

MENTORING MEET-UP

Organizer:
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

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 Presentation to be Announced

8:30 Disrupting B and T Cell Collaboration in Autoimmune Disease: T Cell Engagers versus CAR T Cell Therapy?
Venkat Reddy, PhD, Principal Investigator, 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
Yu Qiu, PhD, Senior Principal Scientist, Sanofi Genzyme R&D Center

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 Structure of CD40-Antibody Complex Uncovers a Unique Mechanism of Action for Fc Gamma Receptors-Independent Agonism
Yu Qiu, PhD, Senior Principal Scientist, Sanofi Genzyme R&D Center

The agonistic activity of anti-CD40 antibodies is often linked to FcγR-mediated crosslinking. However, some anti-CD40 agonists, such as CP-870,893 (Selicrelumab), exhibit agonistic activity *in vitro* without FcγR crosslinking. In this study, we solved the crystal structure of CP-870,893 Fab in complex with CD40 receptor, revealing a unique mechanism of action, which was validated by mutagenesis. Furthermore, to address the short half-life and dose-limiting toxicities, we developed conditionally activated CP-870,893 variants.

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-Organizers:


Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

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.

BIOTHERAPEUTICS 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 HLADQ2.5/Gluten Peptide Complex for Celiac Disease

Noriyuki Takahashi, Research Scientist & Unit Leader, Antibody Generation, 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 Neoepitopes—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 neoepitope 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.

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 Targeted Radioligand Therapy: A New Frontier in Oncology

Ebrahim S. Delpassand, MD, Chairman of the Board & CEO, RadioMedix Inc.

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 clincial 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

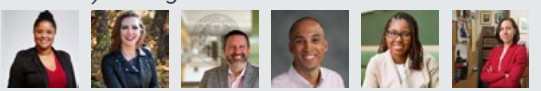
*Separate registration required. See short course page for details.

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*



Co-Moderators:

Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge

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

Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)

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

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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 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

11:25 Sponsored Presentation *(Opportunity Available)*

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 Radipharmaceutical 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

Mark Frigerio, PhD, MBA, Vice President, Chemistry, Bicycle Therapeutics

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

Patrik Kehler, CSO, Pentixapharm AG

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

MENTORING MEET-UP

Organizer:
Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

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, Childrens 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
KACTUS

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 Capital
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 *In vivo* panCAR Therapy Using Circular RNA for the Treatment of B Cell Malignancies
Isin Dalkilic-Liddle, PhD, Director and Head, Rare Genetic Diseases Group, Orna Therapeutics

In vivo CAR therapy could eliminate the need for patient cell isolation and avoid risks associated with conditioning regimens of CAR T therapies. Orna Therapeutic's panCAR combines a synthetic, circular coding RNA platform (oRNA) and proprietary immunotropic lipid nanoparticle (LNP) to drive immune effector cell (e.g.; T cells, NK cells) CAR expression after *in vivo* administration, promising a transient, re-dosable, and scalable immune cell therapy without preconditioning lymphodepletion.

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 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.

COMPUTATIONAL APPROACHES TO NEXT-GENERATION IMMUNOTHERAPIES

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

Dan Rock, CSO, 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, Executie 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, 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

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 Genedata

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 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

ENPICOM
DECODING THE IMMUNE SYSTEM

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-Organizers:

Iris Goldman, Production, Cambridge Innovation Institute
Julie Sullivan, Production, Cambridge Innovation Institute

7:20 Close of Day

TUESDAY, MAY 13

7:30 am Registration and Morning Coffee

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.

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 Presentation to be Announced

Chemical Computing Group

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.

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 Antibody Immunogenicity Risk Assessment with Pep2Vec
Will Thrift, PhD, Senior 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.

3:30 Presentation to be Announced

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 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.

5:10 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.

5:40 A Comprehensive Bioinformatics Pipeline for the Identification of Conserved Conformational Epitopes across the Viral Proteome
Cassie Bryan, PhD, Senior Scientist, Synthetic Biology, Charles Stark Draper Laboratory, Inc.

The C2PEP pipeline is a robust generalized framework for the identification of conserved conformational epitopes and is adaptable to applications in biosurveillance, diagnostics, vaccines, and therapeutic antibody development against known and emerging biological threats. It integrates a suite of AI/ML and biophysics-based software tools to model conformational epitope probability and structural similarity and output a conserved epitope database.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

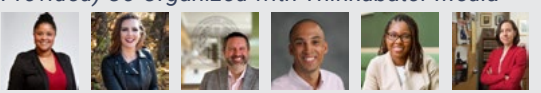
SC6: Developability of Bispecific Antibodies
*Separate registration required. See short course page for details.

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*



Co-Moderators:
Tana Joseph, PhD, Founder & Director, Equity, Diversity, Inclusion, & Decolonisation for the Sciences, AstroComms, Public Engagement Manager, University of Cambridge
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
Sheila Phicil, Equity Architect, Director of Innovation, Health Equity Accelerator, Boston Medical Center (BMC)
Rebecca Pontikes, JD, Employee Rights Lawyer, Pontikes Law, LLC

PLENARY KEYNOTE SESSION

8:45 Plenary Keynote Introduction

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

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.

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

PROIMMUNE www.proimmune.com

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 antibod?ies

IN SILICO STRATEGIES FOR NEW MODALITIES

1:55 Chairperson's Remarks

2:00 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.

2:30 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.

3:00 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.

3:30 Optimizing development-ability of Antibody Therapeutics

Speaker to be Announced, OpenEye Scientific

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

4:40 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.

5:10 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.

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

MENTORING MEET-UP

Organizer:

Mary Ann Brown, Executive Director, Conferences, Cambridge Healthtech Institute

7:40 Close of Predicting Immunogenicity with AI/ML Tools Conference

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 and Vice President, Digital and Biologics Strategy and Innovation, 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.

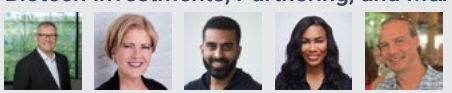
10:15 Sponsored Presentation *(Opportunity Available)*

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, 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

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 Plasticisity of Antibody Developability

Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

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, Scientist, Early-Stage 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.

3:00 Insights from the AIntibody 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 AIntibody 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 Sponsored Presentation *(Opportunity Available)*

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 advanced 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 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 AIntibody 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 AIntibody benchmarking competition: Did AI deliver on the AIntibody challenges?
- Ideas for future benchmarking competitions

BENCHMARKING AND AUTOMATION

8:25 Chairperson's Remarks
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

8:30 The IMMREP TCR-Epitope Prediction Challenge: Lessons Learned and Future Directions
Justin Barton, PhD, Principal Machine Learning Scientist, University College London

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.

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 Sponsored Presentation *(Opportunity Available)*

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 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.

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

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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.

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COMPANIES A-K:

Jason Gerardi
Senior Manager, Business Development
781-972-5452 | jgerardi@healthtech.com

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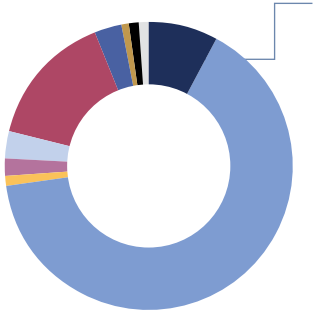

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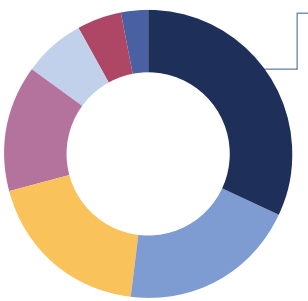

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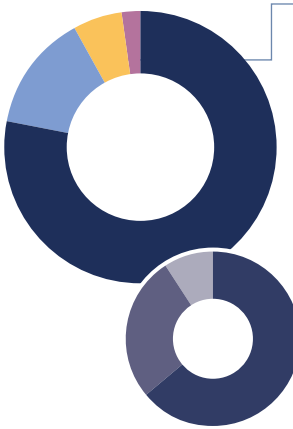

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