2024 CONFERENCE
PROGRAMS

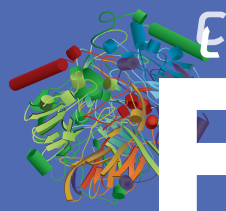
- ENGINEERING
- ONCOLOGY
- MULTISPECIFICS
- IMMUNOTHERAPY
- EXPRESSION
- ANALYTICAL
- IMMUNOGENICITY
- THERAPEUTICS

SC SHORT COURSES

Training SEMINARS

TABLE OF CONTENTS

PEGSummit.com



Celebrating 20 Years

PEGS BOSTON

The Essential Antibody and Protein Engineering Summit

MAY 13-17, 2024
BOSTON, MA + VIRTUAL
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OMNI BOSTON HOTEL AT THE SEAPORT

Register by March 29
SAVINGS UP TO $200

Organized by Cambridge HEALTHTECH Institute

PLENARY KEYNOTE SPEAKERS

Marcela V. Maus, MD, PhD
Massachusetts General Hospital

David R. , PhD
Harvard University

PLENARY FIRESIDE CHAT SPEAKERS

MODERATOR:
K. Dane Wittrup, PhD
Massachusetts Institute of Technology

PANELIST:
Jane K. Osbourn, PhD
Alchemab Therapeutics Ltd.

PANELIST:
Paul J. Carter, PhD
Genentech

PANELIST:
Daniel Chen, MD, PhD
Founder and CEO, Synthetic Design Lab

YOUNG SCIENTIST KEYNOTE

Gabriel J. Rocklin, PhD
Northwestern University

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TABLE OF CONTENTS

PEGS BOSTON

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

The PEGS Boston Summit brings together leading experts at the forefront of biologics innovation, providing insights into the latest technologies, research, and advancements in drug development, protein and antibody engineering, immunotherapy, immunogenicity, expression platforms, multispecific antibodies, machine learning, and AI in biologics, and more.

The PEGS Boston Summit features main conference sessions as well as deep-dive training seminars and topic-focused short courses. PEGS Boston Summit is your number one resource for protein engineering updates and is the conference to attend in 2024 to network, collaborate, and learn from the industry's best.

To provide maximum flexibility, CHI will present this event live in Boston as well as virtually for those unable to travel, forming one unique and valuable experience.

2024 CONFERENCE PROGRAMS

ENGINEERING — VIEW

Display of Biologics

Engineering Antibodies

Machine Learning Approaches for Protein Engineering

EXPRESSION — VIEW

Difficult-to-Express Proteins

Optimizing Protein Expression

Maximizing Protein Production Workflows

ONCOLOGY — VIEW

Antibodies for Cancer Therapy

Emerging Targets for Oncology and Beyond

Driving Clinical Success of Antibody Drug Conjugates

ANALYTICAL — VIEW

Digital Integration in Biotherapeutic Analytics

Biophysical Methods

Characterization for Novel Biotherapeutics

MULTISPECIFICS — VIEW

TRAINING SEMINAR:
Introduction to Multispecific Antibodies

Advancing Bispecific Antibodies and Combination Therapy to the Clinic

Engineering Bispecific Antibodies

IMMUNOGENICITY — VIEW

TRAINING SEMINAR:
Introduction to Immunogenicity

Immunogenicity Assessment and Management

TRAINING SEMINAR:
Introduction to Bioassays

IMMUNOTHERAPY — VIEW

Advances in Immunotherapy

Cell-Based Immunotherapy

In vivo Cell and Gene Engineering

THERAPEUTICS — VIEW

Emerging Indications for Therapeutic Antibodies

mRNA Therapeutics

In vivo Cell and Gene Engineering

SC SHORT COURSES

Training SEMINARS

TABLE OF CONTENTS

CONFERENCE AT-A-GLANCE

2024 PROGRAMS

	SUNDAY MAY 12	TUESDAY MAY 14	MONDAY - TUESDAY AM (MAY 13-14)	TUESDAY PM - WEDNESDAY (MAY 14-15)	THURSDAY-FRIDAY AM (MAY 16-17)
ENGINEERING	SC AFTERNOON SHORT COURSES	SC 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 of Antibody Drug Conjugates
MULTISPECIFICS			TRAINING SEMINAR: Introduction to Multispecifics	Advancing Bispecific Antibodies and Combination Therapy to the Clinic	Engineering Bispecific Antibodies
IMMUNOTHERAPY			Advances in Immunotherapy	Cell-Based Immunotherapy	*In vivo* Cell and Gene Engineering
EXPRESSION			Difficult-to-Express Proteins	Optimizing Protein Expression	Maximizing Protein Production Workflows
ANALYTICAL			Digital Integration in Biotherapeutic Analytics	Biophysical Methods	Characterization for Novel Biotherapeutics
IMMUNOGENICITY			TRAINING SEMINAR: Introduction to Immunogenicity	Immunogenicity Assessment and Management	TRAINING SEMINAR: Introduction to BioAssays
THERAPEUTICS			Emerging Indications for Therapeutic Antibodies	mRNA Therapeutics	*In vivo* Cell and Gene Engineering

Training SEMINARS
By Cambridge Healthtech Institute

- Introduction to Protein Engineering
- Antibody Drug Discovery: From Target to Lead
- Introduction to Immunogenicity
- Introduction to Multispecific Antibodies: History, Engineering, and Application
- Introduction to Machine Learning for Biologics Design
- Label-Free Biosensor Tools in Biotherapeutic Discovery: SPR, BLI & KinExA
- Introduction to Antibody-Drug Conjugate Design: Targets, Payloads, and Linkers
- Bridging the Gap from R&D to Bioprocessing
- Introduction to Bioassay Design, Development, Analysis, Validation, and Monitoring
- Analysis and Interpretation of Antibody Deep Sequencing and Single Cell Analysis Data

PLENARY KEYNOTE SESSIONS

MONDAY, MAY 13 | 4:35 - 5:20 PM

PLENARY KEYNOTE:

Driving New CAR T Cells

MARCELA V. MAUS, MD, PHD

Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

MONDAY, MAY 13 | 5:20 - 6:05 PM

YOUNG SCIENTIST KEYNOTE:

High-Throughput Discovery of Protein Folding Stability and Dynamics

GABRIEL J. ROCKLIN, PHD

Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

TUESDAY, MAY 14 | 10:15 - 11:00 AM

PLENARY KEYNOTE:

Base Editing and Prime Editing: Engineered Proteins that Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

DAVID R. LIU, PHD

Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Broad Institute Core Institute Member and Vice-Chair of the Faculty; Director of the Chemical Biology and Therapeutic Sciences Program; Howard Hughes Medical Institute Investigator; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

THURSDAY, MAY 16 | 12:10 - 12:55 PM

PLENARY FIRESIDE CHAT:

What Comes Next in Antibody Discovery and Engineering?

MODERATOR:

K. DANE WITTRUP, PHD

Massachusetts Institute of Technology

PANELIST:

JANE K. OSBOURN, PHD

Alchemab Therapeutics Ltd.

PANELIST:

PAUL J. CARTER, PHD

Genentech

PANELIST:

DANIEL CHEN, MD, PHD

Engenuity Life Sciences

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

SHORT COURSES*

IN-PERSON ONLY

*Separate registration required.

SUNDAY, MAY 12 2:00-5:00 PM

SC2: How to Use and Improve Microbial Expression Systems for Recombinant Protein Production

Instructors:

Jan-Willem de Gier, PhD, Professor, Biochemistry and Biophysics, Stockholm University

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Many different microbial expression systems are used for recombinant protein production. The choice of an expression system and the way it is used can greatly influence protein production yields. This raises some important questions: what is a suitable expression system for a particular application, how should it be used and can it be improved? This interactive course will address these questions by -i- going through the main bottlenecks hampering microbial-based protein production, -ii- providing a good understanding of how different microbial expression systems work and should be used, and, -iii- how to implement engineering approaches to improve expression systems for further enhancing production yields.

SC3: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

Instructors:

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

Tony Pham, Scientist, Biologics Engineering & Developability, AstraZeneca

Nele Quast, DPhil Candidate, Oxford Protein Informatics Group

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.

SC4: Safety and Efficacy of Bispecifics and ADCs

Instructor:

Rakesh Dixit, PhD, President & CEO, Bionavigen

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.

SC5: Targeting Solid Tumors and Understanding the TME

Instructor:

Tony R. Arulanandam, DVM, PhD, Senior Vice President and Head R&D, Cytovia 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 14 6:30-9:00 PM

SC6: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies

Instructor:

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

Complex membrane proteins 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. This course will examine emerging technologies and strategies for enabling the successful isolation of specific and functional antibodies against GPCRs, ion channels, and transporters, and highlight progress via case studies.

SC7: The Use and Optimization of Eukaryotic Expression Systems to Support Therapeutic Generation and Structural Biology

Instructors:

Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

The choice of a suitable eukaryotic expression system depends mainly on the biological and biochemical properties of an individual protein. The course will focus on insect and mammalian expression systems, which have demonstrated the ability to express complex proteins for a wide variety of applications. We will discuss the concepts, uses, and optimization of these systems. The course combines instruction and case studies in an interactive environment.

SC8: 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

MONDAY, MAY 13, 2024 8:30 AM - 6:05 PM
TUESDAY, MAY 14, 2024 8:00 AM - 1:30 PM

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

Instructor:

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

Introduction to Multispecific Antibodies will be organized as an informative and practical guide to getting up to speed on critical aspects of bispecific 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 the 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 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 14, 2024 3:00 PM - 6:10 PM
WEDNESDAY, MAY 15, 2024 8:30 AM - 6:10 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, 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: Label-Free Biosensor Tools in Biotherapeutic Discovery: SPR, BLI & KinExA

Instructors:

Yasmina Abdiche, PhD, Vice President, Exploratory Research, OmniAb Inc. (Moderator)

Vishal Kamat, PhD, Senior Director, Protein Sciences, Ampersand Biomedicines

Palaniswami (Swami) Rathanaswami, PhD, CEO, PRSwami AbDev Inc.

This training seminar will cover the main applications of commonly used commercial label-free biosensors in the interaction analysis of biologics and guidelines for best practices to generate reliable and reproducible data. We will primarily focus on Surface Plasmon Resonance (SPR), Biolayer Interferometry (BLI), and Kinetic Exclusion Assay (KinExA) technologies and their application in drug discovery.

THURSDAY, MAY 16, 2024 8:45 AM - 6:00 PM
FRIDAY, MAY 17, 2024 8:30 AM - 12:30 PM

TS7C: Introduction to Bioassay Design, Development, Analysis, Validation, and Monitoring

Instructor:

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

This course introduces statistical ideas supporting bioassays (via examples), reviews bioassay properties, and shows how laboratory constraints create the 'statistical design structure' of assays. These structures inform analyses and design of experiments (DOE) and its application to development, validation, and monitoring. Strategic combinations of assay design and good assay analysis methods offer new monitoring tools that support a lifecycle approach.

TS8C: Bridging the Gap from R&D to Bioprocessing

Instructors:

Carissa L. Young, PhD, Independent Consultant

Marieke Koedood Zhao, PhD, Vice President, Process Sciences, Kudo Biotechnology

TS9C: Analysis and Interpretation of Antibody Deep Sequencing and Single Cell Analysis Data

Instructors:

Brandon DeKosky, PhD, Phillip and Susan Ragon Career Development Professor of Chemical Engineering, MIT Core Member, The Ragon Institute of MGH, MIT, and Harvard University

Matias Gutierrez-Gonzalez, PhD, Research Fellow, The Ragon Institute of MGH, MIT, and Harvard

In this training seminar, participants will learn about recently developed methods for Next-Generation Sequencing (NGS) and single-cell analysis of antibody repertoires. The course will be interactive with case studies, participants will be able to download data and examples. Please bring your computer.

NETWORKING AND MEET UPS

Connect. Converse. Collaborate.

The PEGS Boston Summit brings together leading experts at the forefront of biologics innovation, providing insights into the latest technologies, research, and advancements in drug development, protein and antibody engineering, immunotherapy, immunogenicity, expression platforms, multispecific antibodies, machine learning and AI in biologics, and more.

Join us at the PEGS Boston Summit, where connections are nurtured, ideas converge, and opportunities unfold. Elevate your conference experience by seizing the chance to connect in a space designed for collaboration and shared exploration.
Scheduled Networking Events Include:

MONDAY, MAY 13

10:00 – 10:30 am: **Networking Coffee Break**

3:15 – 4:15 pm: **Networking Refreshment Break**

6:05 – 7:30 pm: **Welcome Reception in the Exhibit Hall with Poster Viewing**

7:00 - 7:30 pm: **Young Scientist Meet Up**

TUESDAY, MAY 14

9:00 – 10:00 am: **Coffee Break in the Exhibit Hall with Poster Viewing**

11:00 am – 12:00 pm: **20th Anniversary Celebration in the Exhibit Hall with Poster Viewing**

4:30 – 5:10 pm: **Refreshment Break in the Exhibit Hall with Poster Viewing**

WEDNESDAY, MAY 15

10:30 – 11:10 am: **Coffee Break in the Exhibit Hall with Poster Viewing**

1:40 – 2:25 pm: **Interactive Discussions**

4:40 – 5:10 pm: **Speed Networking**

6:10 – 7:30 pm: **Networking Reception in the Exhibit Hall with Poster Viewing**

THURSDAY, MAY 16

7:30 – 8:30 am: **Women in Science Breakfast Panel: Fostering Mentorship and Company Culture for the Advancement of Gender Equity*** (Continental Breakfast Provided)

10:50 – 11:50 am: **Coffee Break in the Exhibit Hall with Poster Viewing**

11:00 - 11:50 am: **Women in Science Meet Up**

FRIDAY, MAY 17

7:30 - 8:25 am: **Interactive Discussions with Continental Breakfast**

10:30– 11:00 am: **Networking Coffee Break**

**Free to attend; sign up in advance on the registration page*

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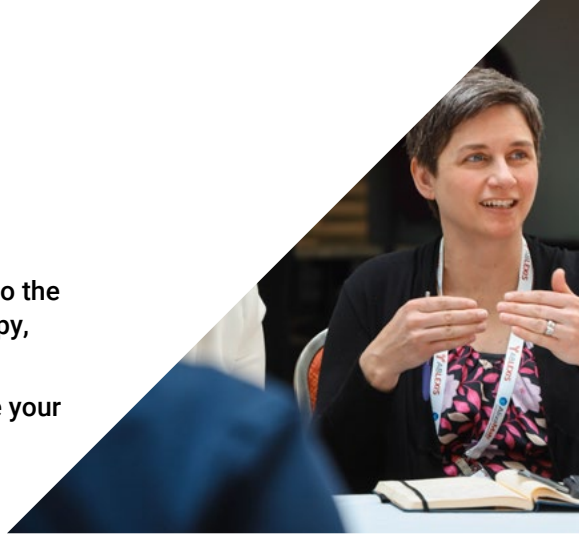

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TABLE OF CONTENTS

The State of the Science in Biotherapeutics Research and Development

ENGINEERING STREAM

Each year, the PEGS Boston Engineering Stream examines the state of the science in biologics R&D, and for 2024, these three programs will explore smarter and higher throughput screening methods, novel discovery platforms, strategies for dealing with challenging targets and modalities, creative engineering approaches for improving the precision and efficacy of therapeutic antibodies, 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 13-14

Display of Biologics

AGENDA

MAY 14-15

Engineering Antibodies

AGENDA

MAY 16-17

Machine Learning Approaches for Protein Engineering

AGENDA

TABLE OF CONTENTS

PEGSBOSTON

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

MONDAY, MAY 13

7:00 am Registration and Morning Coffee

SMALL PROTEIN DESIGN USING PHAGE AND YEAST DISPLAY

8:20 Chairperson's Remarks

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

8:30 Design and Discovery of Synthetic Miniprotein Ligands

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

We have shown that synthetic miniproteins computationally designed for foldedness can function as developable, evolvable scaffolds for ligand discovery. We leverage the data of differential performance across designs to gain fundamental insights and develop stronger scaffolds. Moreover, we advance lead molecules as molecular therapeutics.

9:00 Building the Infinite Loop for Machine Learning Guided Discovery, Delivery, and Rapid Manufacturing of Potential Medicines

Bradley L. Pentelute, PhD, Professor, Chemistry, Massachusetts Institute of Technology

We're facing a challenge in the world of chemistry: our lack of data is slowing down how we can use clever computer programs, known as machine learning, to create powerful new medicines. In this piece, I discuss what we're doing to solve this problem by creating data highways from millions of small molecules, peptides, and small proteins. We now use machine learning to discover and create new functional molecules quickly.

9:30 Engineering Cyclotide Binding Modules by Yeast Display

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

We will describe strategies to select for cyclotide precursors on the yeast cell surface, which are then subsequently converted to cyclotides following soluble expression. These ruggedly stable binders have potential applications for cytoplasmic delivery, radioligand therapy, and oral delivery. The rules for library design, selection & counterselection strategy, and exploitation of NGS data are different than for antibody libraries, and are beginning to be explicated.

10:00 Co-Presentation: Leverage *in vivo* Discovery and Machine Learning to Generate Best-in-Class Antibodies

Piotr van Rijssel, Application Scientist, ENPICOM

Pete Leland, Vice President, Production & Characterization, Genovac

Leverage *in vivo* discovery and machine learning to generate best-in-class antibodies – genetic immunization, single-cell screening and the IGX Platform

10:30 Networking Coffee Break

USING AI FOR IMPROVING ANTIBODIES

10:59 Chairperson's Remarks

Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.

11:00 Combining Active Learning with a Rapid Synthetic Biology Platform to Design Therapeutic Antibodies

Peyton Greenside, PhD, Co-Founder & CSO, BigHat Biosciences

BigHat Biosciences has developed novel machine learning (ML) approaches that leverage our high-speed, automated wet lab in order to rapidly and iteratively design over a thousand next-generation therapeutic antibodies each week. BigHat's algorithmic approach pairs with our unique wet lab to guide the search for better molecules by learning from each cycle of characterization across multi-objective affinity, function, and developability measures of each antibody.

11:30 Exploring the Efficacy of Singular and Combined Approaches: Evolutionary Intelligence, Artificial Intelligence, and Their Synergy in Advancing Antibody Affinity Maturation

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.

Through routine deep sequencing of our internal Gen3 library, which is built on evolutionary intelligence, we have amassed a comprehensive database of drug-like antibody sequences, ideally suited for natural language processing (NLP). In this talk, we will compare our unique approach to affinity maturation, including our latest method which utilizes LLMs trained on our internal databases, and discuss an honest side-by-side comparison with other cutting-edge AI approaches in antibody optimization.

12:00 pm Session Break

12:05 Luncheon Presentation I: Antibody Engineering with Predictive Design

Sridhar Govindarajan, CIO & Co-Founder, ATUM

ATUM's antibody platform combines Machine Learning and empirical approaches. Antibodies are designed in-silico using our proprietary algorithms and synthesized in scale to characterize them for functionality and developability simultaneously, resulting in a high-affinity, high-specificity antibody with developability properties for process development, scale-up, manufacturing.

12:35 LUNCHEON PRESENTATION: Rapid and Scalable Antibody Engineering by Autonomous Hypermutation in Yeast

Alon Wellner, Vice President, Biology, Aureka Biotechnologies

Aureka Biotechnologies integrates autonomous evolution and generative AI for advanced antibody engineering. Antibody fragments are encoded on an error-prone DNA replication system, mutating through yeast culturing for antigen binding. This process swiftly produces high-affinity clones in under two weeks, enriching training data sets for our AI models.

1:05 Session Break

NOVEL PLATFORMS

1:10 Chairperson's Remarks

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

1:15 Engineered CD47 Protects T Cells for Enhanced Antitumor Immunity

Sean Yamada-Hunter, PhD, Postdoctoral Research, Mackall Lab, Stanford Cancer Institute, Stanford University

CAR T and anti-CD47 therapy are two distinct immunotherapies we found to be non-compatible in combination due to depletion of adoptively transferred T cells by macrophages. We engineered CD47 for selective binding to be insensitive to CD47 therapy, but still function as a "don't eat me" signal. We demonstrated that the combination of CAR T cells expressing engineered CD47 and CD47 blockade results in synergistic control of multiple solid tumors.

1:45 Engineering Immune Responses for Epitope-Focused Antibody Discovery

Jerome D. Boyd-Kirkup, PhD, Co-Founder & CSO, Hummingbird Bioscience Pte. Ltd.

Traditional antibody generation allows limited control over the epitopes of resulting sub-optimal antibodies. We have leveraged our approach to conditional gene knockout during immunization to direct optimal antibody responses to epitopes of interest. Our technology can unlock rational antibody discovery for a new generation of antibody-based therapeutics.

2:15 Microfluidic Capture and Rapid Screening of Natively Paired B Cell Repertoires for the Discovery of Potent Biologics

Sarav Rajan, PhD, Director, Biologics Engineering, AstraZeneca R&D

Existing methods for biologics discovery offer complementary advantages but each come with their drawbacks. We present a microfluidics-based discovery engine to generate, enrich, and screen natively paired libraries, thereby combining the strengths of B cell and display-based platforms. We have extensively used this platform to rapidly isolate potent biologics across therapy areas and modalities.

2:45 The Pioneer Antibody Discovery Platform: From difficult targets to modular antibodies and Bispecifics BIO-RAD

Francisco Ylera, PhD, Senior Staff Scientist, Research and Development, Bio-Rad Laboratories, Inc.

Bio-Rad's Pioneer™ Antibody Discovery Platform includes one of the largest Fab libraries ever made. The library contains over 2 x 10^11 unique human antibody sequences and has been optimized for Fab selection and IgG developability. In combination with the SpyDisplay selection technology and TrailBlazer™ modular antibody platform, Pioneer enables rapid lead candidate generation also against GPCRs. We will also introduce SpyLock, a novel approach for rapid high-throughput generation of bispecific antibodies.

3:15 Networking Refreshment Break

4:15 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:25 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

4:35 Driving New CAR T Cells

Marcela V. Maus, MD, PhD, Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

YOUNG SCIENTIST KEYNOTE

5:20 High-Throughput Discovery of Protein Folding Stability and Dynamics

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

6:05 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

Facilitators:



Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Shakiba Nikfarjam, PhD, Postdoc, Lawrence Livermore National Lab

7:30 Close of Day

TUESDAY, MAY 14

7:30 am Registration and Morning Coffee

PRECISION-ACTIVATED BIOLOGICS

7:55 Chairperson's Remarks

E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

8:00 Leveraging the Acidic Tumor Microenvironment to Selectively Target VISTA with a pH-Sensitive, Conditionally Active Antibody

Edward van der Horst, PhD, CSO, Sensei Bio

SNS-101 is a yeast-based, fully human conditionally active anti-VISTA antibody designed to relieve T cell suppression driven by the VISTA-PSGL-1 immune checkpoint within the acidic tumor-microenvironment, currently in a Phase I study (NCT05864144). Biochemical and structural data show SNS-101's exquisite selectivity for active, protonated VISTA. Preclinical data demonstrate SNS-101's pH-selectivity abrogates target mediated drug disposition (TMDD) and significantly reduces the risk of cytokine release syndrome.

8:30 Conditional 4-1BB x 5T4 Antibody for Tumor Immunotherapy

Peter Pavlik, PhD, Senior Director, Protein Engineering, Aptevo Therapeutics

Development of target-activated ADAPTIRs for tumor immunotherapy: we will present our guiding principles for screening and development of conditionally active bispecifics. Our ADAPTIR and ADAPTIR-FLEX platforms allow us to create molecules with different geometries, valency, and functional performance. Data from Aptevo's diverse portfolio of clinical (APVO436, ALG.APV-527) and preclinical (APVO603, APVO711, APVO442) molecules will demonstrate that our engineering strategies can produce safe and potentially efficacious drug candidates.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION

10:00 Transition to Plenary Keynote Session

10:10 Plenary Keynote Introduction

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

10:15 Base Editing and Prime Editing: Engineered Proteins That Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

David R. Liu, PhD, Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Core Institute Member and Vice-Chair of the Faculty, Broad Institute; Director, Chemical Biology and Therapeutic Sciences Program; Investigator, Howard Hughes Medical Institute; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

11:00 Celebrating 20 Years in the Exhibit Hall with Poster Viewing

CHALLENGING TARGETS

12:00 pm Chairperson's Remarks

E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

12:01 When Finding a Needle in a Haystack Is Not Enough

Maria Antonietta Lillo, PhD, Scientist, Los Alamos National Lab

There are different kinds of difficult targets. Sometimes the target differs very minimally from close relatives and needs to be detected with high accuracy and sensitivity. The aim of the selection is finding multiple needles snuggly fitting different pinholes in one piece of cloth. In this case the aim of the selection is finding a set of needles in one haystack, matching a set of needles in a second haystack.

12:30 The Discovery and Engineering of Membrane Protein-Specific Antibodies Using a Yeast-Based Platform

Noel T. Pauli, PhD, Group Leader, Antibody Engineering, Adimab LLC

Integral membrane proteins pose a significant challenge for antibody discovery and optimization. Adimab's platform incorporates immunized llama or wildtype and humanized mice diversities with a highly engineered strain of yeast. Using this integrated platform approach, we can efficiently discover large numbers of clonally diverse, high-affinity antibodies, and further engineer leads for improved target product profiles, even without the aid of soluble recombinant antigen.

1:00 Presentation to be Announced

ABLEXIS
AlivaMab BIOLOGICS

1:30 Session Break

1:40 Luncheon Presentation I: Developing Multi-Specific VHH-Based Antibody Formats Leveraging Proprietary Display Library

Alloy Therapeutics

Kent Bondensgaard, PhD, Senior Vice President, Head, Antibody Discovery Services, Alloy Therapeutics

VHH antibodies are integral in advancing next-generation bi- and multi-specific formats. Alloy has spearheaded proprietary engineered human and semi-synthetic libraries to facilitate the exploration of human germline VHH binders with improved stability and resistance to aggregation. These binders have been pivotal in the development of complex molecular formats such as trimeric and masked biologics, which will be showcased in this presentation.

2:10 Luncheon Presentation to be Announced

DNASCRIPT

2:40 Close of Display of Biologics Conference

6:30 Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

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

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

TUESDAY, MAY 14

TECHNOLOGIES TO ENABLE INTELLIGENT ANTIBODY DISCOVERY

2:55 pm Chairperson's Remarks

Alan Cheng, PhD, Senior Director, Modeling and Informatics, Merck Research Labs

3:00 Rapid Discovery of High-Affinity Antibodies by Deep Screening

Niklas Freund, PhD, Postdoctoral Researcher, MRC Laboratory of Molecular Biology

I present deep screening, an ultra-high-throughput approach leveraging the Illumina HiSeq platform for massively parallel sequencing, display, and rapid affinity screening at the level of >10e8 individual antibody-antigen interactions. Deep screening enabled the discovery of mid- to high-picomolar single-chain Fv (scFv) antibody leads directly from unselected, synthetic scFv repertoires in a three-day experiment, and provides large sequence/function correlation datasets suitable for machine learning to further accelerate antibody discovery.

3:30 Advanced Repertoire Mining Strategies for Antibody Optimization

Isidro Hotzel, PhD, Distinguished Scientist, Antibody Engineering, Genentech

Antibody somatic variants can be mined from immune repertoires to rapidly optimize the affinity of antibodies derived from immunization. Antibody genetics interpreted in the context of functional data can also be used to more broadly mine repertoires for unrelated clones that share epitope specificity for applications beyond affinity optimization.

4:00 Talk Title to be Announced

Desmond Schofield, PhD, Chief Business Officer, evitria AG

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

5:10 Applications of Long-Read Sequencing in Antibody Discovery

Quentin Gouil, PhD, Senior Research Officer, Department of Medical Biology, University of Melbourne

Despite their importance in research, monoclonal antibodies are not systematically sequenced. We developed Nanopore Antibody Sequencing (NAb-seq), a three-day, species-independent, and cost-effective workflow to characterize paired, full-length light- and heavy-chain genes from hybridomas. NAb-seq is accurate, scalable, and can identify multiple heavy- and light-chains within a single cell line. We further show that NAb-seq is applicable to single cells, allowing antibody discovery in rare populations such as memory B cells.

5:40 Leveraging Single-Cell Immune Repertoire Sequencing for Computationally Guided Antibody Discovery

Alexander Yermanos, PhD, Lecturer, Systems & Synthetic Immunology, ETH Zurich

Recent advancements in deep sequencing and microfluidics now enables the high-throughput recovery of paired heavy- and light-chain sequences at single-cell resolution. I will discuss how single-cell immune repertoire sequencing can be used to discover antibodies against model antigens and therapeutic targets, and how computational features such as clonal expansion, transcriptional phenotypes, and antibody evolution relate to biophysical properties such as specificity, affinity, and epitope.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

8:25 Chairperson's Remarks

Pierce J. Ogden, PhD, Co-Founder & CSO, Manifold Biotechnologies Inc.

8:30 PANEL DISCUSSION: AI/ML in Antibody Discovery and Engineering: Reality, Hope, Future, and Hype

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

This panel offers the PEGS community of scientists working on biotherapeutic discovery and engineering an opportunity to examine the current progress, value, and challenges associated with the wide range of new ML/AI tools being applied in this space.

Panelists:

Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.

Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

Peyton Greenside, PhD, Co-Founder & CSO, BigHat Biosciences

Paolo Marcatili, PhD, Director, Antibody Design, Novo Nordisk

Joshua Meier, PhD, Independent Consultant; Former Chief AI Officer, Absci

9:30 KEYNOTE PRESENTATION: mRNA-Encoded Monoclonal Antibodies to Combat Infectious Diseases

Laura Walker, PhD, Head, Infectious Disease Biotherapeutic Discovery & Engineering, Moderna

mRNA-encoded antibodies hold great promise for the treatment and prevention of infectious diseases. Unlike traditional CHO cell-based platforms for IgG1 manufacturing, mRNA technology is amenable to alternative antibody isotypes, multispecific formats, and combinations of antibodies, which can endow antibodies with enhanced functions. In this presentation, I will discuss how we are harnessing the advantages of mRNA technology to develop antibody-based treatments for a multitude of bacterial and viral pathogens.

10:00 There and Back Again - From Early Research to Clinical Development Partner

Lauri Peil, PhD, Key Account and Technology Officer, Icosagen Group

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

DISCOVERY PLATFORMS WITH AI/ML INTEGRATION

11:10 Antibody Developability Prediction and Sequence Generation with AI/ML

Alan Cheng, PhD, Senior Director, Modeling and Informatics, Merck Research Labs

In the discovery of antibodies as therapeutics, traditional methods for screening and optimizing antibodies are limited in the sequence space complexity they can cover and are generally resource intensive. We discuss approaches that combine advances in *in vitro* display and computational deep learning to enable more efficient searching of antibody sequence space. We also discuss how integrating sequence and structural information using deep learning enables improved prediction of antibody properties

11:40 A Critical Evaluation of Machine Learning and Protein Modeling Strategies for Antibody Developability Prediction

Mickey Atwal, PhD, VP Molecular Profiling & Data Science, Regeneron Pharmaceuticals Inc.

Accurate prediction of biophysical properties is an important but challenging problem in antibody therapeutic development. To address the limitations of small training datasets, we constructed a novel hybrid machine learning and protein modeling framework. This framework utilizes structure-derived molecular descriptors, sequence embeddings from protein language models, or 3D geometric representations of structures. Our findings indicate that molecular descriptor-based models trained within an active-learning framework provide superior and more interpretable predictions.

12:10 pm Session Break

12:20 Luncheon Presentation I: Bridging AI and Bench: Mastering Bi-Specific Antibody Production for Next-Gen Drug Discovery

Hengtai Liew, Senior Protein Scientist, GenScript

The ongoing AI revolution is ushering in a new era of antibody design, including multi-specific antibodies (MsAbs). While MsAbs are not novel, their advancement has encountered various challenges. The increased complexity compared to monoclonal antibodies necessitates careful consideration and the implementation of robust engineering strategies to overcome hurdles. Here, we aim to highlight key considerations for designing MsAbs and explore strategies from upstream to downstream processes applicable to diverse MsAb formats.

12:50 Luncheon Presentation II: Leveraging Multiple Discovery Pathways to Improve the Efficiency of Therapeutic Candidate Generation

John Kenney, President, Antibody Solutions

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 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.

TABLE 1: The Impact of Artificial Intelligence (AI) on Biologics Discovery and Optimization - IN PERSON ONLY

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

TARGETING CHALLENGES

2:25 Chairperson's Remarks

Alexander Yermanos, PhD, Lecturer, Systems & Synthetic Immunology, ETH Zurich

2:30 Engineering Antibodies for Receptor Agonism from Top to Bottom (Fc to Fab)

Mark S. Cragg, PhD, Professor, Experimental Cancer Biology, Antibody and Vaccine Group, School of Cancer Sciences, University of Southampton

Agonistic antibodies directed to immunostimulatory receptors are an untapped source for immunotherapy. Here we discuss the properties required to optimally agonize these receptors and describe potential strategies for leveraging them for immune activation and anti-tumor efficacy. Using TNFR superfamily receptors as a paradigm and IgSF members for comparison, we evaluate the key characteristics of the Fc, hinge, and Fab in delivering powerful receptor agonism.

3:00 Pharmacological Analysis of Agonistic and Antagonistic FGFR1 MAbs Reveals a Similar Unique Mode-of-Action

Laetitia D. Comps-Agrar, PhD, Senior Principal Scientist, Biochemical & Cellular Pharmacology, Genentech, Inc.

Fibroblast growth factor receptor 1 (FGFR1) is a promising yet challenging therapeutic target that may require an agonist or antagonist, depending on the indication. We investigated the mechanism-of-action of reported agonistic and antagonistic FGFR1 antibodies and described a novel, functionally-distinct FGFR1-active conformation that impacts *in vivo* activity. We further engineered these antibodies and demonstrated that modulating the geometry of FGFR1 can effectively change the signaling outputs.

3:30 Inverting the Drug Discovery Funnel: *In vivo* First Screening for Blood-Brain Barrier Penetration Yields Molecules with Novel Uptake Properties

Pierce J. Ogden, PhD, Co-Founder & CSO, Manifold Biotechnologies Inc.

Targeting the brain with biologics has proven challenging due to the restrictions of the blood-brain barrier. We introduce a high-throughput *in vivo* screening using Manifold's mCodes to evaluate over 1,000 antibodies' (BBB) penetration. This approach identifies antibodies with varied characteristics and further optimizes their brain uptake using machine learning. Validated in murine and primate models, our findings enhance BBB transcytosis understanding and mark a shift in early drug discovery methodologies.

4:00 Combining Binding and Functional Analyses for Comparison of Anti-TNFα Monoclonal Antibody Biosimilars

David O. Apiyo, PhD, Manager, Application Development, BioAnalytics, Sartorius

To exemplify the use of a combined cell analysis and ligand binding for the characterization of biosimilars, a range of binding and functional characteristics was assessed on Adalimumab antibodies. An Adalimumab clone was subjected to an elution buffer optimization process, with the resulting elution fractions of the antibody assessed using single concentration analyte kinetic screen an against an antigen and a set of Fcγ receptors; CD16a V176 and CD64.

4:15 Epitope-First Antibody Discovery Directed by High-Throughput Structural Analysis

Neal Goodwin, PhD, CSO, Immuto Scientific

We introduce a new paradigm for systematically engineering high-affinity antibodies selective for target epitopes. The approach leverages high-throughput, high-resolution epitope structure determination and ensures exceptional precision in mapping antibody epitope selectivity for structurally uncharacterized and multimeric targets. The structure-guided platform overcomes shortfalls of conventional antibody discovery approaches for overcoming complex challenges in developing next-generation precision-targeted antibody therapeutics.

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

5:10 Strategies for Overcoming Challenging Targets with *in vivo* Antibody Discovery

Trevor Wattam, PhD, Scientific Leader, Antibody Discovery, GlaxoSmithKline

Complex (challenging) targets are now becoming the norm for therapeutic antibody discovery. The availability of new immunogens (genetic, protein, and cellular) combined with novel approaches for immunogen delivery and novel use of adjuvants can make challenging targets less challenging. Here we show our advances in improving the immune response to challenging targets that increase the probability of isolating therapeutic antibodies in our antibody discovery process.

5:40 AI-Guided Antibody Discovery for a Difficult Ion Channel Target

Surge Biswas, PhD, Founder & CEO, Nabla Bio, Inc.

We'll show how we are combining generative AI approaches with high-relevance screening technologies to design selective antibodies for multi-pass membrane protein targets. We'll share examples covering ion channel and GPCR targets. We'll also discuss where we observe AI adding value in such binder biologics discovery projects when state-of-the-art wet lab approaches are available. Our views are optimistic, but sometimes counter to current narratives.

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of Engineering Antibodies Conference

MACHINE LEARNING APPROACHES FOR PROTEIN ENGINEERING

Balancing Theory with Practice

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

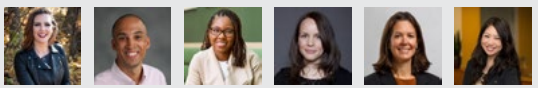
**Separate registration required. See short course page for details.*

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity: IN-PERSON ONLY *(Continental Breakfast Provided)*

Co-Organized with THINKUBATORMEDIA



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

MACHINE LEARNING FOR ANTIBODY DISCOVERY AND DESIGN

8:45 Chairperson's Remarks

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.

8:50 KEYNOTE PRESENTATION: Why Does the Virus Change Its Spots? The Role of Immunodominance in Viral Evolution

Stephen J. Elledge, PhD, Gregor Mendel Professor, Genetics & Medicine, Harvard Medical School

By mapping 376 immunodominant "public epitopes" at high resolution and characterizing several of their cognate antibodies, we conclude that germline-encoded sequences in CDR1 and CDR2 in antibodies drive recurrent recognition. Systematic analysis of antibody-antigen structures uncovered 18 human and 21 mouse germline-encoded amino acid-binding (GRAB) motifs within heavy and light V gene segments that are critical for public epitope recognition. GRAB motifs represent a fundamental component of immune system architecture.

9:20 *De novo* Peptide Sequencing with InstaNovo: Accurate, Database-Free Peptide Identification for Large-Scale Proteomics Experiments

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

InstaNovo, a cutting-edge transformer neural network, addresses the challenges of *de novo* peptide sequencing in mass spectrometry-based proteomics. Trained on 28M spectra, InstaNovo outperforms current state-of-the-art methods and showcases its utility in several applications. We further introduce InstaNovo+, a multinomial diffusion model that improves performance via iterative refinement. Together, these models unlock a plethora of opportunities across different scientific domains, including direct protein sequencing, immunopeptidomics, and dark proteome exploration.

9:50 Predicting Antibody Binders and Generating Synthetic Antibodies Using Deep Learning

David Johnson, PhD, Founder and CEO, GigaMune

First, we generated a large panel of binder and non-binder antibody sequences to the cancer immunotherapy targets PD-1 and CTLA-4. Next, we encoded the antibody light- and heavy-chain complementarity-determining regions (CDR3s) into antibody images, then built and trained convolutional neural network models to classify binders and nonbinders. We then built generative deep learning models, using generative adversarial network models to produce synthetic antibodies against PD-1 and CTLA-4.

10:20 Innovative Antibody Discovery Workflow Leveraging Machine Learning to Prioritize Leads

AZENTA LIFE SCIENCES

Crystal Richardson, Dr., Senior Business Partnership Manager, Azenta Life Sciences

Azenta now offers an innovative end-to-end antibody screening solution that guides your discovery program to more diverse leads while reducing liabilities for antibody development. Utilizing next generation sequencing of your in-vivo samples (i.e. B-cells, PBMCs) or *in vitro* libraries (i.e. Phage display), a bioinformatics platform, and gene synthesis, antibodies are produced with promising biophysical profiles for commercialization.

10:35 Cutting Through the Hype: Real-World Applications of AI in Antibody Discovery and Engineering

Ailux Biologics by XtalPi

Patrick Doonan, PhD, Director of Antibody Engineering, Antibody Discovery, Ailux Biologics

Artificial intelligence (AI) is transforming antibody discovery and engineering. Ailux's platform synergistically combines the best of wet lab and AI. We will explore a series of case studies that exemplify the applications of our AI-driven approach for tackling difficult GPCR targets, designing next-gen display libraries, predicting Ab-Ag complex structures and engineering challenging molecules. This presentation provides a realistic and evidence-based perspective on AI's impact on the industry.

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?




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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:

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

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

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

MACHINE LEARNING FOR ANTIBODY DISCOVERY AND DESIGN *(CONT.)*

2:35 Improving Computational Models of Human Antibodies

Bryan Briney, PhD, Assistant Professor, Immunology & Microbial Science, Scripps Research Institute

Antibody language models are an emerging class of tools with the potential to revolutionize our ability to understand the linkage between antibody sequence, structure, and function. The paucity of natively paired antibody sequence datasets means most antibody language models have been trained exclusively using unpaired antibody sequences, however, we have shown that training with natively paired sequences allows models to learn critically important cross-chain features.

3:05 Building Next-Generation Platforms to Enable AI-Guided Biologics Design

Alicia Kaestli, PhD, Senior Associate, Flagship Pioneering

The fusion of AI with biologics design offers unprecedented potential in drug discovery. However, building platforms that enable AI-guided drug discovery is not a straightforward process. I'll walk through how we've built and scaled new biotech platforms from the ground up for *de novo* biologics design.

AI-GUIDED OPTIMIZATION & RULES FOR DEVELOPABILITY

3:34 Chairperson's Remarks

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.

3:35 Learning Protein Fitness Models from Evolutionary and Assay-Labeled Data

Chloe Hsu, PhD, Co-Founder & CEO, Escalante Bio

Machine learning-based models of protein fitness typically learn from either unlabeled, evolutionarily related sequences (such as in the case of protein language models) or variant sequences, with experimentally measured labels. For regimes where only limited experimental data are available, we combine both sources of information in a simple combination approach that is competitive with, and on average outperforms more sophisticated methods.

4:05 LENSai: Empowering Diversity-Driven Discovery, Intelligent Lead Selection and Optimization

IpA IMMUNOPRECISE ANTIBODIES

Arnout Van Hyfte, Head of Products & Platform, BioStrand, Products & Platform, BioStrand, IPA (ImmunoPrecise Antibodies)

To select the best lead antibody for clinical use, it is crucial to have access to a highly diverse panel of lead candidates, matched with highly scalable down-selection and de-risking technologies. Leveraging our LENSai software, antibody discovery and optimization are accelerated through the integration of advanced ML and AI algorithms combined with experimental methodologies. Our pioneering LENSai software empowers cost-efficient development of next-generation antibodies with precision and speed.

4:20 Talk Title to be Announced

Abterra bio

Natalie Castellana, PhD, CEO, Abterra Biosciences

4:35 Networking Refreshment Break

5:00 The RESP AI Model Accelerates the Identification of Tight-Binding Antibodies

Wei Wang, PhD, Professor, Chemistry and Biochemistry, University of California San Diego

Deep learning techniques hold the potential to accelerate identification of effective antibodies but the existing methods cannot provide the confidence interval or uncertainty needed to assess the reliability of the predictions. Here we present a pipeline called RESP for efficient identification of high-affinity antibodies using uncertainty-aware machine learning methods.

5:30 Meaningful Biological Priors as Guiding Constraints for Graph Neural Network-Based Antibody Developability Prediction

Pranav M. Khade, PhD, Postdoctoral Fellow, Prescient Design, Genentech

Antibody developability properties are dependent on the relative disposition of constituent amino acids. We develop a graph neural network with meaningful biological priors such as Delaunay-based adjacency and Kidera factors to build an efficient and explainable model to predict antibody developability.

6:00 Deploying Synthetic Coevolution and Machine Learning to Engineer Protein-Protein Interactions

Aerin Yang, PhD, Basic Life Research Scientist, Molecular and Cellular Physiology, Stanford University

We present a platform for synthetic protein-protein coevolution, isolating diversely remodeled interacting pairs. This dataset enables comprehensive analysis of protein pairs, uncovering insights into structural diversity, affinities, cross-reactivities, and orthogonalities. Leveraging pretrained protein language models, we expand the amino acid diversity of our coevolution screen *in silico*, predicting remodeled interfaces. This integrated approach simulates protein coevolution, creating protein complexes with diverse recognition properties, benefiting biotechnology and synthetic biology.

6:30 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Roundtable Discussions with Continental Breakfast

Interactive Roundtable 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 Roundtable Discussions** page on the conference website for a complete listing of topics and descriptions.

TABLE 1: Engineering Novel Cytokine Functions through Experimental and Computational Approaches- IN PERSON ONLY

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

- Design parameters and objectives for cytokine engineering
- Tailoring engineering strategies to various cytokine systems
- Considerations for selecting the appropriate evolutionary and/or rational design strategies
- Key factors in choosing a computational workflow for cytokine engineering

TABLE 2: *De novo* peptide sequencing: Applications and opportunities- IN PERSON ONLY

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

- What tools are out there and how good are they?
- What applications benefit most from *de novo* peptide sequencing?
- What are current limitations and opportunities for further development?

AI-GUIDED OPTIMIZATION & RULES FOR DEVELOPABILITY *(CONT.)*

8:25 Chairperson's Remarks

M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.

8:30 A Machine Learning Strategy for the Identification of *in silico* Descriptors and Prediction Models for IgG Monoclonal Antibody Developability Properties

Andrew B. Waight, PhD, Senior Director, Machine Learning, Discovery Biologics & Protein Sciences, Merck Research Labs

Prediction of biophysical properties for protein therapeutics from calculated *in silico* features has potential to reduce the time and cost of delivering clinical-grade material to patients. We have developed an automated machine learning workflow designed to identify the most powerful features from computationally derived physiochemical feature sets. We demonstrate the use of this workflow with medium-sized datasets of IgG molecules to generate predictive regression models for key developability endpoints.

NEXT-GENERATION *IN SILICO* PROTEIN ENGINEERING AND *DE NOVO* DESIGN

8:59 Chairperson's Remarks

Maria Wendt, PhD, Global Head and Vice President, Digital and Biologics Strategy and Innovation, Sanofi

9:00 KEYNOTE PRESENTATION: Launching into the Future: Sanofi's Biologics AI Moonshot Program—Advancing AI Strategy and Innovation for Biologics

Maria Wendt, PhD, Global Head and Vice President, Digital and Biologics Strategy and Innovation, Sanofi

Sanofi recently launched the BioAIM program to push forward on our ambition to transform biologics drug discovery. This talk will discuss the landscape of opportunities for ML and AI in all aspects of antibody generation to design and engineering of advanced modalities, our approach, examples of novel methods developed, and early results.

9:30 *De novo* Cytokine Engineering to Probe and Manipulate Immune Biology

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

Cytokines are soluble factors that signal through stimulation of their cognate transmembrane receptors on target cells to perform critical biological functions, particularly those related to immune homeostasis. We synthesized a best-in-class computational protein design software with directed evolution technologies to generate a *de novo* engineered cytokine mimetic with superior stability and unique biochemical activities compared to naturally derived cytokines.

10:00 Talk Title to be Announced

Satoshi Tamaki, PhD, CEO/CSO, MOLCURE Inc.

MOLCURE

10:30 Networking Coffee Break

11:00 Prediction of Deamidation and Isomerization in Therapeutic Proteins Using Machine Learning Combined with Structural and Dynamical Features

Brajesh K. Rai, PhD, Senior Director, Machine Learning Computational Sciences, Pfizer Inc.

Rapid assessment of potential modification sites in therapeutic mAb candidates in the early discovery stages is crucial for reducing downstream development and clinical issues. In this talk, we will describe our machine learning models for predicting isomerization and deamidation sites in antibodies and discuss potential application of our approach for assessing chemical liabilities in monoclonal antibodies and other protein-based therapeutics.

11:30 Next-Generation Protein Language Model for Antibody Engineering and Discovery

Abhinav Gupta, PhD, Senior Machine Learning Scientist, Next-Generation Biologics Design, Sanofi

Current Ab-specific PLMs are limited in knowledge due to the use of only unpaired sequences and the traditional masked-language-modeling approach of self-supervised training, and therefore, are not ideal for utilization for tasks such as affinity, thermal stability, contact-map/epitope/paratope prediction, etc. We aim to alleviate this knowledge limitation in our Next-Gen PLM by infusing information from multiple internal and external data modalities and developing new training strategies.

12:00 pm Predicting and Optimizing Antibody Stability Using Large Language Models

Willy Voje, PhD, Senior Data Scientist, Protein Language Models, Evotec

Recent work will be discussed on the assessment of out-of-the-box performance of publicly available general-protein language-models and antibody-specific language-models for antibody property prediction. In addition, ongoing work to fine-tune language models with publicly available paired-chain antibody data will be shared. Finally, a description of work to couple protein language models with large, empirical stability datasets to improve performance on antibody property prediction.

12:30 Close of Conference

Novel Approaches and Challenges in Advancing Molecules into the Clinic

ONCOLOGY STREAM

The field of antibody and protein therapeutics has progressed from monoclonals to encompass bispecifics, multispecifics, ADCs, immunocytokines, prodrugs and radio-immunotherapies. As the modality types expand, the need for novel targets and new mechanisms of action has become increasingly important, in order to overcome existing limitations of approved molecules, expand the therapeutic window, and improve efficacy and patient response. PEGS Boston's Oncology stream aims to bring together the latest molecules in clinical development to highlight the lessons learned from the clinic, spotlight emerging and revitalized targets, and showcase inventive approaches for improving the therapeutic index. Together, the three conferences in this stream will present a comprehensive look at strategies driving toward clinical success.

TABLE OF CONTENTS

ONCOLOGY STREAM CONFERENCES

MAY 13-14

Antibodies for Cancer Therapy

AGENDA

MAY 14-15

Emerging Targets for Oncology and Beyond

AGENDA

MAY 16-17

Antibody Drug Conjugates

AGENDA

PEGSBOSTON

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC4: Safety and Efficacy of Bispecifics and ADCs
**Separate registration required. See short course page for details.*

MONDAY, MAY 13

7:00 am Registration and Morning Coffee

NEXT-GENERATION THERAPEUTICS PLATFORM

8:20 Chairperson's Remarks

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

8:30 KEYNOTE PRESENTATION: From the Foundation to the Next Generation of Antibody-Based Therapies: What's Next?

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

Monoclonal antibody therapies represent the majority of approved biologics. Advances in protein engineering, from bioconjugation, payload selection, multispecific constructs, conditional binders, and complete framework redesign enable therapeutic approaches that were not previously possible. When combined with a deep understanding of human biology and AI, we can start to create more specific and potent human therapeutics needed to overcome increasingly difficult and complex clinical challenges in human disease.

9:00 Precision-Guided Bicycle Therapeutics for Treatment of Cancer

Philip E. Brandish, PhD, Senior Vice President, Immuno-Oncology, Bicycle Therapeutics

Small bicyclic peptides constrained by a central scaffold can have pharmacologic and pharmacodynamic properties that fit very well with the design goals that are optimal for targeted delivery of toxins, radionuclides, or immune agonists for the treatment of cancer. This presentation will highlight the application of the Bicycle technology to activation of anti-tumor immunity in the setting of cancer, in particular via the activating receptors CD137 and NKp46.

9:30 Twin Fc-Immune Cell Engager (ICE): A Novel Platform to Potentiate Therapeutic Efficacy of Antibody for Cancer Therapy

Eun Shik Choi, PhD, CTO, Centenaire Biosciences, Inc.

Twin Fc-ICE is an engineered antibody platform designed to effectively engage multiple immune effector cells and complement as well as to maximize the Fc load on tumor targets, while retaining the size and drug-like properties of IgG1. Anti-HER2 Twin Fc-ICEs demonstrated augmentation of diverse immune mechanisms including macrophage-dependent phagocytosis and stronger *in vivo* efficacy against HER2-positive and HER2-low tumors than anti-HER2 IgG1 antibodies, highlighting the clinical potential of Twin Fc-ICE.

10:00 Presentation to be Announced

10:30 Networking Coffee Break

lightcast

11:00 Next-Generation DARPin-Based Protein Therapeutics

Daniel Steiner, PhD, Vice President, Lead Generation, Molecular Partners AG

This presentation unveils the future of protein therapeutics, delving into the design, mechanisms, and therapeutic potential of next-generation DARPin-based drugs. An update on our clinical stage, tetra-specific T cell-engaging DARPin designed for avidity-driven selective killing of heterogeneous malignant AML cells and a deep dive into our Radio DARPin Therapeutics platform for effective and safe delivery of therapeutic radionuclides will be presented.

11:30 HRPro—A Peroxidase for Antibody-Directed Enzyme Prodrug Therapy

Stefan Kittler, PhD, Postdoc Researcher, Institute of Chemical Environmental & Biological, TU Wien

Recombinant horseradish peroxidase produced in *E. coli* has an outstanding advantage since it is not glycosylated. The conjugation of this protein to Herceptin is investigated to develop a site-directed cancer treatment by establishing an enzyme prodrug therapy. A conjugation protocol was developed, and first studies show a high potential for this HRP-antibody conjugate.

12:00 pm Session Break

12:05 Luncheon Presentation I: The Development of NeoMab: A Novel Mouse Model to Facilitate Fully Human Antibody Development

GemPharmatech

Mingkun Zhang, Director, NeoMab Platform, GemPharmatech

Antibodies and their derivatives have proven significant effectiveness against human diseases, but challenges like immunogenicity and engineering failures hinder their progress. GemPharmatech's platform, based on humanized transgenic animal models, addresses these issues, and enable the efficient development of therapeutic antibodies. This presentation will share the development and validation of these models, as well as case studies for antibody discovery.

12:35 LUNCHEON PRESENTATION: Solutions for High Titre Expression of Cancer Immunotherapies

Lonza

Devarshi Kapadia, Associate Director, Licensing, Biologics, Lonza

Biological pipelines for oncology indications are evolving, with next-generation molecules joining more traditional monoclonal antibodies. These advances increase pressure on cell line construction timelines, creating challenges in identifying cell lines that meet production needs. Lonza optimizes the GS Gene Expression System® to address these demands. We present a customer case-study on how GS piggyBac® transposon technology can boost titers and increase the chances of selecting a high performing clonal cell line.

1:05 Session Break

ENGINEERING ANTIBODIES FOR CANCER IMMUNOTHERAPY

1:10 Chairperson's Remarks

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

1:15 Engineering a Therapeutic Monoclonal Antibody Targeting CD24, a Macrophage Checkpoint

John Burg, PhD, Senior Director, Protein Sciences, Pheast Therapeutics

CD24 is a tumor antigen with a restricted expression profile that acts as an important macrophage "don't eat me" signal, but the small size and heavy glycosylation of CD24 make it a challenging target for antibody discovery. We identified an anti-CD24 antibody that reverses CD24-mediated inhibition of phagocytosis. *In vitro* and *in vivo* studies demonstrate efficacy and justified further development of this antibody.

1:45 Characterization of a Novel Anti-A2aR Antagonist Antibody for Cancer Immunotherapy

Changyun (Eric) Hu, PhD, CSO & Co-Founder, Adept Therapeutics Inc.

Currently, small molecule inhibitor is the only modality employed by a handful of companies to modulate the A2aR signaling pathway, due to the challenge of discovering functionally potent antibodies against GPCR target A2aR. The anti-A2aR we will present here represents the first molecule of antibody modality that demonstrated functional potency in antagonizing the A2aR signaling pathway and thus can restore T and NK cell function within an immunosuppressive tumor microenvironment.

2:15 Tumor-Selective Anti-Tumor Immune Response of ROSE12, a Novel Fc-Enhanced Antibody

Kanako Tatsumi, PhD, Global Project Leader, Project Planning & Coordination, Chugai Pharmaceutical Co. Ltd.

One of the remaining issues of antibody therapeutics is on-target, off-tumor toxicity induced by binding to target antigens expressed in normal tissues. Here we report ROSE12, a novel Fc-enhanced tumor-specific antibody which can overcome the safety issue and expect a wide therapeutic window. ROSE12 is currently being tested in a Phase 1 clinical study.

2:45 Bispecific and Trispecific GPRC5D Antibodies with Potent Cell-Killing Activity Against Multiple Myeloma

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

GPRC5D is a G protein-coupled receptor that is expressed on multiple myeloma cells but absent from most healthy tissues. Clinical data demonstrate that combination therapy of T cell-engaging molecules individually targeting GPRC5D and BCMA offers unprecedented therapeutic effects in relapsed/refractory multiple myeloma patients. Comparable or added benefits are expected for a trispecific molecule. We will present *in vitro* and *in vivo* data for our lead molecules targeting GPRC5D.

3:15 Networking Refreshment Break

4:15 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:25 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

4:35 Driving New CAR T Cells

Marcela V. Maus, MD, PhD, Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

YOUNG SCIENTIST KEYNOTE

5:20 High-Throughput Discovery of Protein Folding Stability and Dynamics

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

6:05 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

Facilitators:



Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Shakiba Nikfarjam, PhD, Postdoc, Lawrence Livermore National Lab

7:30 Close of Day

TUESDAY, MAY 14

7:30 am Registration and Morning Coffee

MODULATING THE MOLECULAR MECHANISMS

7:55 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

8:00 FEATURED PRESENTATION: Attacking the Cancer Surfaceome

James A. Wells, PhD, Professor, Departments of Pharmaceutical Chemistry and Cellular & Molecular Pharmacology, University of California, San Francisco

The cell surface proteome, the surfaceome, is a major hub for cellular communication and a primary source of drug targets. Identifying how the surfaceome changes in cancer is a central challenge for identifying and targeting new disease-associated proteins. We have used chemical methods and engineered proteins to facilitate identification of membrane proteins, both native and post-translationally modified versions. We then target proteins upregulated, proteolyzed, or both with recombinant antibodies.

8:30 FEATURED PRESENTATION: Variable Domain and Fc Engineering to Modulate Antibody Viscosity

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

Antibody self-association may lead to high viscosity that is problematic for manufacturing and subcutaneous delivery. In one strategy, extensive mutational analysis of antibody variable domains identified variants with reduced viscosity while maintaining binding affinity and developability properties of the parent antibody. In a second strategy, the high viscosity of several different antibodies was reduced by clinically validated Fc mutations. These strategies may be useful in engineering other antibodies for subcutaneous delivery.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION

10:00 Transition to Plenary Keynote Session

10:10 Plenary Keynote Introduction

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

10:15 Base Editing and Prime Editing: Engineered Proteins That Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

David R. Liu, PhD, Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Core Institute Member and Vice-Chair of the Faculty, Broad Institute; Director, Chemical Biology and Therapeutic Sciences Program; Investigator, Howard Hughes Medical Institute; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

11:00 Celebrating 20 Years in the Exhibit Hall with Poster Viewing

12:00 pm Enhancing NK Cell Invasion to Promote the Anti-Tumor Effects of CAR-NK Cells

Louis M. Weiner, MD, Professor & Director, Oncology, Lombardi Comprehensive Cancer Center, Georgetown University

Fibroblast activation protein (FAP) is a dipeptidyl peptidase and collagenase. FAP enzymatic inhibition or gene knockdown significantly impairs NK cell migration or invasion through tissue matrix, and forced overexpression of FAP enhances both migration and invasion through matrix and into tumor spheroids. These findings point to an important role of FAP in regulating NK cell invasion, and suggest that manipulating FAP biology in NK cells can have therapeutic value in cancer.

12:30 Antibody Fc Domains Engineered for Selective ADCC Activity in the Tumor Microenvironment

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

Antibody-based therapeutics enjoy considerable success as cancer treatments, but can cause serious toxicities due to recognition of tumor-associated antigens in healthy tissues. We will discuss recent efforts to develop advanced antibody therapeutics with Fc-mediated activities that are restricted to the solid-tumor microenvironment. With the intent of decreasing toxicities and expanding therapeutic windows, protein engineering strategies can render antibody activity sensitive to multiple tumor-specific characteristics.

1:00 Engineering Unique Properties in Next-Gen Antibody Therapies AVANTGEN

Jordon Wang, PhD, COO, Senior Vice President, Technology Development, AvantGen

We will explore some of the cutting-edge advancements in our antibody discovery and engineering approaches to engineer unique properties in next generation therapeutic antibodies. With the aim to enhance specificity, potency, and to expand the therapeutic index, we will discuss how they hold the promise to significantly improve patient outcomes.

1:30 Session Break

1:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:40 Close of Antibodies for Cancer Therapy Conference

6:30 Recommended Dinner Short Course

SC8: Developabiilty of Bispecific Antibodies

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

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME
**Separate registration required. See short course page for details.*

TUESDAY, MAY 14

TARGET DISCOVERY & VALIDATION

2:55 pm Chairperson's Remarks

Mitchell Ho, PhD, Senior Investigator & Deputy Chief, Laboratory of Molecular Biology; Director, Antibody Engineering Program, National Cancer Institute (NCI), National Institutes of Health

3:00 Unlocking Novel Therapeutic Targets with Patient-Powered Target Discovery

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

Identifying genuinely novel targets that have immense therapeutic potential is an increasing challenge across CNS diseases and oncology. Alchemab addresses this challenge by truly disrupting the target discovery process—simply put, we let the patient select the best targets. We have discovered novel disease-relevant targets through our proprietary platform that searches for protective auto-antibodies in patients who are resistant to disease.

3:30 Evaluation of Protein/Carbohydrate Combination Epitopes for Targeted Development of Antibodies with Improved Tumor-Specificity

Lisa Kalfhues, PhD, Scientific Project Manager, Glycotype GmbH

A workflow and corresponding database was established to evaluate the O-glycosylation of proteins. This information is subsequently used for targeted discovery of antibodies that bind to protein/carbohydrate combined glycoepitopes (GlycoTargets). Two case studies will be presented that highlight our workflow to identify suitable GlycoTargets and subsequent development of antibodies.

4:00 Presentation to be Announced

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

5:10 Adding TAPAs to the Menu of Targeting Options

Scott A. Lesley, PhD, CSO, R&D, InduPro Inc.

The presentation will introduce the audience to a novel approach to selective targeting which goes beyond conventional tumor antigen selection and expands access to additional targeting strategies. We have established a Membrane Interactomics (MInt) platform to identify unique Tumor Associated Proximity Antigens (TAPAs). Using MInt, we have identified several unique proximity-targeting tumor addresses which we have utilized for selective targeting of bispecific ADCs.

5:40 The Final Frontier: Developing Antibody Drugs against Ion Channels and GPCRs

Verity Jackson, PhD, Principal Scientist, Maxion Therapeutics Ltd.

To overcome challenges in antibody discovery against ion channels and GPCRs, Maxion have developed a novel antibody fusion format (KnotBody), by fusing naturally occurring ion channel modulators (knottins) into peripheral CDR loops. This presentation will present our current progress towards developing safe, efficacious and long-acting drugs against previously undruggable targets.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC6: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies
**Separate registration required. See short course page for details.*

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

TARGETING THE TUMOR MICROENVIRONMENT

8:25 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

8:30 KEYNOTE PRESENTATION: Targeting Myeloid Cells in the Tumor

Tatiana Novobrantseva, PhD, Co-Founder & CSO, Verseau Therapeutics

Tumors co-evolve with the myeloid cells that broadly promote tumorigenesis. TAMs/myeloid cells constitute the largest functional negative influence on the tumor microenvironment and need to be reprogrammed in order to enable successful anti-tumor response. Given the plastic nature of myeloid cells, successful TAM repolarization targets need to be carefully chosen. These targets have the potential to become a staple of immuno-oncology across most indications.

9:00 BDC-3042: A Dectin-2 Agonistic Antibody for Tumor-Associated Macrophage-Directed Immunotherapy

Shelley E. Ackerman, PhD, Director, Bolt Biotherapeutics Inc.

This presentation will highlight the preclinical data supporting the development of BDC-3042, a first-in-class Dectin-2 agonistic antibody leading the way in tumor-associated macrophage-directed immunotherapy. This talk sheds light on the potential of harnessing the immune system against cancer through targeted macrophage modulation via a novel target, Dectin-2.

9:30 LIGHT (TNFSF14) Co-Stimulation Enhances Myeloid Cell Activation and Anti-Tumor Immunity in the Setting of PD-1 and TIGIT Checkpoint Blockade

George J. Fromm Jr., PhD, CSO, R&D, Shattuck Labs, Inc.

TIGIT-Fc-LIGHT was designed to block all TIGIT-ligand interactions, provide immune co-stimulation to CD8+ T and NK cells via HVEM and myeloid cells by LTBR, and broaden clinical responses into PDL1-low and CPI acquired resistance tumors. TIGIT-Fc-LIGHT differs from antibody blockade of TIGIT, since its co-stimulatory activity (HVEM and LTBR versus DNAM-1) is not directly inhibited by PD1 nor down-regulated on TIL in advanced tumors.

10:00 What's Wrong With This Picture? The Danger of Inadequate Screens in Antibody Discovery

Allison Schulkins, COO, Single Cell Technology, Inc.

Hit generation is critical. Also extremely frustrating when you consider speed vs. quality, lower throughput, limited screening options, having to pare down project scope, developability issues, challenging membrane targets..
There's a better way: AbTheneum antibody discovery.

We've successfully developed assays and delivered data for oncology and beyond for years, combining multiple parallel screening assays in the primary screen to produce multi-layered data with sequences in just 3 weeks.

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

NOVEL & RE-EMERGING TARGETS

11:10 Targeting Claudin-6 (CLDN6) in Solid Tumors with CAR-T Cells and an Amplifying RNA Vaccine

Sebastian Klobuch, Medical Oncologist, Netherlands Cancer Institute

CAR-T cell therapies in solid tumors are limited by the lack of cancer-specific cell-surface targets. The oncofetal antigen CLDN6 is a promising target that shows high-level aberrant cell membrane expression in many solid tumors. I will discuss CLDN6, the preclinical and clinical anti-tumor activity and safety of CLDN6-targeting CAR-T cells (BNT211-01), and the effect of a CAR-T cell-amplifying RNA vaccine (CARVac) on CAR-T cell expansion and persistence.

11:40 Nanobody-Based CAR-T Targeting GPC1 and B7-H3 for Solid Tumors

Mitchell Ho, PhD, Senior Investigator & Deputy Chief, Laboratory of Molecular Biology; Director, Antibody Engineering Program, National Cancer Institute (NCI), National Institutes of Health

I will discuss our recent studies on GPC1 and B7-H3 (CD276) as emerging cancer targets, as well as the engineering of CAR T cells for the treatment of pancreatic cancer and neuroblastoma. Additionally, I will describe nanobody technology and single-cell-based transcriptomic analysis of "polyfunctional" CAR T cells to enhance the efficacy of CAR T cell therapy.

12:10 pm Session Break

12:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:20 Session Break

NOVEL & RE-EMERGING TARGETS *(CONT.)*

1:25 Chairperson's Remarks

Tatiana Novobrantseva, PhD, Co-Founder & CSO, Verseau Therapeutics

1:30 Developing ImmTAC against PIWIL1, a Promising Novel Colorectal Cancer Target

Christopher Rowley, PhD, Principal Research Scientist, Protein Science Pipeline, Immunocore

ImmTAC bispecifics are designed to elicit a potent T cell response to kill tumor cells. Here we present engineering of IMC-R117C, targeting a peptide derived from PIWIL1, a novel colorectal cancer target, in complex with HLA-A2. We used a proprietary TCR-phage library to identify an optimal TCR with supraphysiological affinity, and an affinity engineering approach that ensures reduced off-target binding; a common challenge with pHLA targeting molecules.

2:00 OR641: A Novel Dual Antagonist Antibody that Targets LILRB1 and LILRB2 Inhibitory Receptors and Promotes a Th1-Like Immune Response

Kamal D. Puri, PhD, CSO, OncoResponse, Inc.

The immunosuppression of myeloid cells and lymphocytes within the tumor microenvironment limits efficacy of checkpoint inhibitors. LILRB1 and LILRB2 are inhibitory receptors on immune cells that interact with ligands, including HLA Class I, and promote an immunosuppressive phenotype of immune cells. We have identified OR641 as a dual antagonist antibody that relieves LILRB1- and LILRB2-mediated immune suppression and enhances both innate and adaptive anti-tumor immunity.

2:30 OMO-103: The Molecular Journey of a First-in-Class Direct MYC Inhibitor Mini-Protein

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

MYC has so far remained a most wanted but undruggable target in oncology. OMO-103 is the first intravenously delivered cell-penetrating mini-protein to have successfully overcome the challenges to drug MYC and completed a clinical trial in human patients showing safety and first signs of clinical activity, supported by molecular target engagement. Here, we present the preclinical development and results from this first-in-human clinical study.

3:00 The Monoclonal Antibody NOV2 Targeting Leptin-Dependent NRP-1/OBR Complex, Capable to Enter Cancer Cell Nuclei to Induce DNA Damage and Activate Anti-Tumor Immune Response

Zakia Belaid-Sandal, PhD, CEO & CSO & Co-Founder, THERANOVIR

The anti-NRP-1 antibody "NOV2", specific to leptin binding domain presents a unique mode of action. It enters cancer cells nuclei to induce their DNA damage and activates thus the anti-tumor response by increasing the number of Tumor Infiltrating CD4+T lymphocytes and CD8+T lymphocytes activation in correlation with metastasis decrease. NOV2 represents a great therapeutic tool for Targeting DNA Damage Response Immuno-Oncology.

3:30 Targeting CCR8+ Tregs for Depletion in the Tumor Microenvironment Leads to Robust Anti-Tumor Immunity

Brian Weist, PhD, Senior Research Scientist II, Immunology, Gilead Sciences Inc.

Regulatory T cells are necessary for preventing autoimmune disease but may also inhibit cytolytic T cells in the tumor microenvironment. Reducing tumor-specific Tregs without compromising systemic tolerance has been challenging. CCR8, a chemokine receptor highly expressed on Tregs in solid tumors, serves as an ideal target for ADCC-mediated depletion, leading to robust anti-tumor immunity as a monotherapy as well as in combination with multiple complementary anti-tumor agents.

4:00 Discovery of High-Affinity Functional Antibodies Specific for CXCR5 and Other Multi-Pass Membrane Proteins

Ernest Smith, Dr., Chief Scientific Officer / Senior VP Research, Vaccinex Inc.

We have developed a fusion protein technology to enable the direct incorporation of multi-pass membrane proteins such as GPCRs into the membrane of two antigenically distinct poxviruses. The protein of interest is correctly folded and expressed in the cell-derived viral membrane and does not require any detergents or refolding before use. I will describe the use of this technology to discovery antibodies specific for CXCR5 and other multipass membrane proteins.

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

5:10 STRO-003: A Novel, Precisely Designed ROR1-Targeting ADC Enabled by XPressCF and Site-Specific Conjugation

Garrett G. Gross, PhD, Senior Scientist, Protein Engineering & Drug Discovery, Sutro Biopharma Inc.

Sutro's proprietary cell-free protein synthesis and site-specific conjugation platforms enable homogeneous ADCs with best-in-class potential. STRO-003 is an ROR1-targeting ADC with a stable beta-glucoronidase cleavable linker and TOPO-1 inhibiting exatecan warhead, precisely positioned by non-natural amino acids with a drug-antibody ratio of 8. STRO-003 demonstrates potent ROR1-dependent tumor killing in preclinical models and a favorable safety profile in non-human primates, providing a promising clinical candidate for solid-tumor indications.

5:40 Conscripting CD180 into Service for Antigen-Specific Immune Responses

Alan Wahl, PhD, CEO, Abacus Bioscience, Inc.

Vaccination is generally ineffective against established disease. To overcome immune tolerance in cancer and chronic infection we focus on Antigen Presenting Cells, fusing disease antigens to antibody activating the APC-restricted receptor CD180. Coincident antigen delivery and APC activation via CD180 results in potent yet highly antigen-specific activation of both humoral and cellular response. Fusion proteins delivering disease antigens have been produced to demonstrate the potential of this new immunotherapeutic platform.

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of Conference

DRIVING CLINICAL SUCCESS OF ANTIBODY DRUG CONJUGATES Designing the Magic Bullet

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC4: Safety and Efficacy of Bispecifics and ADCs

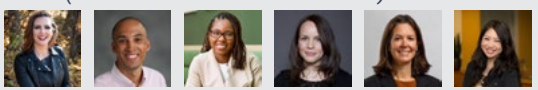
**Separate registration required. See short course page for details.*

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity: IN-PERSON ONLY *(Continental Breakfast Provided)*

Co-Organized with THINKUBATORMEDIA



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

INCREASING THERAPEUTIC WINDOW AND DECREASING NON-TARGET TOXICITIES

8:45 Chairperson's Remarks

E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

8:50 Increasing the Therapeutic Index of ADCs—Translation from Mice and Monkeys to Humans

Rakesh Dixit, PhD, President & CEO, Bionavigen

ADCs have emerged as the fastest-growing and most effective therapies in the war against cancer. The key to the success of ADCs is to achieve a superior therapeutic index (TI) with high efficacy and acceptable safety when compared to cytotoxic chemotherapeutics. The presentation will focus on assessing TI from preclinical animal models to humans, and discuss strategies to improve the translation of preclinical to clinical TI.

9:20 Targeted Cancer Therapy with Best-in-Class Antibody-Drug Conjugates Based on GlycoConnect Technology

Floris Van Delft, PhD, Founder & CSO, Synaffix BV

Conjugation of linker-payloads to the antibody glycan (GlycoConnect) together with a polar linker (HydraSpace) provides ADC with significantly improved TI. By combination with the potent TOP1i exatecan (SYNtecan E), complete and durable tumor regression is observed in multiple models and a strong additive effect by combination with checkpoint or PARP inhibitors. Preclinical and clinical data will be presented on SYNtecan E ADCs from multiple programs.

9:50 MYTX-011: A cMET-Targeting ADC Engineered for Anti-Tumor Activity against a Broader Spectrum of cMET Expression

Brian P. Fiske, PhD, Co-Founder & CSO, Mythic Therapeutics

MYTX-011 is an investigational, pH-sensitive, vcMMAE ADC. It has been designed to benefit a broader population of patients whose tumors express lower/moderate levels of cMET as compared to other cMET ADCs, which have shown clinical activity only in patients whose tumors express high levels of cMET. MYTX-011 drives increased internalization and cytotoxicity and shows robust activity in xenograft models across a range of indications and levels of cMET expression.

10:20 ThioBridge® - A Tool for the Design, Optimization & Manufacture of ADCs

ABZENA Moving medicine forward.

Rob Holgate, PhD, Vice President, Research and Innovation, Abzena

ThioBridge® is a next-generation linker technology that makes use of the naturally occurring interchain disulfide bonds of an antibody to generate antibody-drug conjugates (ADCs). Key features include homogeneity (high conversion to a single DAR species), stability (linker does not deconjugate or cross-conjugate), site-specificity (due to conserved locations of conjugation), and flexibility (different architectures allowing to access single DAR 2, 4 and 8 conjugates).

10:35 POSTER HIGHLIGHT: Drug-to-Antibody Ratio of Maleimide-based ADCs Greatly Impacts Fc Receptor Binding and Fc-mediated Effector Activity

Danielle Fernando, Sr Principal Researcher, Biochemistry & Bioanalytical Dev, Eisai Inc

This study examined the biophysical properties of the antibody-drug-conjugate (ADC) MORAb-202, a humanized anti-folate receptor alpha (FRa) antibody conjugated with maleimido-PEG2-val-cit-pAB-eribulin through partially-reduced interchain disulfide bonds with an average drug-to-antibody (DAR) of 4.0 and a DAR range of 0 to 8. Isolated DAR species of MORAb-202 demonstrated a DAR-dependent loss of FcgR and C1q binding and associated effector activity, with no loss of antigen or FcRn binding.

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?




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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:
Paul J. Carter, PhD, Genentech Fellow, Antibody Engineering, Genentech
Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences
Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

NEXT-GENERATION PLATFORMS

2:30 Chairperson's Remarks

Pamela A Trail, PhD, Consultant, Oncology Research, AGL Biotechnology Consultants LLC.

2:35 KEYNOTE PRESENTATION: Current and Next-Generation ADCs: Successes and Failures

Alain Beck, PhD, Senior Director, Biologics CMC and Developability, Pierre Fabre, France

Despite the success of the ADCs recently, more than 100 ADCs have also failed in clinical trials. Toxicity remains a key issue in the development of these agents, and better understanding and management of ADC-related toxicities will be essential for further optimization. Lessons learned will be discussed as well as alternative formats, payloads, linkers, conjugation technologies currently investigated in preclinical or early clinical phases.

3:05 Antibody-Mediated Delivery of PROTACs

Thomas Pillow, PhD, Senior Scientist, Genentech, Inc.

Small-molecule therapeutics are sometimes limited by toxicity, pharmacokinetics, or cell permeability. Antibody-drug conjugates or ADCs offer the targeted delivery of small molecules that can mitigate such liabilities. This talk will focus on our efforts to link chimeric protein degraders (PROTACs) to antibodies, their efficacy and safety, and how this general approach can expand the utility of directed protein degradation as both a biological tool and a therapeutic possibility.

3:35 Affilin Targeting in Drug Conjugates and Radioligand Therapy—A Next Generation Platform

Ulrich Haupts, PhD, CEO, Navigo Proteins GmbH

The Affilin targeting platform is continuing to accumulate data differentiating it from other targeting approaches including antibodies and antibody fragments. Affilin candidates across different targets show consistently high and long tumor accumulation and outperform benchmarks especially in low expressing tumor models. At the same time the exceptional modularity of the platform allows quick cycle times and designing multiple format types including bi and multispecific targeting ligands with ease.

4:05 Superior Payload-linker and Conjugation Technologies for Novel and Better ADCs

Marie Zhu, Chief Technology Officer for WuXi XDC, CTO, WuXi XDC

Cysteine-based conjugations can result in heterogeneous ADC products with a wide drug-to-antibody ratio distribution. Many conjugation technologies developed address this but come with increasing COGs or technical challenges. In response, WuXi XDC developed the WuXiDAR4™ platform, with benefits including high DAR4 percentage (70-85%), easy manufacturing, high yields, and low COGs. This talk outlines key elements of the WuXiDAR4 technology including efficacy and PK data and a novel payload-linker technology platform.

4:35 Networking Refreshment Break

IMMUNO-MODULATORY ADCs

5:00 Optimzing the Efficacy and PK of Immune-Stimulating Antibody Conjugates

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

We will describe our efforts to understand the efficacy of TLR7 agonist-antibody conjugates, focusing on correlating *in vitro* assays with *in vivo* efficacy. We will describe the impact of Fc-gamma binding, linker type, and payload potency on the functional activity, efficacy, and PK of the resulting conjugate.

5:30 SYN101, a First-in-Class Immunomodulatory Antibody-Drug Conjugate, Safely Restores Immune Function and Drives Tumor Clearance *in Vivo*

Dori Thomas-Karyat, PhD, Founder & CEO, Synthis Therapeutics

Synthis Therapeutics is a NY biotech company developing the next generation of immunomodulatory antibody-drug conjugates (ADCs) for cancer patients. Comprised of an immune cell targeted antibody attached to a non-cytotoxic payload, SYN101 is a first-in-class ADC that selectively and safely blocks immune suppression and drives tumor clearance, in multiple tumor models *in vivo*. We are raising a $35M Series A for IND enabling and Phase I trials.

6:00 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

7:30 FIRESIDE CHAT: Forming and Funding ADC Biotech Companies—Follow the Money

Moderator: Gregory P. Adams, PhD, CSO, Elucida Oncology, Inc.

- Formation and development of VC-backed companies
- What do different VCs look for? How do they look at ADCs?
- Funding: Seed Rounds, Series A, Follow on Rounds, etc.
- Building a company and raising capital during difficult times

Panelists:
Shyam Masrani, Principal, Medicxi
Brian P. Fiske, PhD, Co-Founder & CSO, Mythic Therapeutics

NOVEL PAYLOADS AND MOAs

8:25 Chairperson's Remarks

Robert J. Lutz, PhD, CSO, Iksuda Therapeutics

8:30 OBT076, an Innovative ADC with Dual MOA, Currently in Clinical Phase 1—The Mechanisms, ADC Design, Preclinical Activity, and Clinical Progress to Date

Ben Thomas, Senior Director, External Innovations and Operations, Oxford Biotherapeutics

This presentation will navigate the complexities of OBT076, an innovative ADC with dual mechanisms of action, providing detailed insights into its design, preclinical activity, and the latest clinical advancements in Phase 1 trials.

TABLE OF CONTENTS

9:00 Technology-Enabled Payload Solutions Targeting Topoisomerase-I and Beyond

Björn Hock, PhD, CDO, Tubulis GmbH

Tubulis' versatile ADC technology suite will be introduced, including:
• Tubutecan (Topo-I) DAR8 platform with long-lasting efficacy profile, mAb-like PK properties, and no premature payload loss
• Tubutecan-based lead molecules TUB-040 and TUB-030 will be highlighted
• Alco5, a novel linker enabling easy access to OH-containing compounds to unlock previously unprecedented ADC payloads?

9:30 Overcoming Payload Resistance with Dual Payload ADCs

Ben Ayers, DPhil, Vice President, Antibody Drug Conjugates, Hummingbird Bioscience Pte. Ltd.

Current clinical-stage ADCs utilize a narrow range of payloads. Furthermore, there has been limited clinical validation for payloads with novel modes-of-action. Combination of small molecule cytotoxic agents has shown promise, improving clinical efficacy. However, the untargeted, systemic therapy approach leads potentially to therapeutic window limitations. Combination of two small molecule payloads in an ADC presents a targeted, single agent approach to optimize their potential and improve the therapeutic window

10:00 VIP943, a Novel Antibody-Drug Conjugate with a Kinesin Spindle Protein Inhibitor (KSPi) Payload for Treatment of CD123+ Hematological Malignancies

Melanie M. Frigault, PhD, Vice President, Translational Medicine, Vincerx Pharma

This presentation will discuss the unique features of VIP943, a groundbreaking CD123-targeted ADC with a KSPi payload, cleaved by Legumain for precise and effective treatment of CD123+ hematological malignancies. This presentation elucidates the therapeutic potential and innovative design strategies behind VIP943.

10:30 Networking Coffee Break

NOVEL PAYLOADS (CONT'D)

11:00 Novel Self-Immolative Moiety Containing Antibody-Exatecan Conjugates for Advanced Solid Tumors

Shu-Hui Liu, PhD, CSO, Multitude Therapeutics

We have designed an ADC class using a novel self-immolative T moiety for traceless conjugation and release of exatecan, a more potent topoisomerase I inhibitor with less sensitivity to multidrug resistance (MDR). T moiety-exatecan ADCs showed higher stability, enhanced efficacy, and greater tolerability in preclinical testing across multiple programs. The development rationale and clinical progression of T moiety exatecan ADCs targeting known and novel tumor antigens will be discussed.

ALTERNATIVE SCAFFOLDS AND NON-ANTIBODY MOIETIES

11:30 ANT-045, a Novel Antibody Fragment-Drug Conjugate for cMET-Expressing Solid Tumors

Mahendra P. Deonarain, PhD, Chief Executive & Science Officer, Antikor Biopharma Ltd.

ADCs have failed in gastrointestinal tumors where immunoglobulins dominate. Antibody fragments' advantages (penetration, clearance, manufacturing), are technologically challenging to apply in oncology. ANT-045 is highly stable, demonstrating excellent tumor ablation in gastric models with high/medium/low cMET receptor-levels as low as 8000/cell. ANT-045 is exceptionally well tolerated in cynomolgus-primates at doses of 2mg/kg (~20mg/kg for an ADC) showing none of the ADC dose-limiting hematological toxicities, predicting a TI>32.

12:00 pm Engineered Diabodies with Precisely Loaded Novel ADC Payloads Surpass IgG-ADCs in Cancer Therapy

John M. Lambert, PhD, Consultant

Avibodies (enhanced diabodies) comprise unique surface disulphides for precise loading of drug payloads (auristatins) with superior tumor xenograft regression compared to conventional IgGs (targeting CD30). PK of Tag-72 targeted Avibodies has been demonstrated in a first-in-human Phase 1 clinical biodistribution trial. With TagWorks(NV), Avibodies were shown to pre-target and upload tumors with the ADC-drug subsequently released by a systemic activator. Avipep's novel Avibody designs demonstrate precise site-specific loading of drug payloads.

12:30 Close of Conference

Creating Best-in-Class
Multispecific Antibody Modalities

MULTISPECIFICS STREAM

The multispecific antibodies stream at the PEGS Summit will take you through a review of constructs, engineering, and platform developments all the way to the review of preclinical and clinical results. Newer platforms, innovative approaches, combination strategies, and novel constructs are combining to yield unprecedented efficacy. Don't miss the most significant forum of the year to hear 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 13-14

TS: Introduction to Multispecific Antibodies

AGENDA

MAY 14-15

Advancing Bispecific Antibodies and Combination Therapy to the Clinic

AGENDA

MAY 16-17

Engineering Bispecific Antibodies

AGENDA

PEGSBOSTON

TABLE OF CONTENTS

DAY 1: MONDAY, MAY 13, 2024 | DAY 2: TUESDAY, MAY 14, 2024

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 bispecific 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 the ideal implementation of multispecifics as targeted and immunomodulatory approaches will be discussed.

Instructor:
G. Jonah Rainey, PhD,
Senior Director, Protein Engineering,
Eli Lilly & Co.

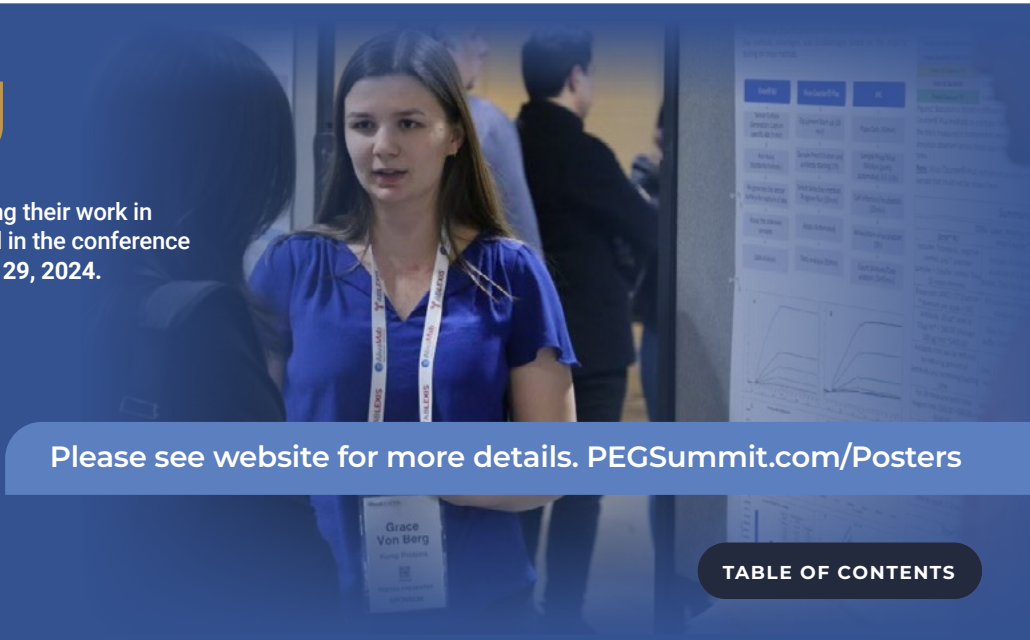
Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered and solutions applied, and extensive coverage of the basic science underlying each topic. Experienced Training Seminar instructors offer a mix of formal lectures, interactive discussions, and activities 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.

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 29, 2024.

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



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

ADVANCING BISPECIFIC ANTIBODIES AND COMBINATION THERAPY TO THE CLINIC

Creating the Killer Combo

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC4: Safety and Efficacy of Bispecifics and ADCs

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

TUESDAY, MAY 14

2:55 pm Chairperson's Remarks

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

3:00 KEYNOTE PRESENTATION: Generating CD8-Selective T Cell Engager Molecules

Mark Cobbold, PhD, Vice President, Oncology Early Discovery, AstraZeneca Pharmaceuticals

T cell engager therapeutics are reshaping oncology treatment, providing patients with more effective and potentially curative therapeutic options. However, limitations relating to tolerability particularly due to cytokine release syndromes (CRS) remain a persistent challenge. Here we describe novel T cell engagers that selectively activate CD8 T cells by directly binding to the T cell receptor, thus reducing the fraction of T cells engaged and creating a more favorable cytokine profile.

PROLIFERATION OF BISPECIFIC ADCs

3:30 Talk Title to be Announced

Peter Lowe, PhD, Director, Antibody Engineering, Merus N.V.

4:00 Antibody Discovery Dead Ends: Novel Approaches for Bispecific and Human Antibody Discovery

Anthony Stajduhar, Director Business Development, Rapid Novor Inc.

The biggest technology gaps in antibody discovery include diversity of antibody repertoires, functional screening, and lack of suitable *in vitro* models. Antibody discovery with mass spectrometry enables the exploration of the natural immune repertoire, and direct discovery of human antibodies from serum. Binding kinetics and epitope mapping experiments enhance lead selection for development. Integration of artificial intelligence with HDX-MS (AI) increases efficiency of human antibody discovery processes through *in silico* modeling.

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

5:10 A METxMET ADC for Cancer Therapy

John DaSilva, PhD, Associate Director, Oncology & Immune-Oncology, Regeneron Pharmaceuticals Inc.

Discussion of the way Regeneron is taking advantage of biparatopic antibody/receptor trafficking for efficient delivery of cytotoxic payloads. Overview of Regeneron's Pro-DXd platform that provides remarkable tumor inhibition with a widened therapeutic window.

5:40 Development of the Tetravalent EGFR x HER3 Bispecific ADC BL-B01D1

Jahan S. Khalili, PhD, Vice President, Immuno-Oncology, SystImmune Inc.

We will present the novel bispecific ADC BL-B01D1, targeting EGFR and HER3. BL-B01D1 consists of a tetravalent bispecific antibody conjugated with the topoisomerase I inhibitor-based payload Ed-04.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

NEWER STRATEGIES FOR CO-STIMULATORY BISPECIFIC ANTIBODIES: CLINICAL RESULTS

8:25 Chairperson's Remarks

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

8:30 Targeted Therapies for the Enhancement of Anti-Tumor T Cell Responses

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

This presentation will describe pre-clinical data informing Regeneron's approach to enhancing the anti-tumor efficacy of T cells, focusing on the combination of costimulatory bispecific antibodies with T cell redirecting bispecifics. In addition, recent pre-clinical data from a PD-1 targeted IL-2 immuno-cytokine will be discussed, both as a single agent and in combination with other T cell-engaging agents.

9:00 Costimulatory Combinations

John R. Desjarlais, PhD, CSO, Xencor

While 1st generation T cell engagers comprise one or more tumor-associated antigen binding domains and a CD3 binding domain, we've also begun to explore the concept of recruiting costimulatory signals via CD28 binding. Costimulation has strong potential to build off endogenous signal 1 but also to enhance the activity of CD3s. We'll describe our efforts to build and characterize CD28 bispecific antibodies against B7H3 and other targets, together with mechanistic deconvolution.

9:30 Rational Combinations to Increase Impact of BiTE Immune Therapy in Solid Tumors

Rajkumar Ganesan, PhD, Executive Director, Amgen Inc

This presentation will focus on recent progress with development of bispecific T cell engager (BiTE) molecules in solid tumors and strategies to improve response rate and durability. Preclinical data for the DLL3-targeted BiTE molecule tarlatamab in combination with standard of care and costimulatory molecules, and translation to the clinic, will be discussed.

10:00 Accelerating Early Discovery through HTP and High-Speed Antibody Production

Lei Shi, PhD, Senior Vice President, R&D, Biointron Biological

Biointron has established an industry-leading 2-week antibody production service, supported by a powerful high-throughput expression platform. Armed with this high-efficiency platform, our FC-MES affinity maturation system is able to provide non-biased antibody optimization and affinity maturation in less than 2 months. Our VHH and Single B cell-based discovery projects are also benefited and expedited by this unique capability.

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

11:10 Bispecific Antibody Combination Strategies for Treating Solid Tumors

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

T cell-engaging bispecific antibodies have had tremendous success in treating hematologic tumors as single agents. Overcoming the immune suppressive environment of solid tumors will likely require combination strategies using bispecific antibodies. In this presentation, we will describe the bispecific platforms developed at Rondo Therapeutics and how we plan to use these to treat solid tumors in the clinic.

TABLE OF CONTENTS

ADVANCING BISPECIFIC ANTIBODIES AND COMBINATION THERAPY TO THE CLINIC Creating the Killer Combo

VARIETY OF MECHANISMS USING BISPECIFIC ANTIBODIES

11:39 Chairperson's Remarks

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

11:40 T Cell-Engaging Antibodies for the Treatment of Hematological Malignancies

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

Within the past decade, therapies that activate T cells and redirect them to cancer cells have changed the landscape of treatment of hematological malignancies. Key factors for a successful T cell-engaging therapeutic include selective target expression on the tumor cells with minimal-to-no expression in other tissues and a potent molecule—e.g., a bispecific antibody—that can eliminate malignant cells to achieve long-term benefit.

12:10 pm Session Break

12:20 Luncheon Presentation I: Deep Screening in Harmony with AI for Bispecific Antibody Discovery

Bob Chen, PhD, Senior Director, Discovery Systems, OmniAb, Inc.

The integration of Biological Intelligence™(BI) and artificial intelligence (AI) has promise to streamline antibody discovery. Our OmniDeep™ AI-augmented workflow enables a deeper exploration of naturally optimized immune repertoires to discover additional non-obvious high-affinity and highly developable antibody candidates. To address the challenge of expressing and testing large numbers of sequences and sequence combinations, we are incorporating mammalian secretion libraries and xPloration® for rapid and efficient evaluation of selected designs. We will be showcasing the application of these tools in discovering common light chain antibodies for a potential bispecific NK cell engager.

12:50 LUNCHEON PRESENTATION: Antibody analysis with SPR — convenient, sensitive, and versatile

Eric Roush, PhD, Biacore Application Scientist, Cytiva

We describe the possibilities for screening and in-depth antibody characterization for a variety of applications e.g. selection and optimization of ADCs, investigation of a disease mechanism, binding to cells and glycoproteins. We will also present how the systems sensitivity and assay design eliminate antibody avidity effects in the strive to perform research that better mimic biological situations and how to increase analytical efficiency and gain more information from a single analysis.

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 Interactive Breakout 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.

TABLE 2: How Model-Guided Design of Multi-Specific Modalities Can Benefit Your Immune-Oncology Program- IN PERSON ONLY

Michael G. Zager, PhD, Associate Research Fellow, Discovery and Early Development, Pfizer

• Designing multi-specific modalities can take significantly more time and resource than standard monoclonal antibodies, and often the project team is still left with the question whether their clinical candidate is optimal for the targets and intended pharmacology

VARIETY OF MECHANISMS USING BISPECIFIC ANTIBODIES *(CONT.)*

2:25 Chairperson's Remarks

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

2:30 Next-Generation Multispecific Biologics for Cancer and Infectious Disease

Joanne Hulme, PhD, CSO, Radiant Biotherapeutics

Increasing antibody valency is a promising approach to improve potency and exploit biology not amenable with current approaches. Here we describe a novel MULTispecific, multi-Affinity antiBODY (Multabody) platform that exploits avidity coupled with multispecificity to deliver potent biotherapeutics with exciting transformative potential. Built on an antibody framework, Multabodies are modular, retain antibody-like developability and pharmacokinetics, and have demonstrated the potential to deliver potent biotherapeutics to treat cancer and infectious diseases.

3:00 Dual Cell Bidirectional Antibodies for Treating Autoimmunity

Jyothsna Visweswaraiah, PhD, Director, Biotherapeutics, Drug Creation, Seismic Therapeutic

Inhibitory checkpoint receptor agonists have the potential to restore immune homeostasis for patients with autoimmunity but are limited by their ability to non-discriminately bind activating FcγRs. Agonists anchored to FcγRIIb, the inhibitory Fc receptor, have the potential to provide superior agonism by avoiding inflammatory cytokine responses and limiting APC activation. Development of therapies that activate multiple inhibitory pathways to regulate both sides of the immune cell synapse will be discussed.

3:30 Surrogate Cytokine Agonists (SCAs): Overcoming Limitations in Cytokine Therapeutics

Sandro Vivona, PhD, Senior Director of Biochemistry and Biophysics, Synthekine, Inc.

Cytokines are key regulators of the immune system and important targets for both immuno-oncology as well as autoimmune diseases, but therapeutic use has been limited due to on-target dose-limiting toxicities. Engineering of partial-agonist cytokines and VHH-based surrogate cytokine agonists (SCAs) allows for the development of therapeutics with improved efficacy and reduced toxicity.

4:00 Early stage determination of the correct pairing of multi-specifics mAbs, using rapid LC-MS and LC-MALS methods.

Guillaume Bechade, Ph.D., Senior Manager, Biologics Marketing, Waters Corporation

Michelle Chen, Ph.D., Sr Director, Research & Development, Waters|Wyatt Technology

The screening of multi-specific mAb constructs and subunit pairings informs strategies for product design and process optimization. Conventional methods, such as SDS-PAGE, provide limited insights. Our case studies will highlight the benefits of accessing precise information in the early stages using modern techniques like LC-MS and LC-MALS, now routinely accessible. Particularly, the BioAccord LC-MS system directly identifies constructs and measures quality attributes, including glycoforms and low molecular weight components.

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

5:10 Improving the Therapeutic Index of T Cell Engagers by Addition of Tumor Protease-Cleavable XTEN Masks

Volker Schellenberger, PhD, President & CEO, Amunix

Overcoming systemic toxicity is the major hurdle to developing effective cancer therapies. We developed XPAT proteins (XTENylated Protease-Activated T cell engagers) that combine the specificity of an antibody with tumor-specific unmasking to maximize the therapeutic index. Multiple clinical trials investigating XPAT proteins have been initiated.

5:40 Optimizing Discovery Strategies for TCR Bispecifics

Pelin Uluocak, PhD, Principal Research Scientist, Immunocore Ltd.

ImmTAX are TCR-based, bispecific biologics that exploit T cell redirection as a mechanism-of-action to target disease-specific intracellular antigens. It is crucial to engineer an ImmTAX-pHLA engagement which results in a signaling-competent T cell response, rather than a mere high-affinity interaction. Here, we present a high-throughput method combining Jurkat-based mammalian display, functional screening, and deep-sequencing to identify potent TCR molecules as therapeutic candidates for ImmTAX engineering.

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship

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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of Advancing Bispecific Antibodies and Combination Therapy to the Clinic Conference

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC4: Safety and Efficacy of Bispecifics and ADCs

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

TUESDAY, MAY 14

6:30 pm Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

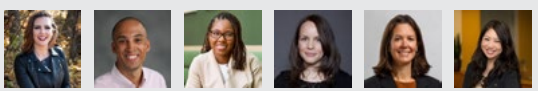
**Separate registration required. See short course page for details.*

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

Co-Organized with THINKUBATORMEDIA

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity: IN-PERSON ONLY *(Continental Breakfast Provided)*



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

ENGINEERING ARMED BISPECIFIC ANTIBODIES

8:45 Chairperson's Remarks

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

8:50 Bispecific ADCs: Modulating Intracellular Trafficking to Improve Efficacy

Julian Andreev, PhD, Research Fellow, Oncology & Angiogenesis, Regeneron Pharmaceuticals, Inc.

Bispecific ADCs—bridging HER2, and high turnover surface protein, PRLR—travel to lysosomes and improve efficacy of HER2 ADCs with non-cleavable linker. Here we present an extended version of this approach to improve ADC therapeutic index, which may be applicable to the broad set of ADC targets.

9:20 Talk Title to be Announced

Jonathan Davis, PhD, Founder and Principal Consultant, Creative Antibodies

9:50 Screening Novel Format Antibodies to Design Bispecific ADCs that Address Target Heterogeneity

Stuart D. Barnscher, BSc, Director, Preclinical Programs, ADC Therapeutic Development, Zymeworks, Inc.

Inter-patient and intra-tumoral target heterogeneity is a challenge for antibody drug conjugates (ADCs). A novel-format bispecific ADC targeting two different TAAs independently could increase the addressable patient population relative to a monospecific ADC or a bivalent bispecific ADC. A library of 48 bispecific molecules was designed, employing multiple paratopes and variable antibody formats with the aim of targeting tumors that express either FRα, NaPi2b, or both targets.

10:20 Presentation to be Announced

ABLEXIS
AlivaMab BIOLOGICS

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?

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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:

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

Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

TARGETING PEPTIDE-MHC WITH BISPECIFIC ANTIBODIES

2:30 Chairperson's Remarks

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

2:35 TRACeR: A Platform for Multimodal Antigen-Focused Targeting of MHC

Possu Huang, PhD, Assistant Professor, Bioengineering, Stanford University

We have developed a novel protein strategy to achieve antigen-specific binding to class I, II, and non-classical Major Histocompatibility Complexes (MHC). The platform, called TRACeR, breaks from classical T cell receptor (TCR)-restricted modalities and offers unprecedented simplicity and speed to develop MHC-antigen specific binders. We believe that the ease of deployment and specificities that this platform offers can be of broad interest for general MHC-targeting applications.

3:05 TCR-Mimic Bispecific Antibodies to Target the HIV-1 Reservoir

Srona Sengupta, MD, PhD, Resident Physician, Immunology, Johns Hopkins University

Using phage display technology, we constructed T cell receptor (TCR)-mimic antibodies to HIV peptide-MHC (pMHC) derived from Gag and Pol proteins that were identified via LC-DIA mass spectrometry from cells infected with a pseudotyped HIV reporter virus (NL4.3 dEnv). These bispecific antibodies induced killing of CD4+T cells infected with reporter strains as well as patient isolates of HIV-1, findings which have significant implications for the HIV-1 cure space.

SYSTEMATIC FORMAT ENGINEERING

3:35 Understanding Paratope-Epitope Interactions for Antibody Engineering, Library Design and Bispecifics

Steffen H.J. Goletz, PhD, Full Professor, Deputy Head, Vice Director, Biotechnology & Biomedicine, Danish Technical University

The talk will present learnings for understanding paratope-epitope interactions from computational analysis of > 850,000 atom-atom contacts from >1800 structurally elucidated antibody-antigen complexes and >11000 functional antibodies. The use of the learnings and patterns for antibody engineering and technologies for the generating of novel in-silico designed humanized single-domain antibody phage display libraries with maximal functional diversity for generating fusion partners.

4:05 New Technology Developments for Future Antibody Discovery and Optimization

Rene Hoet, PhD, Professor, Chief Innovation Officer, FairJourney Biologics

Latest update on validation of Explorer, a novel Diverse Modular Antibody Platform that combines phage and mammalian display to deliver a large diversity of functional developable antibodies to your target. The modular system of the library allows HT IgG functional screening and our unique propriety mammalian display technology enables quick optimization of functional properties and developability of your molecules (including multispecifics) in the final desired therapeutic format.

4:35 Networking Refreshment Break

NOVEL MECHANISMS-OF-ACTION

4:59 Chairperson's Remarks

Mahiuddin Ahmed, PhD, President and CSO, VITRUVIAE

5:00 KEYNOTE PRESENTATION: Widening the Therapeutic Window of Payload Delivery using Bispecific Self-Assembling Dis-Assembling (SADA) Antibodies

Nai-Kong V. Cheung, MD, PhD, Enid A. Haupt Endowed Chair, Pediatric Oncology, Memorial Sloan Kettering Cancer Center

IgG can carry "weapons" to cure cancer. Its firepower can be greatly enhanced and its toxicity reduced by using the "SADA" format built on bispecific antibodies (BsAb). SADA exploits the large size of oligomeric BsAb for tumor targeting and their small monomeric forms for rapid renal clearance. When applied to pretargeted radioimmunotherapy (PRIT), cures are possible without dose limiting toxicities in preclinical studies.

5:30 Long-lived CNS Delivery of IgGs using Bispecific Antibodies Targeting CD98hc

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

The inability of antibodies to penetrate the blood-brain barrier is a key limitation to their use in diverse applications. We are developing bispecific antibodies that engage CD98hc and efficiently transport IgGs into the CNS. Notably, CD98hc shuttles lead to much longer-lived brain retention than transferrin receptor shuttles while enabling more specific targeting due to limited CD98hc engagement in the brain parenchyma, which we demonstrate for several shuttled IgGs.

6:00 Cooperative Armoring of CAR and TCR T Cells by T Cell-Restricted IL-15 and IL-21 Universally Enhances Solid Tumor Efficacy

Rosa Hong Ha Nguyen, MD, PhD, Physician & Scientist, Pediatric Oncology, National Institute of Heath, National Cancer Institute

CAR and TCR T cell therapies are effective in some patients with solid tumors, but new approaches are needed to improve patient outcomes. We developed a technology to leverage the cooperative effects of IL-15 and IL-21 to enhance the efficacy of adoptive T cells. Self-delivery of these cytokines by CAR or TCR T cells enhances the resilience and function of these effectors and could be applicable to multiple therapy platforms.

6:30 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Roundtable Discussions with Continental Breakfast

Interactive Roundtable 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 Roundtable Discussions** page on the conference website for a complete listing of topics and descriptions.

TABLE 3: TRACeR: A Platform for Multimodal Antigen-Focused Targeting of MHC- IN PERSON ONLY

Possu Huang, PhD, Assistant Professor, Bioengineering, Stanford University

IMMUNE CELL ENGAGERS

8:25 Chairperson's Remarks

Eugene A. Zhukovsky, PhD, CSO, Ichnos Sciences

8:30 Dual-Ig: A Novel Next-Generation T Cell Engager Targeting Both CD3 and CD137

Feng Shu, PhD, Director, Chugai Pharmabody Research Pte. Ltd.

The Dual-Ig consist of a Fab which binds to both CD3 and CD137 in a competitive manner. It can be easily converted into a T cell bispecific antibody by attaching to a tumor antigen targeting Fab. This unique binding mode enhanced tumor target-specific T cell activation and eliminated target-independent T cell activation. Different antibody formats generated from Dual-Ig platform and their efficacy in preclinical models will be shared.

9:00 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.

9:30 Engineering and Preclinical Characterization of GS-8588, a Bispecific T-Cell Engager Targeting the HIV Reservoir

Nathan D. Thomsen, PhD, Director, Protein Therapeutics, Gilead Sciences Inc.

The talk will cover engineering of all three component building blocks (anti-CD3, anti-gp120, hetero-Fc) as well as the bispecific format, with a focus on multi-dimensional optimization of both function and drug-like properties. *In vitro* pharmacology and *in vivo* NHP PK and toxicology data supporting the clinical studies of GS-8588 will also be shared.

10:00 Enabling Modular Bispecific Development with a Fully Human Common Light Chain Antibody Discovery Platform

Alloy Therapeutics

Mike Schmidt, PhD, Chief Scientific Officer, Alloy Therapeutics

Alloy provides end-to-end bispecific discovery, optimization, and functional testing by leveraging its fully human common light chain mouse strains, ATX-CLC, to solve heavy and light-chain pairing. In this presentation, Alloy will present case studies utilizing this platform to discover CLC antibodies against challenging targets and highlight a variety of off-the shelf binding arms against modular targets for delivery, tumor targeting, and immune cell engagement that can rapidly advance bispecific programs.

10:15 Presentation to be Announced

10:30 Networking Coffee Break

ANTIBODY DEGRADERS AND SHUTTLES

10:59 Chairperson's Remarks

Christian Klein, PhD, Head, Oncology Programs and Department Head, Cancer Immunotherapy Discovery, Roche Innovation Center Zurich, Roche Pharma Research & Early Development, pRED

11:00 TransTACs for Membrane Protein Degradation

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

Cancer cells require high levels of iron for rapid proliferation, leading to a significant upregulation of the iron carrier protein Transferrin Receptor (TfR) on their cell surface. Leveraging this phenomenon and the exceptionally fast endocytosis rate of TfR, we introduce Transferrin Receptor TArgeting Chimeras (TransTAC), a novel molecular archetype for membrane protein degradation in cancers and other cell types.

11:30 Receptor Elimination by E3 Ubiquitin Ligase Recruitment (REULR): A Targeted "Mix-and-Match" Protein Degradation Toolbox

Dirk H. Siepe, PhD, Senior Research Scientist, Department of Experimental Radiation Oncology, The University of Texas MD Anderson Cancer Center

Targeted protein degradation (TPD) of cell surface proteins has emerged as a novel therapeutic avenue in drug development. While recent strategies have been successful, availability and modularity of suitable binders to generate heterobifunctional molecules is still a limitation. Here, we developed a (VHH)-based TPD toolbox termed REULR, a modular and versatile targeting strategy for the facile modulation of cell surface proteins by induced proximity to transmembrane PA-TM-RING E3 ligases.

12:00 pm Antibody Targeting of E3 Ubiquitin Ligases for Receptor Degradation

Jing Li, PhD, Principal Scientist & Group Leader, Biochemical & Cellular Pharmacology, Genentech Inc

Our lab has recently devised a technology that exploits the elevated expression of the cell-surface E3 ubiquitin ligases ZNRF3 and RNF43 in colon cancer. More specifically, we have generated bispecific antibodies that can tether these E3 ubiquitin ligases to a variety of receptors to promote their degradation. This platform has been dubbed PROTABs for Proteolysis Targeting Antibodies and is attractive for the therapeutic management of colon cancer.

12:30 Close of Conference

Engineering Smarter Immunotherapies to Fight Cancer and Immune Disorders

IMMUNOTHERAPY STREAM

The Immunotherapy Stream at PEGS Boston explores the most exciting engineering strategies driving immunotherapies for cancer and autoimmune disorders. Part One examines recent breakthroughs in understating and augmenting the immune system, solid tumors, targeting, and cancer vaccines; Part Two focuses on supercharging CAR T therapies and other cellular immunotherapies against solid tumors and autoimmune disorders; with Part Three tackling next-generation approaches such as *in vivo* engineering of therapeutic cells, and targeting payload delivery. All tracks feature brand new data and unrivaled access to industry and academic leaders.

IMMUNOTHERAPY STREAM CONFERENCES

MAY 13-14

Advances in Immunotherapy

AGENDA

MAY 14-15

Cell-Based Immunotherapy

AGENDA

MAY 16-17

In vivo Cell and Gene Engineering

AGENDA

PEGSBOSTON

TABLE OF CONTENTS

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME

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

MONDAY, MAY 13

7:00 am Registration and Morning Coffee

ADVANCES IN CANCER VACCINES AND IMMUNOTHERAPY

8:20 Chairperson's Opening Remarks

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

8:30 Vaccine-Boosted CAR T Crosstalk with Host Immunity to Reject Tumors with Antigen Heterogeneity

Leyuan Ma, PhD, Assistant Professor, Pathology & Lab Medicine, University of Pennsylvania

Chimeric Antigen Receptor T cells (CAR T) remain ineffective in solid tumors. We recently engineered a synthetic vaccine to boost CAR T cells through the chimeric receptor directly *in vivo*. Vaccine boosting enhanced CAR T expansion, polyfunctionality, and anti-tumor efficacy in multiple immunocompetent solid tumor models. Importantly, vaccine boosting of CAR T cells triggered robust antigen spreading to effectively treat solid tumors with pre-existing antigenic heterogeneity.

9:00 Personalized Cancer Vaccines—Where Are They Going Now?

Andrew R. Allen, MD, PhD, Co-Founder & President & CEO, Gritstone bio

An exciting, potentially new therapeutic approach to cancer, neoantigen-based personalized cancer vaccines (PCVs) have demonstrated promising signals in single-arm and more recently in randomized Phase 2 study. What do these results mean for patients and the field, and where will neoantigen-based PCV go from here? This discussion will review findings to date discuss the broad potential of this novel approach to drive improved outcomes across the spectrum of solid tumors.

9:30 FEATURED PRESENTATION: Advances in Cancer Treatments: From Immunotherapy to Vaccines and Almost Everything in Between

Nageatte Ibrahim, MD, Oncology Chief Medical Officer, Innovent Biologics

In this presentation, I will discuss the newer checkpoint inhibitors as well as current data from different vaccine platforms studies available to date, and give an update on the melanoma phase 2 data from our collaboration with Moderna.

10:00 Lymph Node–Targeted Vaccine-Boosting of TCR T Cell Therapy Enhances Antitumor Function and Eradicates Solid Tumors

Peter C. DeMuth, PhD, CSO, Elicio Therapeutics

This research investigates a new strategy for treating solid tumors. It combines therapy using TCR T cells with a vaccine that targets lymph nodes. The study explores how this approach improves the effectiveness of T cell therapy against cancer.

10:30 Networking Coffee Break

BISPECIFICS, UNDERSTANDING CANCER IMMUNOTHERAPY

11:00 ImmunOs HLA-based Platform to Target Multiple Checkpoints and to Treat Solid Cancer Indications

Hilmar Ebersbach, PhD, CSO, ImmunOs Therapeutics AG

We demonstrate the proof of concept of a bispecific optimised HLA-Fc fusion conjugated to a SIRPa protein which shows potent *in vitro* anti-tumor efficacy through its multimodal binding of LILRB1, LILRB2 and CD47 receptors. This novel modality of HLA/SIRPa Bispecifics has the unique characteristic of targeting myeloid cells (positive for LILRB1/2) and the ability to be directed to tumor sites by targeting the CD47 checkpoint receptor expressed on cancer cells.

11:30 KEYNOTE PRESENTATION: Non-Coding RNA Expression in Extracellular Vesicles and Chronic Inflammation in Cancer

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

Extracellular vesicles (EVs) are small membranous vesicles released by cells that act as both short- and long- distance communication vehicles in the body. This talk will discuss how the dissemination of these non-coding elements in cancer EVs can drive chronic inflammation and immune dysfunction and how these elements may be used as new biomarkers and targets to detect and treat cancer.

12:00 pm Session Break

12:05 Luncheon Presentation I: WuXiDEEP – A Developability Evaluation & Engineering Platform to Ensure Accelerated Protein Therapeutics Development

Avanish Varshney, PhD, Associate Director, Biologics Innovation & Discovery (BID), WuXi Biologics

Understanding the developability of a biotherapeutic, including its homogeneity, specificity, stability, solubility, aggregation, viscosity, immunogenicity and PK characteristics, is critical to determine if a biotherapeutic will be suitable for CMC and clinical development. WuXiDEEP™ is a leading platform seamlessly integrating smart analysis, *in silico* design, sequence optimization and wet-lab studies for developability evaluation and protein engineering. Case studies will be presented demonstrating the platforms utility in assessing and solving developability issues.

12:35 Luncheon Presentation II: Supercharging SuperHuman2.0: Leveraging the Power of Yeast Display

James Pazar, Supervisor Scientific Development, Charles River

Traditional phage panning is a powerful tool — enabling quick discovery of humanized antibodies. Our fully-human Superhuman 2.0 (SH2.0) library boasts high diversity and developability; however, when panning such a large phage library, consistently finding high affinity binders can be challenging. Yeast display helps overcome this shortcoming by leveraging fluorescent activated cell sorting (FACs) to select the highest affinity clones, screening up to 100 million clones in 1 day. By combining our traditional phage panning approach with yeast display, we can leverage the powerful benefits

of our SH2.0 library by pulling out the highest affinity hits and moving them directly into screening to obtain binding to target cells and affinity estimates.

1:05 Session Break

IMPROVING SAFETY OF CELL THERAPIES

1:10 Chairperson's Remarks

Saad Kenderian, PhD, Assistant Professor, Medicine and Oncology, Mayo Clinic College of Medicine

1:15 High-Throughput Genomics Approaches for Accelerating CAR T Safety and Efficacy

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

Here, I discuss recent advances in the use of high-throughput genomics and single-cell-based technologies that can expedite the discovery mechanisms to improve the safety and efficacy of adoptive cell therapies.

1:45 Overcoming TME-Induced Resistance to CAR T Cell Therapy

Saad Kenderian, PhD, Assistant Professor, Medicine and Oncology, Mayo Clinic College of Medicine

Despite its promising potential, CAR T cell therapy faces challenges due to the tumor microenvironment (TME), which harbors immunosuppressive factors and physical barriers that hinder CAR T cell efficacy. To overcome this resistance, strategies are being developed to enhance CAR T cell fitness, engineer them to resist the TME, and target multiple tumor antigens.

2:15 Mechanisms of Toxicity and Novel Interventions

Matthew J. Frigault, MD, Assistant Professor Medicine, Harvard Medical School; Clinical Director, Cellular Immunotherapy Program, BMT & Cellular Therapy, Massachusetts General Hospital

2:45 Fast-Tracking Checkpoint Antibody Development with MOA-Reflective Assays for Cancer & Autoimmune Antibody Therapeutics

Gaurav Agrawal, PhD, Head of Scientific Market Development, Eurofins DiscoverX

Checkpoint blockade antibodies are established cancer therapeutics. However, in recent years, agonistic antibodies have emerged as therapeutics not only for cancer, but also for suppressing inflammation in autoimmune diseases. The development of agonistic antibodies, however, is challenging since the blockade assay design fails to assess their agonistic activity. Here, we present MOA-reflective assays for development of agonistic antibodies for targets such as CD40, OX40, PD-1, BTLA, & more.

3:15 Networking Refreshment Break

4:15 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:25 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

4:35 Driving New CAR T Cells

Marcela V. Maus, MD, PhD, Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

YOUNG SCIENTIST KEYNOTE

5:20 High-Throughput Discovery of Protein Folding Stability and Dynamics

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

6:05 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

Facilitators:



Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University
Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University
Shakiba Nikfarjam, PhD, Postdoc, Lawrence Livermore National Lab

7:30 Close of Day

TUESDAY, MAY 14

7:30 am Registration and Morning Coffee

IDENTIFYING NEW IMMUNOTHERAPY TARGETS USING ML/AI

7:55 Chairperson's Remarks

Theodore Roth, MD, PhD, Resident, Clinical Pathology, Stanford University; Co-Founder, Arsenal Bio

8:00 Decoding CAR T Cell Phenotype Using Combinatorial Signaling Motif Libraries and Machine Learning

Kyle Daniels, PhD, Assistant Professor, Stanford Genetics, Stanford University

Genome annotation, protein structure prediction, and other biological subfields have been revolutionized by artificial intelligence (AI) and machine learning (ML). Advances in DNA synthesis and high-throughput experimental techniques enable construction and screening of large libraries of modular cell therapy constructs. AI and ML algorithms trained on library screening data can accelerate the development of these cell therapies by generating predictive models, design rules, and improved designs.

8:30 A Unified Genetic Perturbation Language in Human Immune Cells

Theodore Roth, MD, PhD, Resident, Clinical Pathology, Stanford University; Co-Founder, Arsenal Bio

Patient responses to engineered cell therapies are variable and unpredictable. And while hundreds of potential gene targets, CAR sequences, and engineering strategies to improve T cell function have been proposed, no method exists to rapidly examine different classes of genetic manipulations simultaneously or in combination. We have developed CRISPR-All, a unified genetic perturbation language able to arbitrarily and combinatorially examine genetic perturbations across perturbation type and scale in human immune cells.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION

10:00 Transition to Plenary Keynote Session

10:10 Plenary Keynote Introduction

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

10:15 Base Editing and Prime Editing: Engineered Proteins That Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

David R. Liu, PhD, Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Core Institute Member and Vice-Chair of the Faculty, Broad Institute; Director, Chemical Biology and Therapeutic Sciences Program; Investigator, Howard Hughes Medical Institute; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

11:00 Celebrating 20 Years in the Exhibit Hall with Poster Viewing

IDENTIFYING NEW IMMUNOTHERAPY TARGETS USING ML/AI

12:00 pm A Machine Learning–Driven Approach for the Multiparametric Lead Optimization of Anti-Tumor T Cell Engagers

Nathan Robertson, PhD, Director, LabGenius

T cell engagers (TCEs) have great potential for the treatment of solid tumors, but remain limited by their on-target, off-tumor toxicity. We show how our ML-driven optimization process enables the discovery of tumor-targeted bispecific TCEs with best-in-class selective killing profiles. We employed a machine learning platform to co-optimize HER2-targeting TCEs for high potency against tumor cells with high tumor antigen expression and avoiding healthy cells engagement.

TARGETING SOLID TUMORS

12:30 Development of Highly Effective Anti-Mesothelin CAR T Cells with Increased Persistence for Treatment of Solid Tumors

Raffit Hassan, M.D. Chief, Thoracic and GI Malignancies Branch, Center for Cancer Research, NCI, NIH

Mesothelin is an attractive target for cell therapy of solid tumors given its limited expression on normal human tissues and high expression in most solid tumors. In general, anti-mesothelin CAR T cells have had limited efficacy in patients. We have developed a highly active CAR T cell that binds to the membrane proximal region of mesothelin close to the cell surface and is associated with increased persistence in the tumors.

1:00 Talk Title to be Announced Samplix

Cecilie Nyholm Andersen, Business and science manager, Commercial Operations, Samplix Inc.

1:15 POSTER PRESENTATION: Engineering EVOLVE-106: a B7-H4-targeting T cell engager with integrated CD2 co-stimulation

Sonali Dhindwal, PhD, Senior Scientist, EvolveImmune Therapeutics Inc.

1:30 Session Break

1:40 LUNCHEON PRESENTATION: Advancing integral molecular

Antibody and CAR-T therapies Towards IND: Specificity Profiling Using the Membrane Proteome Array

Rachel Fong, Director of Sales and Alliances, Integral Molecular

Assessment of off-target antibody reactivity is a regulatory requirement for clinical development, but conventional screening methods are often ineffective in screening newer therapeutic modalities including cell therapies. We will present the Membrane Proteome Array (MPA), a 6,000-protein cell-array for specificity screening, case studies describing its successful use for regulatory filings, and the status of the MPA being developed as a qualified Drug Development Tool under consideration by the FDA.

2:10 Luncheon Presentation II: Engineering Complex Antigens for Biopharma Industry: MHC and GPCR KACTUS

Manhee Suh, PhD, CTO, Kactus

In support of the biopharmaceutical sector's efforts to innovate therapeutic solutions against debilitating diseases, we have developed two vital complex antigens tailored to meet the industry's pressing demands. Our innovative work includes the development of versatile MHC molecules, enabling rapid peptide loading in TCR-T cell therapy research application and our expansion of the GPCR catalog now encompasses offerings in both VLP and nanodisc formats.

2:40 Close of Conference

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME

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

TUESDAY, MAY 14

ENGINEERING SMARTER, SAFER CAR T THERAPIES

2:55 pm Chairperson's Remarks

Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg

3:00 KEYNOTE PRESENTATION: Utilizing Insights from Signaling Biology to Redesign CAR T Cells

Robbie G. Majzner, MD, Dana Farber Cancer Institute

This talk will discuss how our laboratory is utilizing insights into T cell signaling biology to design more specific and effective CAR T cells.

3:30 Peptide-Centered CAR Generation

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

We develop and employ technologies at the intersection of genomics, proteomics, immunology, antibody engineering, and computational biology. We are generating a pipeline of new therapies for cancer patients in need as well as technologies to enable personalized immunotherapies. Resulting from these approaches, our novel class of peptide-centric (PC)-CAR T cells potently eradicate tumors in preclinical models and are entering clinical trials in 2024.

4:00 Purification of TCR and CAR T Cells Products Leads to Better Cell Products with reduced Toxicity

Michael I. Nishimura, PhD, Professor, Surgery, Loyola University Chicago

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

ENGINEERING SMARTER, SAFER CAR T THERAPIES

5:10 Dual-Receptor System for Effective Targeting of Antigen-Low Tumors

Maksim Mamonkin, PhD, Associate Professor, Center for Cell and Gene Therapy, Baylor College of Medicine

Heterogeneity in antigen expression and scarcity of targetable antigens limit the development of engineered cell therapies against many tumors. I will discuss a strategy of targeting tumors with weak/heterogenous expression of target antigens by selectively boosting anti-tumor cytotoxicity through an additional engineered receptor.

5:40 Cooperative CAR Targeting for Selective Tumor Elimination and Minimal Antigen Escape

Sascha Haubner, MD, Senior Research Scientist, Memorial Sloan Kettering Cancer Center

Tumor target heterogeneity and similarity to normal cells require novel approaches to combinatorial CAR targeting. We utilize cooperative chimeric receptor design to selectively eliminate tumor cells. For acute myeloid leukemia (AML), we combine an attenuated ADGRE2-1XX-CAR and CLEC12A-CCR (ADCLEC.syn1) to enable IF-BETTER logic-gated killing. ADCLEC.syn1 minimizes leukemic escape and normal hematopoietic cell toxicity in humanized AML xenograft models. A clinical trial investigating ADCLEC.syn1 T cells in AML is upcoming (NCT05748197).

6:10 Close of Day

6:10 Dinner Short Course Registration

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

CELL THERAPIES AGAINST SOLID TUMORS—CLINICAL UPDATES

8:25 Chairperson's Remarks

Prasad Adusumilli, MD, FACS, FCCP, Deputy Chief and Attending, Thoracic Surgery; Vice Chair, Department of Surgery; Director, Mesothelioma Program, Memorial Sloan-Kettering Cancer Center; Associate Professor, Cardiothoracic Surgery, Weill Cornell Medical Center

8:30 Solid Tumor-Specific CAR T Cell Therapy

Prasad Adusumilli, MD, FACS, FCCP, Deputy Chief and Attending, Thoracic Surgery; Vice Chair, Department of Surgery; Director, Mesothelioma Program, Memorial Sloan-Kettering Cancer Center; Associate Professor, Cardiothoracic Surgery, Weill Cornell Medical Center

The limited efficacy of chimeric antigen receptor (CAR) T cell therapy for solid tumors necessitates engineering strategies that promote functional persistence in an immunosuppressive environment. CAR T cells with c-Kit D816V mutation (KITv) have upregulated STAT phosphorylation, antigen activation-dependent proliferation, and CD28- and interleukin-2-independent and interferon-γ-mediated co-stimulation-enhanced survival, including in transforming growth factor-ß-rich and low-antigen-expressing solid tumor models. KITv CAR T cells are susceptible to kinase inhibitors (safety switch).

9:00 Advanced CAR T to Tackle Solid Tumors

Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg

Chimeric antigen receptor (CAR) T cell therapy has revolutionized cancer treatment, demonstrating remarkable efficacy in treating hematological malignancies. However, solid tumors present a more formidable challenge, often evading CAR T cell recognition and destruction. To overcome these limitations, researchers are exploring advanced engineering with multiplexed gene-editing, augmented manufacturing, as well as the integration of artificial intelligence into CAR T cell therapy, opening new avenues for efficacious treatment of solid tumors.

9:30 Advances in Local CAR T Therapy for Glioblastoma

Donald M. O'Rourke, Professor, Neurosurgery, University of Pennsylvania

We are using EGFR-IL13Ra2 targeting bivalent CAR T cells to treat recurrent glioblastoma at the University of Pennsylvania. Cells are delivered loco-regionally to CSF via an Ommaya reservoir. We have observed early radiographic responses, along with robust and prolonged CSF engraftment of CAR T cells in CSF in all patients treated. Implications for development of CAR T cell therapeutics to glioblastoma and other CNS tumors will be discussed.

10:00 De-Risk Immuno-Oncology Drug Development with High Throughput Cell Avidity LUMICKS

Rogier Reijmers, Principal Scientist, LUMICKS

Effective bi-specific antibody therapies for oncological patients pose a challenge in development, with 88% of phase I trials failing.

Limited predictive assays hinder progress. Cell avidity (CA), a superior biomarker, emerged to forecast *in vivo* and in patient efficacy. Our service allows ranking of Cell Engagers based on CA, aiding drug developers in selecting potent candidates for streamlined filings, potentially revolutionizing immuno-oncology and enhancing patient outcomes.

10:15 POSTER PRESENTATION: Novel Engineered T-Cells Targeting Glypican-2 Regress Antigen Low Neuroblastoma in Mice

Laura E Hutchins, Postbaccalaureate Research Fellow, Lab of Molecular Biology, NIH NCI

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

LOGIC GATES, IMAGE GUIDED MONITORING OF CAR T CELLS

11:10 b7h3 Targeted CAR T Cells for Solid Tumors

Sujatha Venkataraman, PhD, Associate Research Professor, Pediatrics Hematology Genops, University of Colorado Denver

We have generated bicistronic CAR constructs using Boolean logic to "gate" the function of CAR T cells according to "AND" rules, in which two distinct antigens are required for CAR T cell activation. We identified antigens to co-target in different brain tumor types in children. These "AND" CAR T cells provided specificity and increased efficacy in killing the dual-antigen-expressing tumor cells compared to CAR T cells targeting either antigen alone.

11:40 Adaptable CAR T Cells with Image-Guided Monitoring for Solid Tumor Treatment

Daniel J. Powell Jr., PhD, Professor, Pathology & Laboratory Medicine, University of Pennsylvania

To provide a means for quantitative control of CAR T cell activity, our team first created universal immune receptors (UniCARs), a versatile CAR-like platform for the denovo generation and quantitative control of tumor antigen-specific T cells where human T cells are genetically engineered with adaptable docking immune receptors and can be conferred with highly personalized tumor specificity via pre-targeting with "tagged" antigen-specific small molecules, antibodies, scFvs or receptor ligands.

12:10 pm Session Break

12:20 Luncheon Presentation I: A Novel PBMC Humanized Mouse Model to Assess Efficacy and Safety of CAR T-Cell Therapy

Jiwon Yang, PhD, MBA, Principal Scientist, Department of Innovation & Product Development, The Jackson Laboratory

JAX's innovative PBMC-humanized mouse model evaluates the efficacy and safety of CD19 CAR-T therapy, focusing on individual variability. The platform also explores the impact of tumor burden and CAR-T doses on therapy outcomes, offering insights into their dynamic relationship. This platform enhances our understanding of CD19 CAR-T therapy optimization for hematological malignancies and potentially other areas.

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

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 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: BREAKOUT DISCUSSION: Protein Engineering of Multi-Specifics for Tailored immunotherapies Moderator:

Hilmar Ebersbach, PhD, CSO, ImmunOs Therapeutics AG

CAR-NKS, NKS, CYTOKINE-ENHANCED CELL THERAPIES

2:25 Chairperson's Remarks

Daniel J. Powell Jr., PhD, Professor, Pathology & Laboratory Medicine, University of Pennsylvania

2:30 Cell Therapy Using NK Cells to Treat Solid Tumors

Qun Jiang, PhD, Staff Scientist, TGMB, CCR, NCI, NIH

Adoptive cell therapy using CAR T cells have had limited success in patients with solid tumors. However, recent advances in the development of NK cell therapeutics could result in better outcome in patients. These include differences in the sources of NK cells to make the product, use of more potent antibodies to cell surface tumor antigens and engineering of NK cells to increasing their persistence and activity.

3:00 Novel Cytokine Engineering of NK Cell CARs for Improved Immunotherapy of Solid Tumors

Rizwan Romee, PhD, Associate Professor Medicine & Director, Haploidentical Donor Transplant Program, Dana-Farber Cancer Institute

Immunosuppressive tumor microenvironment is a major barrier for advancing cellular immunotherapy including NK cell CARs. To overcome this barrier, we have developed mesothelin targeting NK cell CARs (MSLN-CAR NK cells) with novel IL-12 arming strategy. This allows us to deliver highly activating cytokine into the TME, leading to enhanced anti-tumor activity against multiple tumor types including ovarian and pancreatic cancer *in vitro* and *in vivo*.

3:30 SYNCAR: Engineered Human IL-2/IL-2Rβ Orthogonal Pairs that Selectively Enhance CAR T Cell Anti-Tumor Efficacy in Liquid and Solid Tumor Models

Paul-Joseph P. Aspuria, PhD, Director, Cell Therapy, Cell Therapy, Synthekine, Inc.

CAR T cell therapy has demonstrated clinical efficacy against relapsed and refractory hematological malignancies. However, prominent barriers have prevented CAR T cell therapies from reaching their full curative potential, especially in solid tumors. This talk will present the innovative SYNCAR technology which leverages engineered IL-2/IL-2Rß orthogonal pairs to selectively enhance the anti-tumor efficacy of CAR T cells, addressing challenges faced in both liquid and solid tumor models.

4:00 Developing Novel TCR-Based Therapies for Hematologic Malignancies and Solid Tumors

Zhimei Du, PhD, CSO, BlueSphere Bio

Founded in 2019, BlueSphere Bio has developed innovative technologies for neoantigen and TCR discovery, aimed at advancing treatments for cancers with significant unmet needs, particularly in blood and solid tumors. The company now boasts a robust pipeline portfolio primarily focused on transformative TCR-based and advanced therapies, including TCR T cell therapies, T cell bispecific

engagers, *in vivo* TCR T cell therapy, and cancer vaccines designed for combination treatments.

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

EMERGING CELL THERAPIES; CAR-MS, TILS

5:10 CAR-M: Engineering Monocytes and Macrophages for Cancer Immunotherapy

Michael Klichinsky, PharmD, PhD, Co-Founder & Vice President, Discovery, Carisma Therapeutics

Cell therapies have revolutionized how we treat cancer; however, there remains an unmet need for improved treatment of solid tumors. Carisma is developing a differentiated cell therapy platform focused on engineered macrophages, cells that play a crucial role in both the innate and adaptive immune response. The presentation will discuss progress on CAR-M and CAR-Mono, including *ex vivo* cell therapy and *in vivo* reprogramming using mRNA.

5:40 Targeting Solid Tumors with TIL

Mark E. Dudley, PhD, CSO, Instil Bio

Tumor-infiltrating lymphocytes (TIL) that recognize tumor antigens experience chronic antigen stimulation in the tumor microenvironment resulting in TIL dysfunction. Genetic modification of TIL with CoStAR—consisting of an scFv for folate receptor alpha and CD28 and CD40 costimulatory signaling domains—improves TIL proliferation and function. CoStAR amplifies TCR signaling without off-tumor T cell activation. A clinical trial investigating CoStAR in NSCLC patients is underway.

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of Conference

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME

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

TUESDAY, MAY 14

6:30 pm Recommended Dinner Short Course

SC9: Factors Leading to Successful T Cell Therapies

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

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

Co-Organized with THINKUBATORMEDIA

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity (Continental Breakfast Provided)






Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

REPROGRAMMING THE IMMUNE SYSTEM FROM WITHIN

8:45 Chairperson's Opening Remarks

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

8:50 KEYNOTE PRESENTATION: Towards *in vivo* Engineering of the Immune System

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

Ex vivo engineered T cell showed significant clinical benefit in several diseases, but novel technologies are needed to broaden access and increase performance of immunotherapy. We developed a scalable and tunable platform to generate *in vivo* CAR-expressing cells, obviating the utilization of cells, viral vectors, or lymphodepletion conditioning. Preclinical evaluation shows effective *in vivo* engineering of T cells accompanied by profound pharmacological effect, providing a springboard for developing transformative immunotherapies.

9:20 FEATURED PRESENTATION: Latest Developments in *in vivo* Engineering of Cell and Gene Therapies

Matthias T. Stephan, MD, PhD, Professor, Translational Sciences and Therapeutics Division, Fred Hutchinson Cancer Center

9:50 ORN-101 isCAR Therapy for the Treatment of B Cell Malignancies

Robert Mabry, PhD, CSO, Orna Therapeutics

Orna Therapeutics is developing off-the-shelf *in situ* CAR (isCAR) therapies. ORN-101 is a CD19 *in vivo* CAR for the treatment of leukemia and lymphoma. Mice treated IV using a clinically relevant dosing paradigm show clearance of tumors that is antigen- and dose-dependent. isCAR delivers CAR to multiple immune effector subsets including T cells, NK cells, and macrophages *in vivo*, potentially increasing efficacy and broadening therapeutic applications.

10:20 Sponsored Presentation *(Opportunity Available)*

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?




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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:

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

Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

IN VIVO ENGINEERING USING mRNA, LNPs, Synthetic Biology

2:30 Chairperson's Remarks

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

2:35 Targeted LNP-RNA for *in vivo* Cellular Reprogramming

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

In this talk, I will describe selective *in vivo* targeting of mRNA therapeutics and interventions to specific cells and cell subtypes such as T cells and hematopoietic stem cells (HSCs) via antibody-modified lipid nanoparticles. I will also discuss the potential applications we explored with this platform technology such as gene editing.

3:05 *In vivo* Production of Functional CAR T Cells by mRNA-Targeted Lipid Nanoparticle

Haig Aghajanian, PhD, Co-Founder & Vice President of Research, Capstan Therapeutics

Using targeted lipid nanoparticles (tLNP), we were able to transiently reprogram T cells *in vivo* by delivering modified mRNA encoding a CAR against fibroblast activation protein (FAP). This treatment resulted in the reduction of cardiac fibrosis and the restoration of cardiac function. The ability to produce transient, functional CAR T cells *in vivo* with mRNA addresses some of the biggest hurdles in cell therapy including manufacturing, scalability, and safety concerns.

3:35 Can Synthetic Biology Unlock the Promise of *In Vivo* Genetic Medicines?

Nicholas A. Boyle, PhD, CEO, Abintus Bio

In the context of *in vivo* genetic medicines, targeting approaches on a particle surface have limitations and may result in payload delivery to millions of off-target cells, resulting in safety and tolerability issues. Immune cell-selective synthetic promoters have the potential to control gene expression within desired cell types and thus enable the high level of precision anticipated for next-generation *in vivo* genetic medicines.

4:05 Sponsored Presentation *(Opportunity Available)*

4:35 Networking Refreshment Break

COMMERCIALIZING *IN VIVO* CELL AND GENE THERAPIES

5:00 PANEL DISCUSSION: Current Challenges and Opportunities in *in vivo* Engineering

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

Panelists:

Philip R. Johnson, MD, CEO, Interius Biotherapeutics

Jagesh V. Shah, Vice President, Gene Therapy Technologies, Sana Biotechnology

Michael Klichinsky, PharmD, PhD, Co-Founder & Vice President, Discovery, Carisma Therapeutics

Haig Aghajanian, PhD, Co-Founder & Vice President of Research, Capstan Therapeutics

6:00 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Roundtable Discussions with Continental Breakfast

Interactive Roundtable 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 Roundtable Discussions** page on the conference website for a complete listing of topics and descriptions.

IN VIVO ENGINEERING OF CELLS USING VIRAL VECTORS

8:25 Chairperson's Remarks

Samuel Lai, PhD, Professor, Pharmacoengineering & Molecular Pharmaceutics, University of North Carolina at Chapel Hill

8:30 *In vivo* Gene Delivery to Therapy-Relevant Cells by Surface-Engineered Vectors

Jessica Hartmann, PhD, Biochemist, Federal Institute for Vaccines & Biomedicines, Paul Ehrlich Institut

Currently approved gene therapies rely on viral vectors harboring a broad cell tropism. The ultimate goal in the gene therapy field is to achieve manipulation of only therapy-relevant cells. This vision will heavily rely on vector technology, especially for *in vivo* applications. This presentation will discuss different vector platforms especially focusing on engineered lentiviral and AAV vectors using cell-specific markers as entry receptor achieved through display of DARPins or scFv.

9:00 Targeted Lentiviral Vectors for Antigen Discovery and Cellular Reprogramming

Michael E. Birnbaum, PhD, Assistant Professor, Biological Engineering, Massachusetts Institute of Technology

Cell-specific transduction remains one of the next frontiers for virally delivered gene therapy. Our lab developed a "receptor-blinded" version of VSVG, enabling co-display of a new LV pseudotype ligand to drive specific lentiviral tropism. Initial experiments have shown modularity of this platform for achieving potent transduction of on-target cells via a range of co-expressed host proteins, across a range of affinities and at frequencies as low as 1-in-100,000.

9:30 *In vivo* Engineering Using iGPS Technology

Emily Beura, PhD, Director, Research, Kelonia Therapeutics

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Networking Coffee Break

IN VIVO ENGINEERING OF CELLS USING VIRAL VECTORS

11:00 Combining Chemical and Virological Approaches to Enable Direct *in vivo* Engineering of Circulating Immune Cells

Samuel Lai, PhD, Professor, Pharmacoengineering & Molecular Pharmaceutics, University of North Carolina at Chapel Hill

Direct *in vivo* engineering of various immune cells not only can greatly reduce costs and broaden access to cellular therapy. In this talk, we will share our published and unpublished data on engineering CAR T by transducing circulating PBMCs *in situ* that can effectively eradicate aggressive tumors, as well as engineering CAR B cells that can secrete immunoglobulins of interest.

11:30 Targeting T Cells *in vivo* Using Evolved AAVs

William Nyberg, PhD, Postdoc Research Fellow, Hematology and Oncology, University of California San Francisco

Adeno-associated viruses (AAV) are commonly used delivery vehicles for gene therapies. We have evolved AAV variants targeting human and mouse T cells. In this talk, I will describe how these AAVs can be used *in vivo* to specifically target T cells for gene editing and more. Additionally, I highlight the use of targeted AAVs as gene therapies to improve T cell therapeutics in immunocompetent tumor models.

12:00 pm Synthetic Cargo and Vector Design for the Modification of Immune Cell States *in Vivo*

Robert Stickel, PhD, Stanford

Ex vivo engineering of immune cells has provided transformative outcomes for patients but has come with associated challenges in access as patient demand increases. An alternative to *ex vivo* therapy is the transformation of immune cells *in vivo*, allowing for widespread dissemination of therapies. Here I present efforts to produce immune cell-specific vectors and synthetic cargo that together allow for highly specific modification of immune cells *in vivo*.

12:30 Close of Conference

Maximizing Quantity and Quality while Minimizing Time and Cost

EXPRESSION STREAM

Addressing industry's increasing needs for recombinant protein expression and production necessitates the utilization of advanced strategies and groundbreaking research, alongside the adoption and implementation of state-of-the-art tools and technologies. The Expression Stream 1) explores expression, production, and purification of difficult-to-express proteins 2) examines expression hosts to determine the best expression system for expressing your protein of choice and 3) concludes with management strategies in an efficient protein production laboratory. These strategic back-to-back meetings investigate the newest data, innovations, and strategies to make the expression of therapeutic proteins more efficient, effective, and trouble-free.

EXPRESSION STREAM CONFERENCES

MAY 13-14

Difficult-to-Express Proteins

AGENDA

MAY 14-15

Optimizing Protein Expression

AGENDA

MAY 16-17

Protein Production Workflows

AGENDA

TABLE OF CONTENTS

DIFFICULT-TO-EXPRESS PROTEINS

Overcoming Expression, Purification, and Production of Challenging Proteins

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: How to Use and Improve Microbial Expression Systems for Recombinant Protein Production

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

MONDAY, MAY 13

7:00 am Registration and Morning Coffee

EXPRESSION AND PRODUCTION OF MEMBRANE PROTEINS

8:20 Chairperson's Opening Remarks

Ethan Dunn, Manager, Protein Sciences, Moderna, Inc.

8:30 Development and Characterization of Functional Antibodies Targeting NMDA Receptors

Nami Tajima, PhD, Assistant Professor, Physiology & Biophysics, Case Western Reserve University

NMDA receptors mediate excitatory neurotransmission and are associated with cancer and brain diseases. The instability and complexity of those multi-domain/subunit membrane protein complexes make yielding properly assembled proteins challenging. Here, I present the developed protein production method, electrophysiological and cryo-EM studies of NMDA receptor complexes, and our recent functional antibodies targeting NMDA receptors. Our work contributes to a better understanding of molecular mechanisms and strategies to target NMDA receptors.

9:00 Production of a Challenging Human Single-Pass ER Membrane Protein: Expression in Multiple Hosts and Screening of Novel Fusion Constructs for Solubility in Expi293

Ethan Dunn, Manager, Protein Sciences, Moderna, Inc.

Moderna is developing multiple mRNA vaccines and therapeutics. Since target protein expression from mRNA drugs is required for their activity, Moderna needs to produce lab-scale quantities of targeted proteins for various studies. Here, we expressed a single-pass transmembrane protein in multiple hosts and screened over 30 fusion constructs for solubility in Expi293, enabling production of the protein in soluble form with successful cleavage of the fusion partners/purification tags.

9:30 Rapid Production of Coatomer WD40 Domains: Lessons from COVID-19 Research

S. Saif Hasan, PhD, Assistant Professor, Biochemistry & Molecular Biology, Center for Biomolecular Therapeutics, University of Maryland

The secretion of medically important proteins like hormones, growth factors, and antibodies from the endoplasmic reticulum (ER) risks accidental leakage of the ER-resident proteome. Here we present cost-effective strategies for enhanced production of the WD40 domains of COPI, which retrieves ER-resident proteins to prevent this leakage. These methods have broad applications, as WD40 domains are vital for direct binding and secretion of proteins like the SARS-CoV-2 spike protein.

10:00 A scalable protein production technology to accelerate biotherapeutic development LenioBio

Ricarda Finnern, Dr., Chief Scientific Officer, LenioBio

Our presentation will showcase the capabilities of the ALiCE® cell-free protein development platform for the development of complex proteins from discovery to lead optimization. Detailed case studies showcase ALiCE®'s potential to accelerate vaccine (VLPs) and biotherapeutic development (monoclonal antibodies and multispecifics). ALiCE® is the go-to platform from screening to protein optimization and beyond.

10:30 Networking Coffee Break

11:00 Systematic Structural Evaluation of Polycystin Variants by CryoEM

Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University

Mutations in polycystin ion channel subunits cause Polycystic Kidney Disease (PKD), a genetic disorder that afflicts 1:1000 individuals worldwide with perfuse kidney cysts. We developed a mammalian protein expression and purification pipeline to produce recombinant polycystin ion channel variants. We applied this methodology in combination with CryoEM to evaluate the structural changes caused by missense PKD causing mutations in specific domains of the PKD2 polycystin homotetrameric channel assembly.

11:30 Reigning in Therapeutic Protein Expression with *Pichia pastoris*

Adam Nylen, Senior Scientist, Merck & Co Inc

Pichia pastoris is a proven expression host that can be utilized for the production of difficult-to-express proteins. The GlycoFi platform humanized the *Pichia* glycosylation pathway which allows it to express glycoproteins with a human-like glycan profile. This platform gives the opportunity to select for the optimal glycan structure through genetic knockouts and over-expressions, while simultaneously tackling the production of many challenging-to-express proteins.

12:00 pm Session Break

12:05 Luncheon Presentation I: Efficient Therapeutic Development Using The Pfenex Expression Technology® Platform primrose bio

Elizabeth Orchard, PhD, Director of Process Development, Primrose Bio

The Pfenex Expression Technology® is a commercially validated P. fluorescens based platform used for recombinant protein production. Case studies are discussed demonstrating how the Pfenex toolbox of genetic elements and host strains enabled rapid exploration of expression strategies for challenging protein scaffolds, including proteins engineered for site-specific chemical modification to enable the development of products such as antibody drug conjugates for use as human therapeutics.

12:35 LUNCHEON PRESENTATION: Optimizing Protein Expression: Leveraging a Robust CLD Platform and Scalable Process Development Framework SAMSUNG BIOLOGICS

Sojeong Lee, PhD, Lead Scientist, Associate Director of Cell Line Development, Cell Line Development, Samsung Biologics

Biologics development organizations face the challenge of accelerating development while enhancing quality and optimizing processes. A robust CLD process is a pivotal technology driver. Leveraging this robust cell line through scalable process development is crucial for success. Samsung Biologics offers proprietary platforms like S-CHOice® and optimized tech transfer processes, providing a seamless workflow that expedites preclinical development with ensured quality and efficiency.

1:05 Session Break

EXPANDING CELL FREE EXPRESSION

1:10 Chairperson's Remarks

Frank Bernhard, PhD, Lab Leader, Institute of Biophysical Chemistry, Goethe University

DIFFICULT-TO-EXPRESS PROTEINS

Overcoming Expression, Purification, and Production of Challenging Proteins

1:15 FEATURED YOUNG SCIENTIST: Harnessing Cell-free Protein Synthesis to Synthesize and Repurpose Viral Fusion Machinery

Ekaterina Selivanovitch, PhD, Postdoctoral Researcher, Cornell Smith School of Chemical and Biomolecular Engineering, Cornell University

We use a bioinspired strategy to address current challenges in targeted drug-delivery, especially those associated with carrier (delivery vehicle)-cell receptor specificity, in which viral membrane protein machinery will be repurposed for targeted delivery mechanisms. By developing adapted cell-free protein synthesis techniques, we construct user-defined proteoliposomes that can be either used towards furthering our understanding of virus ligand-host cell interactions or repurposed for targeted therapies.

1:45 Cell-Free Expression Systems: Methods of Production and Use

Matthew W. Lux, Research Biologist, BioSciences, Edgewood Chemical Biological Center

Cell-free expression systems reconstitute the core cellular functionalities of transcription, translation, and metabolism outside of the confines of the cell. This format enables experimentation simply by adding DNA or other components to a reaction, offering rapid experimental cycles compared to cells and higher control over conditions. Here we describe our work to leverage the high throughput capacity of this technology towards biomanufacturing and sensing applications.

2:15 Molecular Structures of GPCR Complexes Obtained by Rationalized Cell-Free Production Pipelines

Frank Bernhard, PhD, Lab Leader, Institute of Biophysical Chemistry, Goethe University

We present a new cell-free expression platform resulting in high-resolution cryo-EM structures of GPCR/G protein complexes. Key advantages of the modular process are the elimination of detergents; the synthesis of full-length, non-engineered GPCRs; and easy adaptation to new targets. We exemplify the established strategy by showing the first structures of the full-length human ß1-adrenergic receptor and of the histamine-2 receptor in active conformation, coupled to Gs-heterotrimer and embedded in membranes.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Networking Refreshment Break

4:15 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:25 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

4:35 Driving New CAR T Cells

Marcela V. Maus, MD, PhD, Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

YOUNG SCIENTIST KEYNOTE

5:20 High-Throughput Discovery of Protein Folding Stability and Dynamics

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

6:05 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

Facilitators:



Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Shakiba Nikfarjam, PhD, Postdoc, Lawrence Livermore National Lab

7:30 Close of Day

TUESDAY, MAY 14

7:30 am Registration and Morning Coffee

APPLYING ANALYTICS TO OPTIMIZE EXPRESSION AND SCREENING

7:50 Chairperson's Remarks

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

7:55 FEATURED PRESENTATION: Addressing Difficult-to-Produce Protein Challenges in Discovery Research

Erik Vernet, PhD, Senior Director, External Partnerships, Digital Science & Innovation, Novo Nordisk

High-quality biological reagents are a prerequisite for pharmacological research. I will discuss trends from thousands of expression constructs screened in mammalian and bacterial hosts, as well as case studies utilizing stable cell line generation and choice of fusion protein for higher yield and quality of difficult-to-produce proteins.

8:20 Utilizing Deep Learning Protein Representations to Predict Recombinant Expression

Sébastien Ouellet, MSc, Machine Learning Developer, Individual Researcher

Cysteine-dense peptides (CDPs) are an attractive pharmaceutical scaffold that display extreme biochemical properties, low immunogenicity, and the ability to bind targets with high affinity and selectivity. Identifying CDPs that can be expressed in mammalian cells is crucial in predicting their compatibility with gene therapy and mRNA therapy. We developed CysPresso, a novel machine learning approach that predicts recombinant expression of CDPs based on their primary sequence.

8:45 Using Streamlined HTS, High Density Analysis and Data Mining to Optimize DNA Construct Design

Jennifer M Shipman, Associate Principal Scientist, Protein & Structural Chemistry, Merck & Co Inc

The challenge of protein structural enablement is to obtain the target protein of sufficient quality and quantity to support various structural techniques. Our goal is to compile large datasets from a semi-automated, small-scale, data-rich characterization workflow into databases, allowing building correlations between construct designs and favorable outcomes and ultimately to predict successful designs. This workflow leads to fewer design iterations, greater probabilities of success and reduction in resource demand.

9:10 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION

10:00 Transition to Plenary Keynote Session

10:10 Plenary Keynote Introduction

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

10:15 Base Editing and Prime Editing: Engineered Proteins That Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

David R. Liu, PhD, Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Core Institute Member and Vice-Chair of the Faculty, Broad Institute; Director, Chemical Biology and Therapeutic Sciences Program; Investigator, Howard Hughes Medical Institute; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

11:00 Celebrating 20 Years in the Exhibit Hall with Poster Viewing

OPTIMIZING CHO CELLS FOR PRODUCTION OF CHALLENGING BIOTHERAPEUTICS

11:45 Establishment of O-Glycoengineered CHO Cell Line Platform for Producing Better Glycoprotein Drugs

Tongzhong Ju, MD, PhD, Principal Investigator, FDA CDER

While N-glycosylation is a known critical quality attribute (CQA), the impact of O-glycosylation on therapeutic protein quality remains elusive. My presentation describes the establishment of an O-glycoengineered CHO cell line platform to modulate O-glycosylation and provides evidence that O-glycosylation of therapeutic glycoproteins, such as etanercept, impacts the physicochemical properties and biological activity. This O-glycoengineered production platform is valuable to identify O-glycosylation as a CQA for glycoprotein drugs to improve quality.

12:10 pm Screening Biotherapeutics with Bespoke Glycoforms Using Glycoengineered CHO Cells

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

Through gene-specific cell engineering, we have developed a panel of glycoengineered CHO cells, (geCHO) enabling rapid production of bespoke glycoforms of therapeutic proteins. With this platform, we have produced and screened multiple therapeutic drug candidates (vaccines and enzymes) *in vitro* and *in vivo* to determine their optimal glycoform with respect to antigenicity, activity, and stability, etc.

12:35 Repressing Expression of Difficult-to-Express Recombinant Proteins during the Selection Process Increases Productivity of CHO Stable Pools

Jean-Sebastien Maltais, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

Many next-generation therapeutics remain intrinsically challenging to produce in CHO cells. We exploited a cumate-inducible CHO platform allowing reduced expression of various classes of r-proteins during selection of stable pools. Fed-batch productions showed that pools generated without cumate (OFF-pools) were significantly more productive. Using an inducible system to minimize r-protein expression during pool selection can contribute to reducing cellular stresses, including ER stress and metabolic burden, leading to improved productivity.

1:00 PROTiQ: Machine Learning Tools to Mitigate Risks in Traditional & Hypothetical Protein Development Workflows

Carter Mitchell, CSO, Kemp Proteins

ProtIQ is a machine learning-based suite of tools that aggregates protein target information from a variety of sources and annotates and analyzes proteins, when information is lacking. The tool was developed to address the breadth of global hypothetical proteome. Through structural modeling and protein language transformer models, protein sequences are inputted to derive protein design and process development *in silico* to improve the likelihood of success in the protein development cycle.

1:15 CHOnamite® and GlycoExpress®: Versatile expression platforms to reach biopharma productivity and quality goals

Lars Stöckl, PhD, Managing Director, FyoniBio GmbH

- Versatile expression platform for different quality needs of biopharmaceutical: CHOnamite® vs GlycoExpress®
- Special emphasis on glycosylation from different host cell systems of crucial importance for biosimilar development
- Increase of productivity and quality (e.g., glycosylation) by process optimization
- Case studies will be presented

1:30 Session Break

1:40 Luncheon Presentation I: Innovative Platforms for Producing Mini Proteins & T-Cell Related Therapeutic Targets

Jiansheng Wu, PhD, Vice President, Protein Sciences, WuXi Biologics

Mini proteins and T-cell-related proteins are gaining traction as new modalities of biologic drug. Our Mini Protein Line innovates beyond traditional *E. coli* methods, using high-titer CHO expression for enhanced mammalian expression and extra-low endotoxin level. Our T Cell Mate efficiently produces challenging T-cell-related proteins like sTCR, TCR-Ab fusions, SCT, and RF-pMHC, ensuring high throughput and yields, critical for therapeutic protein advancement.

2:10 LUNCHEON PRESENTATION: Microbial Production Platform Suitable for Long-Chain Peptides and VHHs

Yumi Nagase, MS, Lead Researcher, Biopharma Solutions Group, Research Institute for Bioscience Products & Fine Chemicals, Ajinomoto Co., Inc.

Ajinomoto Bio-Pharma Services as a fully integrated CDMO offers a broad range of innovative platform technologies and end-to-end solutions for biopharmaceutical development and manufacturing. In this presentation, we will introduce our CDMO capabilities and highlight the Corynex® protein and peptide expression platform technology, including its application towards the high-quality manufacture of GLP-1 related peptides, VHHs and ancillary materials to produce pharmaceuticals.

2:40 Close of Difficult-to-Express Proteins Conference

6:30 Recommended Dinner Short Course

SC7: The Use and Optimization of Eukaryotic Expression Systems to Support Therapeutic Generation and Structural Biology
**Separate registration required. See short course page for* details.

OPTIMIZING PROTEIN EXPRESSION

Exploring and Expanding Expression Platforms for Efficient Recombinant Protein Production

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC: How to Use and Improve Microbial Expression Systems for Recombinant Protein Production

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

TUESDAY, MAY 14

PROTEIN PURIFICATION TOOLS

2:55 pm Chairperson's Remarks

David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

3:00 GET-VVIRAL: A Comprehensive Toolbox for the Continuous Purification of Therapeutic Antibodies, Enzymes, and Gene-Editing Products

Stefano Menegatti, PhD, Associate Professor, Chemical & Biomolecular Engineering, North Carolina State University

Modern biopharmaceutics pose a key challenge: how to produce large amounts of complex and labile biologics flexibly and affordably? Our team introduced allotropic chromatography using peptide ligands that respond to Ca2+/Mg2+ to purify antibodies, butyrylcholinesterase, Cas9, and a-1-antitrypsin: flow-through affinity chromatography wherein a feedstock is continuously fed to a peptide-functionalized adsorbent that selectively retains host cell proteins and DNA—and lets the product flow through—enabling continuous purification.

3:30 Development of the nanoCLAMP Scaffold and Its Application to Preparing Custom Affinity Chromatography Resins for Single-Step Purification

Richard J. Suderman, PhD, Director R&D and Co-Founder, Nectagen, Inc.

Single-step purification of proteins using affinity chromatography is often hampered by the lack of appropriate affinity ligands. We have developed a robust platform called the nanoCLAMP for producing custom affinity chromatography resins. nanoCLAMPs bind with mid- to low-nM Kd, have melting temperatures of >70°C, resist digestion by proteases, are compatible with multiple regeneration cycles with NaOH, and are elutable at neutral pH. Several purification studies will be described.

4:00 Chemically Defined Media Optimized for Improved CHO DG44 Cell Densities and Antibody Titers in Fed-Batch Processes

Luis Rodriguez, PhD, Bioproduction R&D Manager, R&D Bioproduction, FUJIFILM Irvine Scientific

Learn how BalanCD CHO DG44 and DG44 Media Survey Panel can be used to:

- Consistently achieve and sustain high cell densities for DG44 cell lines
- Maximize peak antibody titer and cell-specific productivity
- Identify optimal media for cost-effective biologics production

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

5:10 Self-Removing Tandem Tags for Optimized Expression and Purification of Challenging Proteins

David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

The commercial availability of a practical self-removing affinity tag has provided a new platform for the rapid and inexpensive development of new therapeutic proteins. These tags can be combined with additional expression- and solubility-enhancing domains, where the self-removal reaction is also largely insensitive to buffer excipients. Hear case studies on the use of self-removing tags for expression and purification of difficult targets, including cytokines, membrane proteins, and multimeric proteins.

5:40 PANEL DISCUSSION: Meeting the Challenges of Recombinant Protein Purification

Moderator: David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

What kinds of products are driving innovation and how should scale, performance, and cost be considered? Hear from this panel of experts as they share who is developing disruptive technologies, what they are, and are these innovations in products enough for now?

Panelists:
Stefano Menegatti, PhD, Associate Professor, Chemical & Biomolecular Engineering, North Carolina State University

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC: The Use and Optimization of Eukaryotic Expression Systems to Support Therapeutic Generation and Structural Biology

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

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

EXPLORING EXPRESSION AND PRODUCTION PLATFORMS

8:25 Chairperson's Remarks

Kanika Bajaj Pahuja, PhD, Senior Scientific Manager, Protein Sciences, Genentech Inc.

8:30 Exploring Parametric and Mechanistic Differences between Expi293F and ExpiCHO-S Cells for Transient Antibody Production Optimization

Jing Zhou, MS, Senior Scientist, BioMedicine Design, Pfizer Inc.

In this study, we explored various parameters for antibody production in the TGE cell host Expi293F and ExpiCHO-S with the transfection reagents ExpiFectamine and polyethylenimine. We discovered that there are significant differences between Expi293F and ExpiCHO-S cells with regards to DNA complex formation time and ratio, complex formation buffers, DNA complex uptake trafficking routes, responses to dimethyl sulfoxide and cell cycle inhibitors, as well as light-chain isotype expression preferences.

9:00 Democratizing Biomanufacturing Using Eukaryotic Microbes

Laura Crowell, PhD, Director, Research & Development, Sunflower Therapeutics PBC

Accessibility and affordability of proteins globally is poor. Disruptive innovations, such as highly automated small-footprint manufacturing, could enhance local biomanufacturing capacity and support global access. At Sunflower, we have developed integrated, continuous, and automated small-footprint manufacturing technologies for the production of pharmaceutical-quality proteins using eukaryotic microbes. Here, we describe the benefits of an alternative host (*Pichia pastoris*) for the production of high-quality proteins using Sunflower's small-footprint biomanufacturing equipment.

9:30 An Integrated *in vivo/in vitro* Protein Production Platform for Site-Specific Antibody Drug Conjugates

Jacquelyn Blake-Hedges, PhD, Senior Scientist, Protein Biochemistry, Sutro Biopharma

Sutro Biopharma's XpressCF+ cell-free protein synthesis (CFPS) system is a powerful platform to produce antibodies containing non-natural amino acids that facilitates homogenous site-specific conjugation of ADCs. A novel hybrid IgG production process has been developed in which light chains, pre-fabricated in *E. coli*, are added to CFPS reactions to produce full-length antibodies. This integrated process increases CFPS titers and enables the production of high-DAR and dually conjugated ADCs.

10:00 Optimizing Cell-Free System: From Basic Research to Industrial Applications

Takashi Ebihara, PhD, COO, GeneFrontier Corporation

Our unique platform, PURExfrex, is a rebuilt type cell-free protein expression system. It's easy to customize for various applications and useful for high-throughput screening of various kinds of biologics including difficult-to-express protein or novel modalities. Furthermore, we established robust ribosome display with customized PURExfrex named PURExfrexRD, which has great advantages in screening of highly diversified libraries to generate new antibodies or cyclic peptides having the synergy with the AI/ML platform.

10:15 Breaking Boundaries: A Moss-Based Expression System for Complex Protein Production

Andreas Busch, Dr, COO, eleva GmbH

Pharmaceutical development requires more versatile expression systems to produce complex and challenging proteins. To overcome the limitations of existing production systems, we have developed a unique expression system using the moss Physcomitrium patens. This innovative production system has now reached a pre-commercial state using state-of-the-art single-use bioreactors.The unique features of the system will be discussed using the example of the production of the recombinant factor H (CPV-104).

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

11:10 Monoclonal Antibodies' Expression in *E. coli* and Other Platforms

Zvi Kelman, PhD, Director, Biomolecular Labeling Laboratory (BL2), National Institute of Standards and Technology (NIST) and the Institute for Bioscience and Biotechnology Research (IBBR)

In order to obtain high-resolution NMR structural data, monoclonal antibody needs to be isotopically labeled. As labeling in mammalian cells is not practical, protein was expressed in *E. coli* and yeast. mAb expression in non-mammalian cell types was compared to mammalian-expressed mAb, and differences will be discussed, including a surprising result from *E. coli* codon optimization.

11:40 High-Throughput Protein Expression and Optimization Strategies to Enable Production of Challenging Proteins and Complexes

Kanika Bajaj Pahuja, PhD, Senior Scientific Manager, Protein Sciences, Genentech Inc.

The drug discovery landscape is ever-evolving and constantly demands revolutionary technology advancements in protein expression and production laboratories. We have implemented several high-throughput small- and mid-scale screening strategies for challenging proteins to enable faster protein production for structural and biochemical studies. These strategies enable parallel testing of multiple parameters to improve protein yields and allow identification of optimal constructs and co-expression partners for poorly expressing proteins and multi-protein complexes.

12:10 pm Session Break

12:20 Luncheon Presentation I: Speeding Up Transient HEK293 and Transient/StableCHO from 96 Well, 24 Well, 6 Well, 125mL-7L Optimum Growth flasks

Sam Ellis, CEO, Sales, Thomson Instrument Company

12:50 Luncheon Presentation II: A New Era in Automated Plasmid Maxi-prep: AmMag™ Quatro Solution

Rouba Najjar, Head of MKT and BD, Product Divisions, GenScript USA Inc

GenScript's AmMag™ Quatro automates large-scale plasmid purification, overcoming the challenges of laborious maxi-prep. With modular design, it handles up to 24 samples, ensuring high-quality pDNA for diverse biotechnological applications.

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 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.

TABLE 4: Accelerating Preclinical Discovery and Development: Getting Your Favorite Protein Quickly and Cleanly- IN PERSON ONLY

David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

- Deciding the best expression strategy for new proteins: shotgun or informed guess?
- Balancing the best host: slow and reliable or quick and messy?
- How pure is pure enough? Do we always need tags?
- What happens when you just can't get what you need out of your strategy? What next?

CELL LINE ENGINEERING AND DEVELOPMENT

2:35 Chairperson's Remarks

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

2:40 RaGene: Novel AI-driven Gene Optimization Platform Enabling Maximized Yield for Biologics

Wafaa Ashraf, MSc, MBA, AI Product Manager, Proteinea, Inc

3:00 A Machine Learning Method for Genome Engineering Design Tool Attribution

Nicholas Guido, PhD, Technical Staff, MIT Lincoln Laboratory

As biological engineering improves, the risk of release of a dangerous genetically modified organism becomes greater. Without evidence that ties a release directly to the individuals responsible, discovering the *in silico* tools used to design the engineered genetic components can aid attribution. A random forest classifier was

developed that achieves more than 97% accuracy in predicting which tools were used to design codon optimized genes for expression in other organisms.

3:30 Protein Production from HEK293 Cell Line-Derived Stable Pools with High Protein Quality and Quantity to Support Discovery Research

Benjamin Alba, PhD, Scientific Associate Director, Discovery Protein Science, Biologic Therapeutic Discovery, Amgen Inc.

Research programs require high-quality recombinant proteins to enable proof-of-concept studies and structural biology. Some proteins present production and quality issues. To increase success, we developed a robust method for expressing proteins in HEK293-derived stable pools, producing recombinant proteins with less clipped species and high yields. This method also works with HEK293S GnTI- and Expi293F GnTI- suspension cells, facilitating production of proteins with less complex glycans for structural biology projects.

4:00 Advancing Antibody Development: Cutting-Edge Technologies for Faster Solutions

Amanda Grimm, Sr. Segment Marketing Manager, GenScript USA Inc

New technologies are revolutionizing therapeutic antibody development, enabling the targeting of challenging epitopes and antigens to combat diseases more efficiently. GenScript's suite of products and services meets the critical needs of biopharmaceutical companies and research institutions to optimize development of next-gen antibodies, from custom cell line development to antibody humanization and process optimization. Join us to learn how our integrated solutions address key challenges in antibody drug development.

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

5:10 The Integration of a GS Mutant Marker and a Modified CMV Promoter in a New Antibody Expression Vector Significantly Enhances Antibody Productivity

*Zhiwei Song, PhD, Senior Principal Scientist, Bioprocessing Technology Institute, A*STAR*

We identified a panel of GS mutants as potential selection markers in GS-knockout CHO-cells. Our modified CMV promoter boosted antibody production over sixfold in stably transfected bulk pools compared to the leading commercial vector with a standard CMV promoter. Combing the GS mutant marker and modified CMV promoter in a single vector yielded a mini-pool antibody productivity of 4.98g/L in a simple fed-batch setup in 50 mL tubes without optimization.

5:40 FEATURED PRESENTATION: Improving Protein Production from Insect Cell Lines Using Chaperone Co-Expression and Baculovirus Genome Modifications

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

The generation of well-behaved, high-yield protein complexes remains a major obstacle in preclinical drug discovery. To improve isolation of functional multi-protein complexes, we have developed a variety of technologies including combinatorial cloning, multi-protein coexpression, and identification of novel and specific chaperone/accessory proteins to enhance protein production. Taken together, these methods have allowed us to determine the structures of a variety of protein complexes essential for early-stage cancer drug discovery

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of Optimizing Protein Expression Conference

MAXIMIZING PROTEIN PRODUCTION WORKFLOWS

Decreasing Delivery Times of High-Quality Proteins to Support Research & Development

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC2: How to Use and Improve Microbial Expression Systems for Recombinant Protein Production

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

TUESDAY, MAY 14

6:30 pm Recommended Dinner Short Course

SC7: The Use and Optimization of Eukaryotic Expression Systems to Support Therapeutic Generation and Structural Biology

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

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity: IN-PERSON ONLY *(Continental Breakfast Provided)*

Co-Organized with

Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

MEETING PRODUCTION CHALLENGES: DOING MORE WITH LESS

8:45 Chairperson's Remarks

Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

8:50 FEATURED PANEL DISCUSSION: Protein Production Lab 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:

Kanika Bajaj Pahuja, PhD, Senior Scientific Manager, Protein Sciences, Genentech Inc.

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

Jessica Williamson, PhD, US Protein Sciences Lead, UCB

9:50 Collaboration-Based Communities to Support Expression/Production Projects

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

PIG and P4EU are professional networks, engaged in various aspects of protein expression, purification, and characterization in settings such as core technology platforms. It is a forum for informal exchange of experiences and solutions to common problems to avoid "re-invention of the wheel" in parallel and facilitates contacts between like-minded scientists in an open atmosphere with the meetings being highly stimulating events with high-quality talks as rich sources of inspiration.

10:20 Presentation to be Announced

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

TelesisBio

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?

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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:

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

Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

HAPPY CELLS ARE PRODUCTIVE CELLS

2:30 Chairperson's Remarks

Jessica Williamson, PhD, US Protein Sciences Lead, UCB

2:35 Maximizing Recombinant Protein Quality and Quantity in Cells

Brian Meyer, PhD, Principal Scientist, Merck

The following presentation focuses on key factors to consider to increase both the quantity and quality of the recombinant protein of interest. These include the following: system/organism utilized to generate the recombinant protein, ability to enhance the properties of the subject protein via nucleic or amino acid sequence changes, and purification process utilized, such as standard vs. affinity chromatography methods.

2:57 Rapid CHO Cell Pools, a Gentler Alternative to Large Scale Transient Transfection

Mark Ellis, Senior Principal Scientist, UCB BioPharma

Large-scale transient antibody expression is essential for the progression of UCB's therapeutic pipeline. For over 10 years, we have routinely used our proprietary cell line CHO SXE for large-scale transient expression of antibodies. Recently, we engineered these cells to be GS knockouts which enabled the rapid generation of stable pools using a transposase system. From these pools we obtain higher yields, with less heterogeneity.

3:19 Impacts of Cell Substrate on Therapeutic Protein Products

Erica J. Fratz-Berilla, PhD, Senior Research Scientist, Office of Pharmaceutical Quality Research, FDA CDER

Cell substrate manufacturing changes can generate challenging regulatory questions because of the potential to impact therapeutic protein structure, potency, and/or impurity profiles, which in turn may or may not impact pharmacokinetics, pharmacodynamics, clinical safety, and/or efficacy. This presentation will summarize current knowledge on the impacts of cell substrate on therapeutic protein product quality attributes and present process and product quality data from cell lines expressing non-originator NISTmAb.

3:41 BioPhorum CLD Workstream Series: Evaluation of Genetic Re-arrangements in Site-Specific Integration Cell Lines

Barbara Tevelev, PhD, Senior Scientist, Cell Line Development, Biotherapeutics Pharmaceutical Sciences, Pfizer

Site Specific Integration (SSI) expression systems offer robust means of generating highly productive and stable cell lines for standard mAbs. However, the SSI system is not immune to genetic rearrangements and complex multi-specific modalities can prove challenging. Here we present two SSI cell lines which were characterized to contain off-target genetic events. These events were found to have no impact on the stability nor product quality.

4:05 Talk Title to be Announced

Fabian Mohr, PhD, Chief Scientific Officer, IBA Lifesciences

4:20 Bringing the unproducible to the clinic: Complement factor H produced in moss

Andreas Schaaf, Dr, CSO, eleva GmbH

Several complex proteins fail to yield satisfactory expression results in established systems. Factor H, a large, repetitive and highly glycosylated regulator of complement constantly resisted recombinant production. Its therapeutic potential remained therefore inaccessible as purification from donor blood remains both insufficient and insecure.Moss-produced Factor H yields high titers, outstanding quality and process robustness. CPV-104, the moss-produced factor H proved efficacious and safe in preclinical development and currently produced for clinical testing.

4:35 Networking Refreshment Break

THINK TANKS

Expression Think Tanks—IN PERSON ONLY

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

6:00 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Roundtable Discussions with Continental Breakfast

Interactive Roundtable 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 Roundtable Discussions** page on the conference website for a complete listing of topics and descriptions.

TABLE 4: R&D with the End-in-Mind- IN PERSON ONLY

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

- Determine what your end-product could look like
- Consider the full pipeline of your candidate as early as possible
- Select suitable expression systems early on
- Use regulatory acceptable hosts as soon as possible

TABLE 5: Biotherapeutic Expression & Production Pipeline – Week in Review- IN PERSON ONLY

Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific

Dominic Esposito, PhD, Director, Protein Sciences, Frederick National Laboratory

OPTIMIZING WORKFLOWS WITH AUTOMATION

8:25 Chairperson's Remarks

Felix Findeisen, PhD, Associate Director, Discovery Biotherapeutics, Bristol Myers Squibb

8:30 A New High-Throughput Screening Method for Selections of CHO Cell Lines Unsusceptible to Recombinant Antibody Reduction

Tsuyoshi Yamaguchi, Research Scientist, Bioprocess Research and Development Laboratories, Manufacturing Division, Kyowa Kirin Co., Ltd.

Reduction of interchain disulfide bonds in monoclonal antibodies (mAbs) is one of the critical issues in large-scale mAb production using Chinese hamster ovary (CHO) cells. mAb reduction susceptibility has been reported to be cell line-dependent, but there are no efficient methods for screening reduction-unsusceptible cell lines. Here we present a novel screening method with Ambr15 for the susceptibility, which allows 48 different cell lines to be evaluated simultaneously.

9:00 Building a Robust Informatics and Automation Framework to Accelerate High-Throughput Workflows

Avinash Gill, PhD, Group Leader, BioMolecular Research, Genentech Inc.

High-throughput (HTP) workflows are critical elements of large-scale drug discovery campaigns, especially during screening and lead identification. By incorporating automation and informatics tools, HTP workflows can be built to effectively manage tasks, optimize resource usage, ingest large volumes of data, and improve productivity. By capturing and leveraging data from automated processes effectively, we aim to enhance decision-making to positively impact the discovery and development of therapeutics for patients.

9:30 Increasing Automated Expression and Purification Processes for Higher-Throughput Platforms

Felix Findeisen, PhD, Associate Director, Discovery Biotherapeutics, Bristol Myers Squibb

We have built automated custom expression and purification systems, allowing accelerated protein production of antibodies and target proteins at microgram-to-gram production scales. These semi-automated workflows allow flexible support of early drug discovery pipelines from earliest production to upscaling of lead panels, providing material for HTP characterization, *in vitro* and *in vivo* experiments. Production processes will be exemplified using examples of rapid and scalable support of example projects.

10:00 Protein-in-hand in 48 hours: Multiplexing protein expression and purification screen on a digital microfluidic device nuclera

Michael Chen, PhD, CEO & CoFounder, Nuclera

The eProtein Discovery™ System can screen multiple protein expression and purification profiles and deliver reliable proteins in-hand in less than 48 hours. eProtein Discovery reduces the timelines and costs associated with protein production through 24 customizable expression conditions and subsequent identification of optimal conditions for scale-up. Integrating cell-free protein synthesis and digital microfluidics on smart cartridges, Nuclera's eProtein Discovery enables rapid access to even challenging proteins at high quality.

10:30 Networking Coffee Break

11:00 Accelerating Drug Discovery: High-Throughput Semi-Automated Expression Platform for Antibody Lead Generation

Goncalo Silva, PhD, Senior Scientist, Biopharm Discovery, GSK

We report the development of a semi-automated platform to express panels of antibodies in high-throughput at mid-scale for developability and functional assays whilst minimizing hands-on lab work. Our platform enables parallel production of 100 mg of material for 96 clones, keeping the discovery funnel wide for longer. We have created digital workflows for sample and data-tracking, enabling data reuse and driving refinement of AI/ML models.

11:30 Progressive Automation: Developing a High-Throughput Pipeline for the Expression, Purification, and High-Fidelity Affinity Analyses of CHO-Expressed Antibodies

Edwin A. Saada, PhD, Scientist, Infectious Diseases, Lawrence Livermore National Laboratories

Here, we present a multi-component experimental pipeline designed for efficiency and adaptability within the Generative Unconstrained Intelligent Drug Engineering (GUIDE) program. This semi-automated laboratory integrates processes from molecular cloning to CHO-derived antibody affinity and characterization assessments in high-throughput fashion, emphasizing scalability and speed. Through the generation of comprehensive experimental data, our approach empowers computational models for antibody engineering, marking a significant leap forward in the efficiency of high-throughput antibody development.

12:00 pm FEATURED PRESENTATION: Generating and Measuring Protein-Antibody Interactions in Cell-Free Lysate Reaction Systems without the Need for Protein Purification

Matthew Coleman, PhD, Senior Scientist & Group Leader, Biosciences and Biotechnology Division, Lawrence Livermore National Laboratory

Computational platforms can provide multitudes of candidate antibody designs in extremely short timescales but requires extensive experimental validation. Cell-free protein synthesis (CFPS) systems are versatile and can facilitate swift turn-around in design, production, and characterization of antibodies. We use CFPS systems for producing computationally designed affinity reagents for validating antigen interactions without any purification. This approach implements microfluidics combined and fluorescent correlation spectroscopy, for screening interaction kinetics in real time.

12:30 Close of Conference

Best Practices and Next-Generation Solutions for Characterization of Novel Biologics

ANALYTICAL STREAM

The popular PEGS Analytical Stream focuses on the application of characterization tools to help gain detailed knowledge of proteins from discovery through all stages of development and production. For 2024, this three-meeting stream offers comprehensive individual programs focused on novel therapeutic modalities, biophysical methods, and the implementation and impacts of digital tools and big data in this function. The more than fifty conference speakers in this stream will be augmented by focused short courses and hosted roundtable discussions on themes related to this field.

ANALYTICAL STREAM CONFERENCES

MAY 13-14

Digital Integration in Biotherapeutic Analytics

AGENDA

MAY 14-15

Biophysical Methods

AGENDA

MAY 16-17

Characterization for Novel Biotherapeutics

AGENDA

TABLE OF CONTENTS

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

MONDAY, MAY 13

7:00 am Registration and Morning Coffee

DATA MANAGEMENT AND CURATION

8:20 Chairperson's Remarks

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

8:30 Enhancing Molecule Developability Studies with Automated Analytical Systems

Benjamin Weiche, PhD, Senior Scientist, Roche Diagnostics GmbH

Developability or molecule assessment represents a key capability across biopharmaceutical research and development to guide selection of the best clinical lead molecules. We present the use of cutting-edge automated analytical systems transforming efficiency and precision of developability studies and impacting drug development timelines.

9:00 High-Throughput Biophysical Characterization and Comprehensive Analysis

Ivan Budyak, PhD, Director, Analytical Development, Biophysical Characterization, Eli Lilly and Co.

High-throughput biophysical characterization and comprehensive analysis are essential to understanding colloidal and conformational behaviors of bioproducts. This presentation will discuss the use of high-throughput biophysical characterization techniques, implementation of data curation tools, and data analysis using machine learning algorithm to provide platform level understanding of colloidal, thermal, and chemical stability of bioproducts.

9:30 KEYNOTE PRESENTATION: Enabling Pipeline Programs Lead Candidate Selection & Optimization through Data Structure, Statistical Analysis & ML/AI

Marc Bailly, PhD, Principal Scientist, Protein Sciences Analytical Characterization, Merck

This presentation focuses on the utilization of structured data to enable discovery biologics pipeline programs for lead candidate selection and optimization through statistical analysis and ML/AI techniques. By leveraging the potential of structured data and the power of data-driven approaches, this research aims to enhance the effectiveness and efficiency of the lead candidate selection process in drug discovery, ultimately facilitating the development of novel and effective therapeutic solutions.

10:00 Machine Learning Applications for the Characterization and Classification of Particulates

Amber Raines, Senior Director Rapid Analytics, AFS, KBI Biopharma

Flow Imaging is a proven method for characterization of particulates in therapeutic products. Machine learning provides a sophisticated approach to more accurately classify particles in therapeutic products by leveraging the information present in the raw particle images. We will demonstrate how various machine learning algorithms facilitate improved classification compared to the traditional approach, leading to superior sample descriptions.

10:15 Advancing Discovery: Leveraging Hybrid-mechanistic Modelling for Development of a Robust mAb Platform Process

Brian Berquist, PhD, SVP and Chief Development Officer, Wheeler Bio

Wheeler Bio's Portable CMC™ open-source upstream and downstream platform processes generates a predictable, reliable, and scalable approach for accelerating the movement of molecules from discovery, through lead candidate selection, and into clinical manufacturing. The Portable CMC™ platform and hybrid-mechanistic process model was developed using data from both stable bulk cultures (SBCs, also known as bulk pools) and derivative clones to enable well-controlled cell lines, high titers, process robustness, scalability, and speed-to-clinic.

10:30 Networking Coffee Break

11:00 Standard-Based Strategies for Agile Systems Integration and Interoperability

Serm Kulvatunyou, PhD, Computer Engineer, Process Engineering, National Institute of Standards and Technology (NIST)

Businesses rely on numerous information systems to achieve production goals and improve global competitiveness. Semantically integrating those systems is essential for businesses to achieve both. Using an open data exchange standard has been recognized as a better integration approach than using a homegrown one. But standard has also been viewed as too slow and oftentimes difficult to use. This presentation will go over recent developments that address these issues.

11:30 SPECIAL PRESENTATION: *In silico* 3D Protein Structure Prediction and Validation of PTM Risk Sites

Varsha Daswani, PhD, PMP, Senior Director, Data Strategy, Lumilytics

The *in silico* methods of identifying three-dimensional protein structure from primary sequence data is an active area of research with applications in drug discovery and development. We will be presenting our approach to adapt recent advancements in structure prediction technology to risk-site identification and validation in biologics. We will also discuss a newly developed model for scoring the accuracy of a predicted protein structure in the absence of experimental results.

12:00 pm Session Break

12:05 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:05 Session Break

DATA INTEGRATIONS IN ANALYTICAL DEVELOPMENT

1:10 Chairperson's Remarks

Dan (Cassie) Liu, Principal Statistician, Bristol Myers Squibb

1:15 An Integrated System for the Full Automation of Analytical Method Performance Monitoring: A Case Study and Lessons Learned

Dan (Cassie) Liu, Principal Statistician, Bristol Myers Squibb

Method performance monitoring (MPM) is an integral part of analytical method lifecycle to ensure that the methods remain

suitable for intended purpose. A case study will introduce the fully automated potency MPM system that integrates data collection, data management, visualization, analyses, and results-sharing. This digital advancement remarkably boosts efficiency and productivity by eliminating manual MPM work, reducing wet-lab experiments, bringing more method insights, and allowing quicker data-driven decisions.

1:45 Cross-Disciplinary Collaboration: Bridging Industry, Academia, and Public Sector for Life Science Automation Advancements

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

Life science automation promises enhanced solutions and efficiency but faces challenges like high equipment costs and shortage of skilled personnel. Thus, there's a pressing need for interdisciplinary collaboration and education. The Danish Center for Life Science Automation (DALSA) aspires to be one of the leading European facilities addressing these issues. By creating an interdisciplinary space, DALSA hopes to connect experts and sectors, aiming to bridge gaps and facilitate automation advancements.

2:15 Integrating Process and Analytical Data: Trends, Opportunities, and Threats

Jared Auclair, PhD, Director, Bioinnovation; Associate Teaching Professor, Chemistry & Chemical Biology, Northeastern University

This presentation explores the critical role of integrating process and analytical data in biotherapeutic development. We'll discuss current trends, opportunities for improved process optimization and product quality, and potential threats associated with data integration. We'll also explore innovative approaches for data harmonization, advanced analytics, and robust data governance frameworks, highlighting how effective integration can streamline development and elevate biotherapeutic companies.

2:45 Presentation to be Announced

EVQLV

3:00 Why Not Zero-Shot; Cradle's Approach to ML for Protein Engineering

Cradle

Eli Bixby, Co-Founder, Head of ML, Cradle

Eli Bixby (Co-Founder & Head of ML) will introduce Cradle's software platform for ML-based protein optimization. He'll discuss why many zero-shot generative methods struggle to provide value when moving from chip to lab, and describe the work done to investigate this phenomena. He'll highlight Cradle's solutions to issues like poor generalization, batch variance, and diverse batch generation, and present diverse case studies which show the promise of Cradle's active learning approach.

3:15 Special Presentation: Implementation of FDA's Knowledge-Aided Assessment and Structured Application (KASA) System: Perspectives for CMC Analytics

Bazarragchaa Damdinsuren, MD, PhD, Product Quality Team Leader, OBP, U.S. Food and Drug Administration

KASA is FDA's internal tool to capture and manage information about intrinsic risk and mitigation approaches for product design, manufacturing, and facilities. The CDER/OPQ is developing KASA for the assessment of biological products as an aid to streamline reviews and increase efficiency. This talk will provide a summary of the current progress and future directions of the biologics KASA platform and discuss the incorporation of CMC analytical functions into KASA.

3:45 Networking Refreshment Break

4:15 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:25 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

4:35 Driving New CAR T Cells

Marcela V. Maus, MD, PhD, Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

YOUNG SCIENTIST KEYNOTE

5:20 High-Throughput Discovery of Protein Folding Stability and Dynamics

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

6:05 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

Facilitators:



Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Shakiba Nikfarjam, PhD, Postdoc, Lawrence Livermore National Lab

7:30 Close of Day

TUESDAY, MAY 14

7:30 am Registration and Morning Coffee

IMPACT OF AI/ML ADOPTION ON THE ANALYTICAL FUNCTION

7:55 Chairperson's Remarks

Michail Vlysidis, PhD, Senior Engineer, AbbVie

8:00 Protein Language Models Enable Prediction of Polyreactivity of Monospecific, Bispecific, and Heavy-Chain-Only Antibodies

Anusha Prakash, Associate Scientist, AbbVie

Michail Vlysidis, PhD, Senior Engineer, AbbVie

Early assessment of antibody polyreactivity is essential for mitigating risks. I will present the development of an ensemble model trained in a transfer learning network to predict the outcomes in the baculovirus particle and bovine serum albumin assays.

The training was conducted on a large dataset of sequences augmented with experimental conditions, collected through a highly efficient application. The resulting models demonstrated robust performance on different types of antibodies.

8:30 Collection and Management of Binding Data to Support Development of AI and ML Training

Wei Wang, PhD, Principal Scientist, Therapeutic Discovery, Amgen, Inc.

Generative biology incorporates cutting edge biology, high throughput automation and AI to speed up drug development. It's critical to provide meaningful data to feed machine learning models and to predict developability of the therapeutic candidates. To adapt to the demands of larger sample size and shorter turnaround time, we are transforming our SPR binding assays, including automated assay plate preparation and customized data analysis module in GeneData Screener.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION

10:00 Transition to Plenary Keynote Session

10:10 Plenary Keynote Introduction

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

10:15 Base Editing and Prime Editing: Engineered Proteins That Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

David R. Liu, PhD, Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Core Institute Member and Vice-Chair of the Faculty, Broad Institute; Director, Chemical Biology and Therapeutic Sciences Program; Investigator, Howard Hughes Medical Institute; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

11:00 Celebrating 20 Years in the Exhibit Hall with Poster Viewing

12:00 pm ML-Based Digital Formulation Development

Nicholas Michelarakis, PhD, Postdoctoral Research Fellow, Boehringer Ingelheim Pharmaceuticals

For early-stage development, the time for trial formulation 1 (TF1) decision is a major driver. Due to the vast multidimensional experiment space, finding the most promising formulation remains a major challenge up to this day. Here we will present an *in silico*, machine learning (ML)-based, digital formulation development tool. This approach leverages the powers of high-throughput experimental measurements in combination with molecular modelling tools.

12:30 Machine Learning Models for Immunogenicity and Developability Prediction and Design for Development of New Protein Therapeutics

Jung-Eun (June) Shin, PhD, Machine Learning Scientist, Seismic Therapeutic

The accurate identification of B cell epitopes is crucial to biologics development, but traditional methods for epitope identification are time-consuming and resource-intensive. Therefore, reliable *in silico* approaches for epitope prediction are needed to accelerate drug discovery.

1:00 Work Smarter, Not Harder: Emerging Lessons on Data from Biopharma R&D

Genedata

Jana Hersch, PhD, Head of Scientific Engagement, Genedata

Digital transformation drives change in biopharma companies of all sizes. With the increase in lab automation, growing data stores across all modalities including multispecifics, CGTs, and RNA therapeutics are being leveraged for AI/ML approaches. Biopharma and biotech companies need to connect and structure their data and analytics solutions into robust data streams for R&D projects. I'll discuss how they do this to extract maximum value, reduce effort duplication, and implement AI/ML.

1:30 Session Break

1:40 Luncheon Presentation I: Improving and Expediting Biologics Discovery with a Centralized, Collaborative Informatics Platform

Schrödinger

Cindy Gerson, Senior Lead Product Manager, Enterprise Informatics, Schrödinger

Biologics discovery teams are in need of an efficient and comprehensive way to capture and analyze immense amounts of data and to make informed decisions across all stages of the discovery process. This presentation will discuss how LiveDesign, Schrödinger's enterprise informatics platform, has been developed to enable biologics workflows. LiveDesign expedites and improves decision making by 1) uniting all *in vitro* and *in silico* data and metadata in one centralized hub, 2) supplying in-platform tools for decision tracking and streamlined communication, 3) integrating and democratizing computational modeling execution, delivery, and 3D visualization, and 4) providing an agnostic snap-in/snap-out framework for flexible evolution of workflows.

2:10 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:40 Close of Digital Integration in Biotherapeutic Analytics Conference

6:30 Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

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

TUESDAY, MAY 14

HIGH-THROUGHPUT METHODS AND MODELS TO ASSESS DEVELOPABILITY PROPERTIES

2:55 pm Chairperson's Remarks

Marilia Barros, PhD, Principal Scientist, Regeneron Pharmaceuticals

3:00 Assessing Expression-Ability of Complex Protein Modalities Using Biophysical-Mass-Spec Analytical Techniques

Hirsh Nanda, PhD, Director, Analytical Sciences, Janssen

Biologics, an advancing therapeutic class for life-altering illnesses, require developable molecules with high expression and quality. Complex molecular formats like bi- and multispecific antibodies present challenges in clinical manufacturing due to modifications and impurities. We employ mass spectrometry and biophysical assays, including SEC-MS and micro-fluidic cIEF-MS, with automation for investigating poorly expressing multispecific antibodies. This integrated approach streamlines processes, providing valuable insights into structural properties and improving precision and throughput.

3:30 Accelerating Antibody Discovery through the Integration of AI/ML Methods with in-House Experimental Data

Nasser Hashemi, PhD, Senior Scientist, Discovery Biologics, Merck

It has been demonstrated that integrating AI/ML methods with in-house experimental data can accelerate the antibody discovery process. Utilizing these methods, next-generation sequencing (NGS) data combined with biophysical assays can guide strategies for antibody lead selection. Furthermore, recent AI techniques, particularly those inspired by protein language models, can be effectively combined with experimentally annotated data for the antibody optimization process, such as affinity maturation.

4:00 Double-dip with low-volume, automation friendly protein characterization

UNCHAINED LABS

Kevin Lance, PhD, Market Director, Gene Therapy, Unchained Labs

Benchtop developability validation has to be more than high-throughput, it has to squeeze as much data as you can from the smallest possible sample volumes. A new twist on a classic biophysical technique screens quantification, sizing, molecular weight and monitors aggregation on a single sample. We'll also look at taking benchtop validation further with low-volume, rapid viscosity testing and the most flexible conformational and colloidal stability tool around.

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

5:10 Antibody Developability Assessment: End-to-End Automated Simulation Workflow for Predicting Physical and Chemical Stability

Saeed Izadi, PhD, Scientist, Early-Stage Pharmaceutical Development, Genentech, Inc.

I will highlight the methodological nuances and sensitivity involved in calculating structural and molecular descriptors for antibody developability assessment. I will discuss the impact of structure prediction methods, conformational sampling, underlying surface patch calculation methods, and more, by presenting benchmarks against experimental developability data, including viscosity, polyspecificity, and aggregation. I'll introduce an MD-based framework that leverages the outlined models to predict antibody developability risk flags in a high-throughput automated manner.

5:40 Profiling the Biophysical Developability Properties of Common IgG1 Fc Effector-Silencing Variants

Robert Pejchal, PhD, Director, Antibody Engineering, Adimab LLC

Antibodies possess effector functions through binding of the constant region (Fc) to Fcγ receptors (FcγR). We have profiled a panel of commonly used FcγR binding interface mutations and identified a preferred variant and isotype that silences effector functions and retains ProA binding. In addition, we identify an optimal combination of these and FcRn-enhancing mutations to extend half-life.

6:10 Close of Day

6:10 Dinner Short Course Registration

6:30 Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

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

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

8:25 Chairperson's Remarks

Saeed Izadi, PhD, Scientist, Early-Stage Pharmaceutical Development, Genentech, Inc.

BIOPHYSICAL CHARACTERIZATION FOR GENETIC MEDICINES

8:30 Developing a High-Throughput Serotype-Independent Capsid Titer Method to Support Accelerated AAV Formulation and Drug Product Development

Marilia Barros, PhD, Principal Scientist, Regeneron Pharmaceuticals

The determination and monitoring of critical quality attributes play a crucial role in the development of AAV-based gene therapies. For instance, accurately quantifying capsid titers is key to safely and efficaciously dose patients. Traditional capsid titer methods rely on ELISA which commonly suffers from relatively larger assay variability. Thus, requiring development of alternative high-throughput capsid titer methods to support AAV formulation screening and development studies.

9:00 KEYNOTE PRESENTATION: Biophysical Characterization across Modalities

George Bou-Assaf, PhD, Associate Director, Analytical Development, Biogen

Despite their rare appearance on lot release panels, biophysical characterization methods are an essential element of every characterization package and an indispensable tool during comparability assessments or investigations. In this talk, we take a look at the biophysical characterization toolbox and we describe how these methods are employed to enhance our understanding of therapeutic products in different modalities, including biologics (mAbs, fusion proteins), gene therapy products (AAV), and oligonucleotides (ASO).

MASS SPECTROMETRY APPLICATIONS

9:30 A Modality-Agnostic High-Throughput Mass Spectrometry Method: From Small Molecule Covalent Screening to Large Multispecific Antibodies, and Everything Else in Between

Iain D.G. Campuzano, PhD FRSC, Scientific Director, Molecular Analytics, Amgen, Inc.

Reversed phase liquid chromatographic mass spectrometry (RPLC-MS) is a universal, platformed, and essential analytical technique within pharmaceutical and biopharmaceutical research. Typical RPLC method gradient times can range from 5-20 mins. As monoclonal antibody (mAb) therapies continue to evolve and

bispecific antibodies (BsAbs) become more established, research-stage engineering panels are clearly evolving in size. Therefore, high-throughput (HT) mass-spectrometric (MS) and automated deconvolution methods are key for success.

10:00 Comprehensive Multi-Attribute Method for Biotherapeutic Developability Assessment and End-to-End Comparability

Belinda Pastrana, CSO /CTO and Founder, Protein Dynamic Solutions

ProteinMentor® has the proven capability of assessing multiple-critical quality attributes and the relationship between these attributes to de-risk decision making. One example is the determination of the site and extent of deamidation and its impact on loss of stability and aggregation. The streamlined approach makes it ideal for end-to-end implementation allowing for comparability assessment.

10:15 Presentation to be Announced

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

11:10 Combination of Mass Spectrometry Instrument and Workflows for Antibody-Based Products Characterization and QC

Alain Beck, PhD, Senior Director, Biologics CMC and Developability, Pierre Fabre, France

Mass Spectrometry (MS) instrumentation has improved in recent years. Both high-resolution and routine MS have been increasingly used to characterize canonical IgGs and complex antibody-based products. Cyclic Ion Mobility (cIM-MS) for conformational characterization of native therapeutic monoclonal, bispecific, and ADCs will be discussed, as well as user-friendly benchtop MS for multiple-attribute monitoring studies and advanced MS workflows for accurate quantification of trace-level host cell proteins in antibody-based products.

11:40 Benefits and Challenges of MAM Implementation at Novartis

Thomas Pohl, PhD, Director, Analytical Characterization, Novartis Pharma AG

Multi-attribute method by mass spectrometry (MAM) is an emerging analytical technology that allows for simultaneous monitoring of multiple quality attributes of therapeutic proteins on the level of individual amino acid residues in a single analysis. We will present the implementation of an automated MAM platform across six Novartis development laboratories and its application to streamline biopharmaceutical analysis and improve product and process development of mAb- and non-mAb-derived therapeutic proteins.

12:10 pm Session Break

12:20 Luncheon Presentation I Learn How High-Quality, Multi-Parameter Stability Data De-Risks Antibody Development Workflows

Rebecca Hood, Product Manager, Product, NanoTemper Technologies

Developability profiles for monoclonal antibodies require stability data to direct rational design and selection of therapeutic constructs that are most likely to succeed in the clinic. Prometheus Panta – a tool for multi-parameter stability characterization of biologics – delivers high-quality data on your constructs with reliable, high-resolution data on many stability parameters with low sample consumption. See real examples of how high-quality data impacts antibody development.

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

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 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.

TABLE 5: Challenges and Advancements on AAV Drug Product Formulation Development - IN PERSON ONLY

Marilia Barros, PhD, Principal Scientist, Regeneron Pharmaceuticals

ADVANCES IN LEGACY METHODS AND INSTRUMENTS

2:25 Chairperson's Remarks

Thomas Pohl, PhD, Director, Analytical Characterization, Novartis Pharma AG

2:30 Characterization of mAb Therapeutics Size Variants Using Sedimentation Velocity Analytical Ultracentrifugation (SV-AUC)

Zahid Khan, MS, Biopharmaceuticals Investigator, R&D Analytical Development, GSK

Sedimentation Velocity Analytical Ultracentrifugation (SV-AUC) is utilized throughout mAb therapeutic development for aggregate characterization as an orthogonal technique to other size-variant methods such as SEC. SV-AUC enjoys advantages such as the ability to analyze samples in their native matrix and broader dynamic range. However, establishing appropriate detection limits for low-abundance species remains a challenge. This session will describe preliminary work to establish detection limits for mAb aggregate characterization.

3:00 2D-Correlation Methods to Rejuvenate Biopharmaceutical FTIR Spectroscopy

Curtis W. Meuse, PhD, Research Chemist, Macromolecular Structure & Function Group, NIST

Site-specific deamidations of asparagine and glutamine residues in monoclonal antibodies can be observed using temperature perturbation and infrared two-dimensional correlation (2D-COS) methods. We will describe the rejuvenation of FTIR experiments using similar 2D-COS methods to characterize protein physical and chemical stability.

EMERGING METHODS AND INSTRUMENTS

3:30 High-Throughput Characterization of Antibodies in Early Research

Merika Reinau, Specialist, Global Research Technologies, Novo Nordisk

Numerous molecules are screened for optimal activity and developability in early drug development. Chemical and biophysical properties can affect activity—making them key for data interpretation—and provide a developability profile. Traditional chromatography-based methods often prove resource-intensive for this phase, where low volumes and numerous samples are analyzed. Here, we contrast data from traditional methods with those from more efficient, high-throughput approaches like chip-based capillary electrophoresis and spectroscopy.

4:00 Automated and High-Throughput Characterization of Antibodies Using the Novel AutoFox System

Jiana Duan, PhD, Research Scientist, GenNext Technologies

The covalent addition of oxygen to protein surfaces using Hydroxyl Radical Protein Footprinting (HRPF) is prominent in MS-based Higher Order Structural (HOS) analysis. The novel AutoFox® System is the first-in-class, fully automated HRPF method using inline radical dosimetry, automated sample handling (96-well plate), and LC-MS data analysis software to determine protein structural characteristics. This talk demonstrates the characterization of antibodies in different experimental conditions from a single HRPF experiment.

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

5:10 Effects of Pressure and Salt on Protein Interactions

Susana Teixeira, PhD, Research Associate Professor, University of Delaware; Guest Researcher, NIST Center for Neutron Research

Proteins are exposed to hydrostatic pressure (HP) *in vivo* and in processing conditions, e.g., freeze-thaw or sterilization. HP is a powerful tool to probe and drive protein-protein interactions (PPIs) of interest, and synergistic effects with salt have been previously reported. An empirical approach to scale combined HP and salt effects on PPIs is presented for SAXS data on ovalbumin solutions, applicable to other proteins and techniques in the literature.

5:40 Measuring Solution-Phase Kinetics Using Solid-Phase SPR: Measuring the True Stability of the Ranibizumab-VEGF Complex

John Quinn, PhD, Distinguished Scientist, Biophysical Group, Biochemical and Cellular Pharmacology, Genentech

Accurate estimation of affinity and kinetics is critical to developing potent therapeutic antibodies and for prediction of pharmacodynamics, yet this has become increasingly difficult given the extremely high potency and high binding-stability that can now be attained. We present optimized SPR-based methodologies that enable reliable characterization of such affinity complexes and report results for the Ranibizumab-VEGF complex.

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of Biophysical Methods Conference

TUESDAY, MAY 14

6:30 pm Recommended Dinner Short Course

SC8: Developability of Bispecific Antibodies

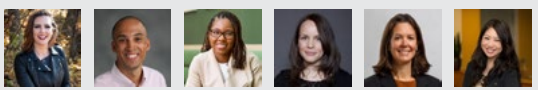
**Separate registration required. See short course page for details.*

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity: IN-PERSON ONLY *(Continental Breakfast Provided)*

Co-Organized with THINKUBATORMEDIA



Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

CONJUGATES AND FUSIONS

8:45 Chairperson's Remarks

Dennis Åsberg, PhD, Senior Project Manager, Global Research Technologies, Novo Nordisk A/S

8:50 Capillary Gel Electrophoresis for the Separation of Highly Glycosylated Heterodimeric Fusion Proteins

Kyle Jones, Scientist III, Manufacturing & Analytical Development, Shattuck Labs Inc.

The development and manufacture of heterodimeric proteins has been hindered by the lack of readily available analytical methods to distinguish homodimer impurities from the target heterodimeric therapeutic molecule. An SDS-CGE method has been developed to separate structurally similar molecules based on their level of N-linked glycosylation. The method is utilized to support process development decisions to enrich for the heterodimeric protein, which has been confirmed through a dual binding assay.

9:20 Complementary Bioanalytical Approaches for Characterizing Emerging Modality Therapeutics from Biomatrices

Rachel Liuqing Shi, PhD, Principal Scientist, Genentech, Inc.

Charge detection-mass spectrometry (CD-MS) directly measures the charge and mass-to-charge ratio, generating the molecular weight distribution for highly heterogeneous biomolecules that cannot be determined by conventional MS. Here we applied CD-MS to characterize antibody-drug conjugates, cytokine fusion proteins, and the disulfide-constrained peptides from biomatrices. Combined with bottom-up MS, CE, and HIC-UV, the CD-MS studies allowed us to perform the bioanalyses of the emerging modalities to understand their pharmacokinetics and efficacy.

9:50 FEATURED POSTER PRESENTATION: ABBV-400, a c-Met ADC: *In Vitro* Immunosafety Data Analysis

Susanne Scesney, Senior Scientist, Biologics, AbbVie

ABBV-400 is an ADC consisting of the anti-cMet antibody, telisotuzumab, and a topoisomerase-1 inhibitor (Top-1i). During the development of this molecule *in vitro* immunosafety studies were performed. To this end ABBV-400 was evaluated for FcgR and Fc neonatal binding, ADCC-CD16 signaling, and PBC activation by means of cytokine release, CD69 expression and proliferation. This presentation will highlight the results of those studies.

10:20 Talk Title to be Announced

Ross Walton, PhD, Sr. Applications Scientist, Biologics, Unchained Labs

UNCHAINED LABS

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?

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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:

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

Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

2:30 Chairperson's Remarks

Richard Rogers, PhD, Director, Product Sciences, Umoja Biopharma

2:35 KEYNOTE PRESENTATION: Phase-Appropriate Analytical Strategies for Developability Assessment and Formulation of Biotherapeutics

Hristo Svilenov, PhD, Associate Professor, Ghent University

In this presentation, I will talk through orthogonal approaches for developability assessment and early formulation development of therapeutic proteins. I will also discuss how formulation optimization can alleviate specific issues with physiochemical properties of protein drug candidates. The keynote is aimed at a broader audience interested in characterization, selection, and formulation of therapeutic proteins.

GENE AND CELL THERAPIES

3:05 Manufacturing Properties of Engineered AAV versus Natural Serotypes

Lionel Galibert, Senior Principal Research Scientist, Biotherapeutics and Genetic Medicine, AbbVie

AbbVie is extending the use of Recombinant Adeno-Associated Virus (rAAV) to deliver DNA-encoding antibody-based biotherapeutics to target a wide range of proteins involved in neurological and eye diseases. Using engineered capsids for the delivery of the rAAV genome, we explore their manufacturability properties in comparison to the natural AAV serotypes. Insights into the production efficiency, thermal stability, and full-length rAAV genome and DNA contaminant packaging will be discussed.

3:35 Assessment of Size and Charge Variant Profiles for Complex Antibody Formats

Patrick Bulau, Control Strategy Scientist, Pharma Analytical Science and Global Quality Control, Roche Diagnostics GmbH

Identification and further characterization of antibody size and charge variants is a crucial step during biopharmaceutical drug development of novel antibody formats. At Roche Pharma Research and Technical Development, native mass spectrometry and multi-dimensional liquid chromatography is routinely used for the characterization of biologics. This presentation will summarize the strategy and challenges that were encountered during method development of these assays.

4:05 Accelerating Charge Variant Analysis using Maurice icIEF to Support Monoclonal Antibody Development

bio-techne

Siddharth Sapa to be Announced, Associate Scientist, Teva Pharmaceuticals

With multiple programs and aggressive timelines, development of biologic drugs often generates large analytical data packages in support of high-quality formulation development. Maurice icIEF was used for charge analysis of two IgG1 antibodies, comprising about 450 samples of different compositions and conditions. Maurice icIEF was able to increase throughput while providing comparable data to historical iCE3 data sets. Similar advantages can be achieved throughout process development as well.

4:35 Networking Refreshment Break

5:00 Characterization of VivoVec: A Surface-Engineered Lentiviral Drug Product for *in vivo* Generation of CAR T Cells

Richard Rogers, PhD, Director, Product Sciences, Umoja Biopharma

VivoVec, a novel off-the-shelf surface-engineered lentiviral vector platform, is designed to achieve specific and efficient *in vivo* T cell transduction following direct administration. The VivoVec manufacturing process control and product release strategy employs methods to measure the identity, purity, potency strength, and safety attributes. Characterization of VivoVec process impurities, product attributes, and transduced T cells will be described.

5:30 Current and Emerging Applications of Droplet Digital PCR in CRISPR Gene Therapy

Jeehae Park, PhD, Principal Scientist, Early Development, Intellia Therapeutics, Inc.

In recent years, investigational CRISPR therapies have shown control of target gene expression in humans, demonstrating the modalities' potential therapeutic capabilities. Development of these therapeutics poses a challenge for tracking these components' PK/PD/BD. Oligonucleotide bioanalysis using droplet digital PCR is an emerging technology and is becoming the preferred method for several applications. Here, we discuss current and emerging applications of droplet digital PCR in CRISPR gene therapy development.

6:00 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

7:30 Interactive Roundtable Discussions with Continental Breakfast

Interactive Roundtable 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 Roundtable Discussions** page on the conference website for a complete listing of topics and descriptions.

TABLE 6: Characterization, Screening and Design of Bispecific Antibodies - IN PERSON ONLY

Dennis Åsberg, PhD, Senior Project Manager, Global Research Technologies, Novo Nordisk A/S

BI- AND MULTISPECIFIC ANTIBODIES

8:25 Chairperson's Remarks

Erik V Munsell, PhD, Associate Principal Scientist, Discovery Pharmaceutical Sciences, Merck Research Labs

8:30 Biophysical Characterization of Bispecific Antibodies and Antigen-Antibody Complexes

Dennis Åsberg, PhD, Senior Project Manager, Global Research Technologies, Novo Nordisk A/S

An increasing number of bispecific antibodies is entering clinical trials. However, bispecific antibodies add complexity to variant screening and characterization. Here, I will give an overview of techniques we use to study the developability, purity profiles, and antibody-target complexes. I will provide case stories including application of mass photometry to study antibody-antigen complexes and examples of how developability profiles of different parent mAbs translate to the final bispecific format.

9:00 Effective Application of Biosensing Technologies for IgG-Based Multispecific Antibody Characterization

Daniel Fallon, Scientist, Protein Analytics, Dragonfly Therapeutics

Identifying drug candidates from antibody libraries requires careful assessment of their binding properties. The appropriate application of different biosensing technologies at each stage of antibody discovery and development can aid in advancing or screening out candidates. Here, I will discuss how Dragonfly Therapeutics uses a Carterra LSA, Biacore 8K, and KinExA 4000 to characterize

IgG-based multispecific antibodies, from discovery through lead characterization.

9:30 Analytical Development and Characterization of a Bispecific Antibody Therapeutic

Pamela Peng Feng, Scientist, Analytical Development, Biogen

Bispecific antibodies are capable of binding to two antigens or two domains of the target antigen(s). This presentation will briefly discuss the analytical development and characterization strategies that are applied to elucidate the structure of bispecific antibody molecules and to better understand the potential impurities and post-translational modifications (PTMs), in support of the technical development of such non-platform program during cell line selection, formulation selection, and stability studies, etc.

10:00 Presentation to be Announced by Bioinformatics Solutions, Inc.

10:15 Understanding Biomolecular Behavior with Mass Photometry

Gael Nicolas, Key Account Manager, Sales, Refeyn Inc.

Mass photometry is a revolutionary new way to analyze biomolecules. It enables the accurate mass measurement of single molecules in solution, in their native state and without the need for labels. This approach opens up a wide variety of applicatons in the biophyscial characterization space, including but not limited to: routine sample characterization, oligomerization studies, interaction studies, monitoring molecular assemblies, and cell and gene therapy.

10:30 Networking Coffee Break

CHARACTERIZATION CHALLENGES

11:00 Analytical Challenges and Strategy to Support a Low-Concentration in-Use Comparability Study

Yan Wang, PhD, Principal Scientist, Takeda

To enable administration of highly potent drug products in the clinic, a closed system transfer device (CSTD) is often used. Recovery and product quality after passing through a CSTD must be evaluated and it can be challenging to measure product attributes at the very low concentrations involved. In this talk, we'll discuss analytical approaches for assessing concentration and for monitoring product quality for low-concentration in-use samples.

11:30 Accelerating Discovery to FIH through Early Formulation Risk Assessments of Novel Biologics

Erik V Munsell, PhD, Associate Principal Scientist, Discovery Pharmaceutical Sciences, Merck Research Labs

Non-mAb proteins encounter several CMC developability challenges. To expedite these modalities to clinic, CMC and discovery teams collaborate to identify structural weaknesses and degradation pathways of the molecules and enable the selection of the optimal lead. In this presentation, we will share case studies that utilize high-throughput (HT) tools to assess various properties, including the propensity for self-interaction and aggregation, thermal stability, colloidal stability, and biochemical stability.

12:00 pm Autonomous Bioanalytical Single-Cell Imaging Device for Advanced Biomanufacturing Applications

Umer Hassan, PhD, Assistant Professor, Electrical & Computer Engineering, Rutgers University

Single-cell characterization is one of the most critical measurements, being utilized in medical diagnostics, cellular therapeutics, and biomanufacturing applications. Different cellular therapies-based biomanufacturing assays require single-cell monitoring and enumeration while determining cellular potency, viability, and activity. Single-cell measurements serve as QC in many biomanufacturing processes. Recently, we developed a 3D printed, autonomous bioanalytical imaging and characterization setup based on florescence microscopy capable of imaging cells at point-of-care.

12:30 Close of Conference

Strategies and Tools for Safe and Efficacious Therapeutics

IMMUNOGENICITY STREAM

Development and adoption of novel biologic therapies is accelerating, but complex immunogenicity considerations require early risk management, analytical capabilities, and mitigation strategies. The Immunogenicity Stream at PEGS begins with an introductory training seminar providing a comprehensive overview of immunogenicity. The stream then leads into the Immunogenicity Assessment and Management conference, which details tools for risk assessment and mitigation, Nab characterization, assay development and validation, and challenges faced in novel modalities. The stream concludes with an in-depth training seminar on bioassay design, development, analysis, validation, and monitoring.

IMMUNOGENICITY STREAM CONFERENCE

MAY 13-14

TS: Intro to Immunogenicity

AGENDA

MAY 14-15

Immunogenicity Assessment and Management

AGENDA

MAY 16-17

TS: Intro to Bioassays

AGENDA

TABLE OF CONTENTS

DAY 1: MONDAY, MAY 13, 2024 | DAY 2: TUESDAY, MAY 14, 2024

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 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.

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME

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

TUESDAY, MAY 14

MANAGING IMMUNOGENICITY OF GENE EDITING AND GENE THERAPIES

2:55 pm Chairperson's Remarks

Klaudia Kuranda, PhD, Head of Immunology, Spark Therapeutics, Inc.

3:00 Using Liquid Biopsy Proteomics to Decipher Immune Responses in the Eye

Vinit B Mahajan, MD, PhD, Professor, Ophthalmology, Vice Chair, Research, Stanford University

Molecular therapeutic testing for eye disease is a major biomedical and pharmaceutical focus, but immune mechanisms that limit outcomes remains a challenge. Liquid biopsy proteomics can be used in living humans to identify specific immune pathways active in individuals to optimize human clinical trials in gene and molecular therapies.

3:30 Unpacking AAV Vector Immunogenicity

Justin Ishida, Scientist, Translational Sciences, Clinical Immunology and Gene Therapy, BioMarin Pharmaceutical Inc

Immunogenicity assessment of AAV gene therapies is multifaceted and layered, within the vector and beyond. We will discuss the interpretation of clinical and non-clinical findings with divergent vectors and applications that inform strategies to mitigate risk to patients.

4:00 Immunogenicity assessment and Ankyrons: Target binding reagents beyond antibodies PROIMMUNE www.proimmune.com

Andrew Isidoridy, PhD, Immunology Sales Specialist, ProImmune

Immunogenicity risk assessment is critical to winning in today's drug market. Learn from real-world case studies applying MAPPS, T cell proliferation, MHC-peptide binding and cytokine release assays. Ankyrons are next generation recombinant animal-free monoclonal binding reagents 10x smaller than antibodies with demonstrated success in a wide range of applications. Learn how these high affinity tools can be used to interrogate target proteins providing solutions to problems that were previously not addressable.

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

CLINICAL RELEVANCE OF ADA AND DATA HARMONIZATION

5:10 Clinical Case Studies of Different ADA Testing Strategies—What Do We Gain with 3 Tiers of Assessment?

Mu Chen, PhD, Principal Scientist, Bioanalytical Strategy Group, Regeneron Pharmaceuticals

The conservative, resource-intensive 3-tiered ADA testing strategy is under scrutiny for immunogenicity monitoring after two decades of use. A retrospective analysis of clinical ADA data from a mAb therapeutic using 1-tiered ADA testing strategy with a 1% false-positive cut point showed very similar results to the 3-tiered approach. This simplified strategy for ADA assessment could speed up data delivery and reduce resources for clinical program development without compromising patient safety.

5:40 Neutralizing ADA Sample Testing and Report Harmonization

Michele Gunsior, PhD, Senior Director, Astria Therapeutics

Assessment of neutralizing antibody (NAb) is an important aspect of characterizing the confirmed anti-drug antibody (ADA) response and to better understand the impact of ADA in a particular clinical trial and broadly to a drug development program. A cross-industry group of experts established harmonized recommendations and a report template for summarizing the essential aspects of clinical study NAb testing and reporting. The results of the harmonization efforts will be presented.

6:10 Close of Day

6:10 Dinner Short Course Registration

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

CHARACTERIZATION STRATEGIES FOR NOVEL MODALITIES

8:25 Chairperson's Remarks

Jaya Goyal, PhD, Executive Vice President, Research and Preclinical Development, PepGen

Pallavi Lonkar, PhD, Vice President, Bioanalytical, Biomarkers, and DMPK, PepGen

8:30 Challenges Due to Pre-existing Antibodies in AAV Gene Therapy

Renuka Pillutla, PhD, Senior Vice President, Head, Development Sciences, Spark Therapeutics Inc

The presence of pre-existing antibodies to AAV presents challenges in development of systemically-delivered gene therapies. Pre-screening for anti-AAV antibodies in patients is a critical step in clinical development of AAV-based gene therapy. This presentation will discuss technical and regulatory considerations in the development of phase-appropriate assays that can identify the right patients for therapy. Critical activities towards co-development of a CDx that must parallel path drug development will be discussed.

9:00 Considerations for Immunogenicity Assessment of Oligonucleotide-based Therapeutics

Susovan Mohapatra, PhD, Director, DMPK, Stoke Therapeutics

This talk will focus on anti-drug antibody (ADA) assay development for Oligonucleotide therapeutic (ONT) programs. A case study will describe development and validation of ELISA assays for detection of ADA for STK-001, an antisense oligonucleotide in clinical development for treatment of Dravet Syndrome, and highlight differences in immunogenicity assays for GLP toxicity studies and clinical studies. Using data for approved ONTs, recommendations will be made for immunogenicity assessment strategies.

9:30 A Single Point Mutation on FLT3L-Fc Protein Increases the Risk of Immunogenicity

Yinyin Li, PhD, Principal Scientist, Biochemical & Cellular Pharmacology, Genentech Inc

This talk focuses on risk assessment for FLT3L-Fc variants. We utilized various risk assessment methods that include in-silico prediction, dendritic cell loading, MHC-associated peptide proteomics, in-vitro HLA peptide binding, and in-vitro T cell proliferation and ELISpot assays. The results indicated that a single point mutation on the FLT3L-Fc introduces immunogenic T cell epitopes with high immunogenic risk. Analysis of HLA genotyping shows certain HLA-DR alleles are associated with immunogenic response.

10:00 Identification of Anti-Idiotype Antibodies using Digital SPR nicoya

Benjamin Hoffstrom, PhD, Assistant Adjunct Professor, Medicine, UCLA

Anti-idiotypic antibodies (anti-IDs) are used in bioanalytical assays to monitor pharmacokinetics (PK) and the immunogenicity of therapeutic antibodies. Traditional anti-IDs discovery workflows can be labor and reagent intensive, limiting the number of

candidates that can be investigated. This study aims to streamline the discovery of anti-IDs by combining digital surface plasmon resonance (SPR) and high throughput flow cytometry to efficiently screen thousands of anti-ID candidates and ultimately identify high-performance pairs.

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

LIFECYCLE MANAGEMENT AND CLINICAL DEVELOPMENT

11:10 Immunogenicity of Protein Therapeutics When Administered Intravenously vs. Subcutaneously

Kamalika Mukherjee, PhD, Principal Scientist, Bioanalytical Strategy, Regeneron Pharmaceuticals Inc

Subcutaneous delivery of therapeutic proteins can increase patient compliance and reduce burden on healthcare systems compared to intravenous infusion. However, subcutaneous administration has been proposed to increase immunogenicity. We reviewed anti-drug antibody (ADA) data for numerous biotherapeutics that were administered both intravenously and subcutaneously, and overall, no difference in immunogenicity incidence was observed. Although route of administration may in some instances influence ADA, other risk factors are likely more impactful.

11:40 Immunogenicity and Hypersensitivity Assessment through Clinical Development

Karen Robbins, MD, Safety Physician and Clinical Lead, Immune Safety Knowledge Group, Patient Safety Oncology and Center of Excellence, AstraZeneca

Through development of an immune-specific consultation group, we present a model of risk assessment and focused clinical feedback to guide product teams through all phases of development and post-marketing. This model presents a novel and streamlined approach to addressing common concerns and unique issues throughout a global organization.

12:10 pm Session Break

12:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

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

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 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.

IMMUNOGENICITY ASSESSMENT AND MANAGEMENT

2:25 Chairperson's Remarks

Jack A. Ragheb, MD, PhD, Senior Vice President, Translational Sciences and Medicine, NexImmune

2:30 Anti-Drug Antibodies: From von Behring to Today

Jack A. Ragheb, MD, PhD, Senior Vice President, Translational Sciences and Medicine, NexImmune

The original recognition of ADA and immune complex disease, the evolution of ADA responses, their continued impact on both clinical and preclinical studies, as well as novel ways to mitigate their formation will be examined.

3:00 Pre-Clinical Immunogenicity Risk Assessment Strategy for Diverse Biological Modalities: Lead Selection and Mitigation

Jochem Gokemeijer, PhD, Senior Director, Molecular Discovery Technologies, Bristol-Myers Squibb

Immunogenicity of biotherapeutics has the potential to negatively affect efficacy and patient safety. Identifying immunogenicity liabilities early in the discovery process allows for the selection of alternative leads or protein engineering to mitigate these liabilities. Increased complexity of biotherapeutics (TCEs, ADCs, bispecific mAbs, engineered cytokines) require modifications of the immunogenicity liabilities assessment strategy. Here we will discuss our discovery strategy to develop new biotherapeutics with minimized immunogenicity liabilities.

3:30 Antigen-Specific Immune Tolerance as a Strategy to Mitigate Immunogenicity of Biologic Therapies

Kei Kishimoto, PhD, Consultant, Former CSO, Selecta Biosciences, Inc.

The development of anti-drug antibodies is a common cause for treatment failure and adverse events associated with biologic therapies. Here, I will describe the preclinical and clinical development of ImmTOR tolerogenic nanoparticles, culminating in successful completion of Phase 3 clinical trials, as an example of an antigen-specific approach to induce immune tolerance to immunogenic biologic therapies. I will further discuss some of the challenges and lessons learned from this experience.

4:00 Sponsored Presentation *(Opportunity Available)*

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

5:10 Case Study Applying Patient-Centric Sampling to Immunogenicity Assessments

Joleen White, PhD, Head of Bioassays, Bill & Melinda Gates Medical Research Institute

Patient-centric sampling aims to improve the patient experience in clinical trials while maintaining quality assessments. In this case study, the application of capillary blood microsampling for immunogenicity aims to reduce the sampling burden for infants by decreasing volume and using a less invasive sampling technique. Assay development and validation will be presented alongside practical tips and clinical concordance.

5:40 New *in silico* Immunogenicity Profiling Approach—Based on Drug/Pathogen Analogy

Michael Gutknecht, PhD, Principal Scientist II, Novartis Pharma AG

We developed a new *in silico* immunogenicity profiling method with which we could show that biotherapeutic sequences can bear analogues to pathogen sequences. This may result in a high number of memory T cells that are cross-specific to the biotherapeutic and may result in unwanted immunogenicity in a large proportion of the patient population. This new method can be utilized in de-immunization approaches in early biotherapeutic development.

6:10 **Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing**

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 **Close of Immunogenicity Assessment and Management Conference**

DAY 1: THURSDAY, MAY 16, 2024 | DAY 2: FRIDAY, MAY 17, 2024

INTRODUCTION TO BIOASSAY DESIGN, DEVELOPMENT, ANALYSIS, VALIDATION, AND MONITORING

This course introduces statistical ideas supporting bioassays (via examples), reviews bioassay properties, and shows how laboratory constraints create the 'statistical design structure' of assays. These structures inform analyses and design of experiments (DOE) and its application to development, validation, and monitoring. Strategic combinations of assay design and good assay analysis methods offer new monitoring tools that support a lifecycle approach.

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

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.

Applying Next-Generation Therapies to Expanded Indications

THERAPEUTICS STREAM

The Therapeutics Stream at PEGS explores the landscape of emerging therapeutics, applying what has been learned in antibodies, RNA-based therapeutics, *in vivo* cell engineering, CAR T therapies, and more, to non-oncology indications. The stream begins with a conference on emerging indications for therapeutic antibodies, such as autoimmunity, infectious disease, metabolic/cardiovascular disease, and neuroscience. The stream continues with a conference on mRNA therapeutics, showcasing exciting progress in mRNA-based therapeutics and vaccines, and concludes with a conference on the strides made in next-generation immunotherapies.

THERAPEUTICS STREAM CONFERENCES

MAY 13-14

Emerging Indications for Therapeutic Antibodies

AGENDA

MAY 14-15

mRNA Therapeutics

AGENDA

MAY 16-17

In vivo Cell and Gene Engineering

AGENDA

TABLE OF CONTENTS

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC3: In silico and Machine Learning Tools for Antibody Design and Developability Predictions

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

MONDAY, MAY 13

7:00 am Registration and Morning Coffee

AUTOIMMUNITY AND INFLAMMATION

8:20 Chairperson's Remarks

Ahuva Nissim, PhD, Professor, Antibody and Therapeutic Engineering, William Harvey Research Institute, Queen Mary University of London

8:30 Development of Izokibep: An IL-17A Selective Affibody Molecule for Autoimmune Diseases

Fredrik Frejd, PhD, CSO, Affibody AB

Izokibep is a novel Affibody molecule engineered to develop a potentially best-in-class IL-17A blocking ligand trap with femtomolar binding affinity and small molecular size that translates to high therapeutic efficacy in patients with psoriasis, psoriatic arthritis, and hidradenitis suppurativa. Excellent three-year safety and efficacy data support both the IL-17 program as well as the Affibody drug class in general. Izokibep is now in late-stage clinical development.

9:00 Engineering Long-Circulating IL-35 to Suppress Inflammation and Autoimmune Diseases

Jun Ishihara, PhD, Lecturer, Bioengineering, Imperial College London

IL-35 is a strong multi-pathway anti-inflammatory cytokine, but it is difficult to produce. Our computational structural analyses identified the intracellular binding site of IL-35, succeeding large-scale production by mammalian cells. For autoimmune diseases, current therapies are treating the symptoms. We engineered lymph-node targeted IL-35, which achieves therapeutic effects in rheumatoid arthritis and directly suppresses activated immune cells. IL-35 would offer long-term treatment-free periods for patients with many inflammatory diseases.

9:30 Biomarker-Driven Therapeutic Antibody Discovery and Development for Fibro-Inflammatory Diseases

Laurent Audoly, PhD, Co-Founder & CEO, PriveBio Inc.; Executive Partner, Apollo Health Ventures; Senior Advisor & Professor of the Practice, AI Drug Discovery & Development, Northeastern University

Biomarker-driven therapeutic intervention increases the probability that a novel medicine will benefit the right patient population at the right time. PriveBio is advancing a pipeline of first-in-class therapeutics built in tandem with a precision medicine framework for testing in patients to achieve efficient proof-of-biology and early proof-of-concept in fibro-inflammatory diseases to ultimately achieve disease modification.

10:00 TRB-061: A Selective, Potent TNFR2 Agonist for the Treatment of Autoimmune and Inflammatory Diseases

Robin Aglietti, PhD, Principal Scientist, BioTherapeutics, TRexBio

TNFR2 is highly expressed on immunosuppressive regulatory T cells (Tregs) that modulate immune homeostasis. We developed a TNFR2-selective agonist, TRB-061, that demonstrates potent *in vivo* Treg augmentation, providing protection in preclinical inflammatory models. Our deep biology platform reveals the molecular details of TNFR2 agonism on Treg activation and expansion. Interrogation of TRB-061 signaling suggests differentiated clinical opportunities that position TRB-061 as a promising Treg modulator for inflammatory and autoimmune indications.

10:30 Networking Coffee Break

NEURODEGENERATIVE DISEASE STRATEGIES

11:00 Targeting TDP-43 with Next-Generation Vectorized Antibodies

Damien Nevoltris, PhD, Senior Team Leader Antibody Engineering, AC Immune SA

TAR DNA binding protein-43 (TDP-43) is a hallmark of devastating neurodegenerative diseases, such as amyotrophic lateral sclerosis (ALS) and frontotemporal dementia (FTD). Recently, we reported that a monoclonal antibody (mAb) targeting TDP-43, ACI-5891, conferred neuroprotection in ALS/FTD models. To improve brain penetration of mAbs which necessitates high dosing regimens, we created and evaluated the potency of a single-dose vectorized full-length antibody delivered by adeno-associated virus in mouse model.

11:30 Antibodies to Re-Target AAV Delivery to the Brain

Abhishek Chatterjee, PhD, Professor, Chemistry, Boston College

The genetic code expansion technique enables precise incorporation of noncanonical ncAAs carrying diverse chemical functionalities into proteins expressed within living cells. This technology offers new opportunities to precisely engineer next-generation biotherapeutics with new capabilities. This presentation explores recent strides made in enhancing the scalability of this approach, and its application in generating homogeneous site-specific antibody conjugates, and precisely modified adeno-associated virus capsids for GT applications with heightened precision and efficacy.

12:00 pm Session Break

12:05 Luncheon Presentation I Nona's Fully Human Heavy Chain Only Antibodies to Develop Next-Gen Biotherapeutics

Jason Noon, Associate Director of Biology, Nona Biosciences

Nona Biosciences a biotechnology company specializes in proprietary transgenic mice for fully human antibody production. Our fully human heavy chain only antibody (HCAb) platform offers compact size, efficient discovery, and minimal immunogenicity.Join us to explore HCAb's application in Next-Gen biotherapeutics like ADCs, mRNA, and immune cell engagers. Learn about NonaCAR for Next-Gen cell therapies, featuring successful NonaCAR-T projects and our robust HCAb discovery via NonaCarFx screening

1:05 Session Break

CHALLENGES AND SOLUTIONS FOR EMERGING INDICATIONS

1:10 Chairperson's Remarks

Laurent Audoly, PhD, Co-Founder & CEO, PriveBio Inc.; Executive Partner, Apollo Health Ventures; Senior Advisor & Professor of the Practice, AI Drug Discovery & Development, Northeastern University

1:15 Universal Vaccines and Universal Antivenom: How to Elicit Broadly Neutralizing Antibodies *in Vivo*

Jacob Glanville, Founder, CEO & President, Centivax

From infectious disease to snake venom, mutational diversity of target proteins frequently limits the utility of vaccines and therapeutics. Here we present two examples of *in vivo* elicitation of broadly neutralizing antibodies. In the case of vaccines, we review how this enables pan-influenza and pan-coronavirus vaccines. In the case of snake envenoming, we review how a cocktail of two

bnAbs and an inhibitor enables protection against hundreds of snake species.

1:45 Developing pHLA-Targeting T Cell Engagers against Novel Targets in Solid Tumors

Leah Sibener, PhD, Co-Founder & Vice President, Therapeutic Discovery, 3T Biosciences, Inc.

Numerous immunotherapy modalities leverage T cells' unmatched ability to recognize and kill tumor cells; however, clinical responses in cold tumors have been limited. Recently, T cell engagers targeting peptide-HLA molecules (pHLA) have demonstrated transformative responses in these indications. We've developed 3T-TRACE to rapidly identify pHLA antigens recognized orphan T cells from patient tumors, and 3T-PRIME, a TCR mimetic platform to expand the development of this promising modality.

2:15 KEYNOTE PRESENTATION: Challenges and Opportunities in Therapeutic Antibodies for Non-Cancer Indications

Antonios Aliprantis, MD, PhD, Vice President, Program Leadership, Pioneering Medicines, Flagship Pioneering

Therapeutic antibodies have been available for almost 3 decades for non-oncology indications, particularly in inflammation and immunology. However, progress has relied on empiric discovery processes resulting in long cycle times from conception to approval. We will review technologic advances in systems modeling, antibody identification, and the modulation of antibody function, which have led to optimized candidates and opened the door to new indication opportunities for patients.

2:45 Therapeutic Silencing Spp1 in Cardiac Macrophages Suppresses Atrial Fibrillation

Noor Momin, PhD, Assistant Professor, University of Pennsylvania

Atrial fibrillation and the risk of its lethal complications are worsened by atrial fibrosis. Our recent study implicates osteopontin, which is encoded by Spp1, and secreted by atrial macrophages in this fibrosis. We now find that silencing Spp1 in this subset of cardiac macrophages using an engineered antibody-siRNA conjugate reduces atrial fibrosis and suppresses AFib, thus offering an immunotherapy for this common arrhythmia.

3:15 Networking Refreshment Break

4:15 Transition to Plenary Keynote Session

PLENARY KEYNOTE SESSION

4:25 Plenary Keynote Introduction

Laszlo G. Radvanyi, PhD, President & Scientific Director, Ontario Institute for Cancer Research

4:35 Driving New CAR T Cells

Marcela V. Maus, MD, PhD, Associate Professor, Medicine; Director, Cellular Immunotherapy, Massachusetts General Hospital

We will talk about various roads and challenges in driving new CAR T cells toward the clinic, and learnings from clinical experience.

YOUNG SCIENTIST KEYNOTE

5:20 High-Throughput Discovery of Protein Folding Stability and Dynamics

Gabriel J. Rocklin, PhD, Assistant Professor, Pharmacology, Northwestern University

Every protein has its own conformational energy landscape that governs its folding stability and dynamics. These varied landscapes are rarely predictable in protein engineering but strongly influence function, aggregation, immunogenicity, and more. Our lab develops new large-scale methods to measure stability and dynamics. I will share lessons from stability measurements of >750,000 protein domains and dynamics measurements of >5,000 domains, highlighting the potential to rationally engineer stability and dynamics.

6:05 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

Facilitators:



Orhi Esarte Palomero, PhD, Postdoctoral Fellow, Pharmacology, Northwestern University

Alexandros Karyolaimos, PhD, Researcher, Department of Biochemistry & Biophysics, Stockholm University

Shakiba Nikfarjam, PhD, Postdoc, Lawrence Livermore National Lab

7:30 Close of Day

TUESDAY, MAY 14

7:30 am Registration and Morning Coffee

OTHER EMERGING INDICATIONS

7:55 Chairperson's Remarks

Leah Sibener, PhD, Co-Founder & Vice President, Therapeutic Discovery, 3T Biosciences, Inc.

8:00 Targeting GIP and GLP-1 for Treatment of Obesity

Michael Wolfe, MD, Professor, Physiology and Biophysics, Case Western Reserve University

GLP-1 and GIP are incretin hormones, whose primary physiological role is to stimulate postprandial pancreatic insulin release. During the past decade, GLP-1, and more recently GIP, have been found to very effectively promote weight loss by suppressing appetite. Ironically, disruptions in GLP-1 and GIP expression likewise effectively treat obesity through appetite-independent mechanisms that decrease nutrient absorption and storage. Antibodies to GIP and to its receptor are currently under clinical development.

8:30 Biotherapeutics for Mast Cell-Associated Inflammatory Diseases

Joel Goldstein, PhD, Executive Director R&D, Celldex Therapeutics

Mast cells (MCs) play a significant role in various immune-related disorders. Their survival depends on KIT receptor activation by SCF. Barzolvolimab, a KIT-directed inhibitory antibody, has shown

promise in treating chronic urticarias by reducing MCs. Neutralizing SCF is expected to have a similar effect. TSLP neutralization has demonstrated activity in asthma. CDX-622, a bispecific antibody, neutralizes both SCF and TSLP, offering potential benefits by targeting complementary pathways in chronic inflammation.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION

10:00 Transition to Plenary Keynote Session

10:10 Plenary Keynote Introduction

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

10:15 Base Editing and Prime Editing: Engineered Proteins That Precisely Correct Pathogenic Mutations in Cells, Animals, and Patients

David R. Liu, PhD, Richard Merkin Professor and Director, Merkin Institute of Transformative Technologies in Healthcare; Core Institute Member and Vice-Chair of the Faculty, Broad Institute; Director, Chemical Biology and Therapeutic Sciences Program; Investigator, Howard Hughes Medical Institute; Thomas Dudley Cabot Professor of the Natural Sciences and Professor of Chemistry and Chemical Biology, Harvard University

In this lecture, I describe the development and therapeutic application of two precision gene editing technologies that install or correct targeted mutations without requiring double-strand DNA breaks, thereby minimizing undesired consequences of chromosomal cleavage. We developed base editors, proteins that directly perform chemistry on individual DNA bases in living cells to install or correct mutations at targeted positions in genomic DNA.

11:00 Celebrating 20 Years in the Exhibit Hall with Poster Viewing

12:00 pm New Biotherapeutic Strategies to Treat Heart Disease

Nicholas Marston, MD, MPH, Preventive Cardiologist and Assistant Professor, Brigham and Women's Hospital and Harvard Medical School

How we treat heart disease has evolved significantly in recent years. Monoclonal antibodies and RNA-based therapies have dominated new drug development, and CRISPR-based gene editing has entered clinical trials. Large-scale genomics has identified numerous novel proteins for these platforms to target, and nowhere has this been more evident than in hyperlipidemia, where over a dozen new therapies have been developed for four genetically validated therapeutic targets: PCSK9, Lp(a), ANGPTL3, Apo-CIII.

12:30 FEATURED POSTER PRESENTATION: Anti-Idiotypic Antibody as Booster Vaccine Against Respiratory Syncytial Virus

Shreya Mukhopadhyay, PhD, Postdoctoral Research Fellow, Antibody Discovery, Merck

RSV causes respiratory infections in both children and adults globally. This study investigated using anti-idiotypic antibodies as a booster vaccine for RSV by targeting a broad RSV-neutralizing antibody RB1. Cryo-EM analysis confirmed the Anti-ID mimics the binding of RSV prefusion F protein (RSV-F) to RB1. Mice primed with RSV-F and boosted with Anti-ID showed specific B-cell responses. This suggests Anti-IDs have potential as booster vaccines for RSV and other IDs.

1:00 Close of Emerging Indications for Therapeutic Antibodies Conference

6:30 Recommended Dinner Short Course

SC6: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies

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

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME

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

TUESDAY, MAY 14

RNA BIOLOGY AND MODIFICATIONS

2:55 pm Chairperson's Remarks

Lior Zangi, PhD, Associate Professor, Department of Medicine, Cardiology and Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai

3:00 FEATURED PRESENTATION: SMRTs Way to Treat Breast Cancer (*Specific Modified mRNA Translational System)

Lior Zangi, PhD, Associate Professor, Department of Medicine, Cardiology and Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai

Modified mRNA (modRNA) showed high efficacy and safety when used for COVID-19 mRNA vaccines. However, in most disease settings it is crucial to restrict translation of therapeutic genes only to clinically relevant cells. Here, we designed a systemic breast cancer-specific modRNA translation system for enriched gene expression or creating antibodies to fight breast cancer tumor growth. This is a modular platform to allow screening of gene-based treatment for solid-tumor cancer.

3:30 Modified mRNA Therapeutics for Cardiovascular Diseases

Ajit Magadum, PhD, Associate Scientist, Lewis Katz School of Medicine, Temple University

Modified mRNA (modRNA) technology, lauded for its triumphs in COVID-19 vaccine development, is emerging as a promising strategy against cardiovascular diseases (CVD). With 19.1 million global deaths in 2020 and a prevalence of 620 million, CVD demands innovative solutions. My presentation spotlights our work on modRNA therapies fostering cardiac repair, and combating cardiac fibrosis, hypertrophy, and cell death in CVD animal models, and development of cell-specific modRNA expression platforms for CVD.

4:00 Sponsored Presentation *(Opportunity Available)*

4:30 Refreshment Break in the Exhibit Hall with Poster Viewing

5:10 RNA Modifications Control Muscle Homeostasis

Federica Accornero, PhD, Associate Professor, Molecular Biology, Cell Biology and Biochemistry, Brown University

Naturally occurring post-transcriptional chemical modifications serve critical roles in impacting RNA structure and function. The combination of effects caused by modifications are ultimately linked to gene expression regulation at a genome-wide scale. Although examples of the importance of RNA modifications in translation are accumulating rapidly, still what these contribute to the function of complex physiological systems such as muscle is only recently emerging and addressed by our work.

5:40 Programming mRNA for Cancer Immunotherapy

Prashant Nambiar, DVM, PhD, MBA, Senior Vice President, R&D, Strand Therapeutics

6:10 Close of Day

6:10 Dinner Short Course Registration

WEDNESDAY, MAY 15

8:00 am Registration and Morning Coffee

BIOANALYTICAL ASSESSMENTS AND IMMUNOGENICITY

8:25 Chairperson's Remarks

Darshana Jani, PhD, Senior Director, Preclinical and Clinical Bioanalytical Sciences, Clinical Biomarkers, Moderna

8:30 Strategies for qRT-PCR Assay Development and Validation for Clinical PK Studies of mRNA Drug Products

Vasily Vagin, PhD, Associate Director, Molecular Bioanalytics, Moderna

This talk will explore effective strategies for the development and validation of qRT-PCR assays for PK studies of mRNA drug products. The presentation will cover key considerations in assay design, optimization, and validation processes to ensure accurate and reliable measurement of mRNA levels in clinical samples. Attendees can expect insights into methodologies aimed at enhancing the robustness and reproducibility of qRT-PCR assays in the evaluation of mRNA-based therapeutic products.

9:00 End-to-End Bioanalytics and Life-Cycle Management for mRNA Therapeutics

Jason DelCarpini, Director, Bioanalytical and Molecular Assays, Moderna

mRNA-based therapeutics offer treatments ranging from infectious disease to oncology to rare disease. Due to the rapid emergence of this technology, bioanalysts have needed to adapt bioanalytical approaches for monitoring pharmacokinetics, pharmacodynamics, and immunogenicity from the protein-based and gene-based therapies. In this presentation, we will discuss end-to-end bioanalytical support for mRNA-based therapeutics based on indication, as well as important life-cycle management considerations such as critical reagents.

9:30 Immunogenicity Assessment Strategy for mRNA-LNP Therapeutics

Xiaobin Zhang, PhD, Principal Scientist, Takeda Pharmaceuticals

Lipid nanoparticles have been used for the efficient delivery of different therapeutics. However, the LNP composition may be recognized by the immune system as foreign materials and activate the unintended immune response. In this talk, we will explore the immunogenicity risk of LNP composition, summarize the regulatory guidance and requirements for immunogenicity risk identification and evaluation, and provide immunogenicity assessment strategy for the novel mRNA/LNP therapeutics during drug development stage.

10:00 Sponsored Presentation *(Opportunity Available)*

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

TARGETED mRNA DELIVERY & FORMULATION

11:05 Chairperson's Remarks

Michael J. McGuire, PhD, Scientific Director, Shenandoah Valley Labs, SRI International

11:10 Going beyond the Blood-Brain Barrier: Delivery of Diverse Cargo to Targeted Cells within the Central Nervous System

Michael J. McGuire, PhD, Scientific Director, Shenandoah Valley Labs, SRI International

SRI International has developed an unbiased screening platform to identify peptides that mediate delivery throughout the CNS without disrupting the blood-brain barrier or destroying biological cargo. This approach, DiaCyt (Dia: Through, Cyt: Cell), utilizes phage-displayed libraries to identify ligands called

molecular transport systems (MTS). Upon intravenous injection into a rat, MTSs are transported into the CNS and distributed throughout the ventricular system and within the surrounding parenchyma of the brain.

11:40 Delivering mRNA Using Extracellular Vesicles to Treat Human Diseases

Betty YS Kim, MD, PhD, Professor, Physician Scientist, Department of Neurosurgery, UT - MD Anderson Cancer Center

mRNA therapeutics offer great promise to treat a variety of human diseases. Here, we will present how we can engineer extracellular vesicles to deliver endogenously transcribed designer mRNAs to restore tumor suppressor genes to fight cancer and replenish diminishing production of proteins to reverse natural aging.

12:10 pm Session Break

12:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:20 Session Break

INTERACTIVE DISCUSSIONS

1:30 Find Your Table and Meet Your Discussion Moderator

1:40 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.

Table 6: Bioanalysis and Immunogenicity of mRNA Therapeutics - IN-PERSON ONLY

Xiaobin Zhang, PhD, Principal Scientist, Takeda Pharmaceuticals

TARGETED mRNA DELIVERY & FORMULATION *(CONT.)*

2:30 AI-Aided LNP Development for mRNA Delivery

Bowen Li, PhD, Assistant Professor, Pharmaceutical Sciences, University of Toronto

The traditional process of LNP development remains labor-intensive and cost-inefficient, relying heavily on trial and error. In this study, we present the AI-Guided Ionizable Lipid Engineering (AGILE) platform that streamlines the iterative development of ionizable lipids, crucial components for LNP-mediated mRNA delivery.

3:00 Delivery of Nucleic Acids for Next Generation Medicine

Wei Tao, PhD, Farokhzad Family Distinguished Chair for Innovation; Principal Investigator, Center for Nanomedicine; Assistant Professor, Faculty of Medicine, Harvard University

3:30 Targeted mRNA Delivery via LNP Design and Optimization – Today and Tomorrow

Liping Zhou, PhD, Senior Director, Advanced Drug Delivery, AstraZeneca Pharmaceuticals

This presentation will cover mRNA delivery approaches and technologies involved in transporting the nucleic acid to its target site to achieve the desired therapeutic effect, current challenges and opportunities in mRNA/LNP formulation development, and future directions for targeted mRNA delivery via LNP design and optimization.

4:00 Sponsored Presentation *(Opportunity Available)*

4:30 Ice Cream Break in the Exhibit Hall with Poster Viewing

SPEED NETWORKING

How Many New Contacts Can You Make?

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

IMPACT OF MODEL-INFORMED DRUG DEVELOPMENT (MIDD)

5:09 Chairperson's Remarks

Husain Attarwala, PhD, Vice President, Bioanalytics, DMPK, Clinical Pharmacology and CMC, Aera Therapeutics

This session on model-informed drug-development (MIDD) for mRNA therapeutics and vaccines explores the emerging field of utilizing mathematical modeling and data-driven approaches to optimize the development and dosing of innovative mRNA-based therapies and vaccines. Presentations will encompass a wide range of topics, including preclinical and clinical trial design, population pharmacokinetics/pharmacodynamics analyses, and systems pharmacology approaches for rational drug development. Discover the future of mRNA-based medicines in this evolving domain.

5:10 Optimizing mRNA Therapeutics through MIDD

Linh Van, PhD, Head, Clinical Pharmacology and Pharmacometrics, Moderna

MIDD intertwined with quantitative pharmacology requires a shift in mindset towards a "learning and confirming" paradigm to support informed decision-making. Large amounts of data are generated on a continuum in discovery and development, requiring a holistic and systematic approach to curate results for evidence generation. This talk explores the different techniques and *in silico* tools that can be applied when developing a MIDD strategy for mRNA therapeutics across drug development.

6:10 Cheers to 20 Years Reception in the Exhibit Hall with Poster Viewing

MENTORING MEET UP

Creating and Fostering a Productive and Effective Mentor-Mentee Relationship


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

Deborah Moore-Lai, PhD, VP, Protein Development Platform, Abcam

This meet-up is designed for senior scientists that are interested in becoming a mentor for junior scientists. Over casual conversation, we will discuss what it takes to be a mentor, finding the right match, establishing safety and confidentiality, time commitment/frequency of meetings and remote vs in-person.

7:30 Close of mRNA Therapeutics Conference

SUNDAY, MAY 12

1:00 pm Main Conference Registration

2:00 Recommended Pre-Conference Short Course

SC5: Targeting Solid Tumors and Understanding the TME
**Separate registration required. See short course page for details.*

THURSDAY, MAY 16

WOMEN IN SCIENCE BREAKFAST

7:30 am PANEL DISCUSSION: Fostering Mentorship and Company Culture for the Advancement of Gender Equity: IN-PERSON ONLY *(Continental Breakfast Provided)*

Co-Organized with THINKUBATORMEDIA







Co-Organized with

Moderator: Lori Lennon, Founder & CEO, Thinkubator Media

Advancing gender equity in the workplace is an effort that requires mentorship, shifts in company culture, and investment from all levels of an organization. Join us for a robust and insightful conversation on how companies can foster quality mentorship, create team-based success models, develop meaningful and measurable commitments to DEI, and how this important work can greatly benefit an organization and its goals.

Panelists:

Tom Browne, Director of Diversity, Equity, & Inclusion, MassBio

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

Nicole Renaud, PhD, Director, Global Co-Lead of Human Genetics and Targets, Discovery Science, Biomedical Research, Novartis

Kerry Robert, Senior Vice President, Head of People & Culture, Entrada Therapeutics

Minmin (Mimi) Yen, PhD, CEO & Co-Founder, PhagePro Inc.

7:30 Registration and Morning Coffee

REPROGRAMMING THE IMMUNE SYSTEM FROM WITHIN

8:45 Chairperson's Opening Remarks

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

8:50 KEYNOTE PRESENTATION: Towards *in vivo* Engineering of the Immune System

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

Ex vivo engineered T cell showed significant clinical benefit in several diseases, but novel technologies are needed to broaden access and increase performance of immunotherapy. We developed a scalable and tunable platform to generate *in vivo* CAR-expressing cells, obviating the utilization of cells, viral vectors, or lymphodepletion conditioning. Preclinical evaluation shows effective *in vivo* engineering of T cells accompanied by profound pharmacological effect, providing a springboard for developing transformative immunotherapies.

9:20 FEATURED PRESENTATION: Latest Developments in *in vivo* Engineering of Cell and Gene Therapies

Matthias T. Stephan, MD, PhD, Professor, Translational Sciences and Therapeutics Division, Fred Hutchinson Cancer Center

9:50 Can Synthetic Biology Unlock the Promise of *In Vivo* Genetic Medicines?

Nicholas A. Boyle, PhD, CEO, Abintus Bio

In the context of *in vivo* genetic medicines, targeting approaches on a particle surface have limitations and may result in payload delivery to millions of off-target cells, resulting in safety and tolerability issues. Immune cell-selective synthetic promoters have the potential to control gene expression within desired cell types and thus enable the high level of precision anticipated for next-generation *in vivo* genetic medicines.

10:20 Sponsored Presentation *(Opportunity Available)*

10:50 Coffee Break in the Exhibit Hall with Poster Viewing

WOMEN IN SCIENCE MEET-UP

Meet Fellow Women Scientists, Celebrate Successes, and Inspire the Future Generations of Female Leaders

Lori Lennon, Founder & CEO, Thinkubator Media

The Women in Science Meet-Up celebrates female trailblazers who are setting their own course in science. We invite all to come celebrate the successes of these women in breaking down barriers and inspiring future generations of female leaders. Come join fellow scientists and share your personal and professional journey.

11:50 Transition to Plenary Fireside Chat

PLENARY FIRESIDE CHAT

12:00 pm Chairperson's Remarks

12:10 What Comes Next in Antibody Discovery and Engineering?




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

- How significantly will domain antibodies supersede Fabs in antibody-like structures in the future?
- Is the field of antibody engineering nearing a point where it can be considered a solved problem?
- If we had access to a completely predictive computational method for antibody design, how would this quantifiably enhance the antibody discovery and optimization process?

Panelists:

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

Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences

Jane K. Osbourn, PhD, CSO, Alchemab Therapeutics Ltd.

12:55 Luncheon in the Exhibit Hall and Last Chance for Poster Viewing

IN VIVO ENGINEERING USING mRNA, LNPs, Synthetic Biology

2:30 Chairperson's Remarks

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

2:35 Targeted LNP-RNA for *in vivo* Cellular Reprogramming

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

In this talk, I will describe selective *in vivo* targeting of mRNA therapeutics and interventions to specific cells and cell subtypes such as T cells and hematopoietic stem cells (HSCs) via antibody-modified lipid nanoparticles. I will also discuss the potential

applications we explored with this platform technology such as gene editing.

3:05 *In vivo* Production of Functional CAR T Cells by mRNA-Targeted Lipid Nanoparticle

Haig Aghajanian, PhD, Co-Founder & Vice President of Research, Capstan Therapeutics

Using targeted lipid nanoparticles (tLNP), we were able to transiently reprogram T cells *in vivo* by delivering modified mRNA encoding a CAR against fibroblast activation protein (FAP). This treatment resulted in the reduction of cardiac fibrosis and the restoration of cardiac function. The ability to produce transient, functional CAR T cells *in vivo* with mRNA addresses some of the biggest hurdles in cell therapy including manufacturing, scalability, and safety concerns.

3:35 Exploring Viral Phylogeny for Engineering Optimized Gene Delivery Vectors

David Johnson, PhD, Founder and CEO, GigaMune

4:05 Presentation to be Announced

4:35 Networking Refreshment Break

COMMERCIALIZING *IN VIVO* CELL AND GENE THERAPIES

5:00 PANEL DISCUSSION: Current Challenges and Opportunities in *in vivo* Engineering

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

Panelists:

Philip R. Johnson, MD, CEO, Interius Biotherapeutics

Jagesh V. Shah, Vice President, Gene Therapy Technologies, Sana Biotechnology

Michael Klichinsky, PharmD, PhD, Co-Founder & Vice President, Discovery, Carisma Therapeutics

Haig Aghajanian, PhD, Co-Founder & Vice President of Research, Capstan Therapeutics

6:00 Close of Day

FRIDAY, MAY 17

7:00 am Registration Open

INTERACTIVE DISCUSSIONS

7:30 Interactive Roundtable Discussions with Continental Breakfast

Interactive Roundtable 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 Roundtable Discussions** page on the conference website for a complete listing of topics and descriptions.

IN VIVO ENGINEERING OF CELLS USING VIRAL VECTORS

8:25 Chairperson's Remarks

Samuel Lai, PhD, Professor, Pharmacoengineering & Molecular Pharmaceutics, University of North Carolina at Chapel Hill

8:30 *In vivo* Gene Delivery to Therapy-Relevant Cells by Surface-Engineered Vectors

Jessica Hartmann, PhD, Biochemist, Federal Institute for Vaccines & Biomedicines, Paul Ehrlich Institut

Currently approved gene therapies rely on viral vectors harboring a broad cell tropism. The ultimate goal in the gene therapy field is to achieve manipulation of only therapy-relevant cells. This vision will heavily rely on vector technology, especially for *in vivo* applications. This presentation will discuss different vector platforms especially focusing on engineered lentiviral and AAV vectors using cell-specific markers as entry receptor achieved through display of DARPins or scFv.

9:00 Targeted Lentiviral Vectors for Antigen Discovery and Cellular Reprogramming

Michael E. Birnbaum, PhD, Assistant Professor, Biological Engineering, Massachusetts Institute of Technology

Cell-specific transduction remains one of the next frontiers for virally delivered gene therapy. Our lab developed a "receptor-blinded" version of VSVG, enabling co-display of a new LV pseudotype ligand to drive specific lentiviral tropism. Initial experiments have shown modularity of this platform for achieving potent transduction of on-target cells via a range of co-expressed host proteins, across a range of affinities and at frequencies as low as 1-in-100,000.

9:30 *In vivo* Engineering Using iGPS Technology

Emily Beura, PhD, Director, Research, Kelonia Therapeutics

Kelonia's *in vivo* gene placement system (iGPSTM) comprises a lentiviral particle with modified envelope proteins that enables highly specific cell targeting and efficient gene transfer. By eliminating the need for *ex vivo* manufacturing and toxic lymphodepleting chemotherapy, we believe our iGPS technology will remove barriers that currently prevent patients from accessing transformative genetic medicines.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Networking Coffee Break

IN VIVO ENGINEERING OF CELLS USING VIRAL VECTORS

11:00 Combining Chemical and Virological Approaches to Enable Direct *in vivo* Engineering of Circulating Immune Cells

Samuel Lai, PhD, Professor, Pharmacoengineering & Molecular Pharmaceutics, University of North Carolina at Chapel Hill

Direct *in vivo* engineering of various immune cells not only can greatly reduce costs and broaden access to cellular therapy. In this talk, we will share our published and unpublished data on engineering CAR T by transducing circulating PBMCs *in situ* that can effectively eradicate aggressive tumors, as well as engineering CAR B cells that can secrete immunoglobulins of interest.

11:30 Targeting T Cells *in vivo* Using Evolved AAVs

William Nyberg, PhD, Postdoc Research Fellow, Hematology and Oncology, University of California San Francisco

Adeno-associated viruses (AAV) are commonly used delivery vehicles for gene therapies. We have evolved AAV variants targeting human and mouse T cells. In this talk, I will describe how these AAVs can be used *in vivo* to specifically target T cells for gene editing and more. Additionally, I highlight the use of targeted AAVs as gene therapies to improve T cell therapeutics in immunocompetent tumor models.

12:00 pm Close of Conference

SPONSORSHIP & EXHIBIT OPPORTUNITIES

CII offers comprehensive packages that can be customized to your budget and objectives. Sponsorship allows you to achieve your goals before, during, and long after the event. Packages may include presentations, exhibit space and branding, as well as the use of delegate lists. Signing on early will maximize your exposure to qualified decision-makers and drive traffic to your website in the coming months.

PODIUM PRESENTATIONS

Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific program, breakfast, lunch, or a pre-conference workshop. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CII. Lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly! Sign on early to secure your talk.

INVITATION-ONLY VIP DINNER/ HOSPITALITY SUITE

Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending the invitations, to venue suggestions, CII will deliver your prospects and help you make the most of this invaluable opportunity.

ONE-TO-ONE MEETINGS

CHI will set up 6-8 in-person meetings during the conference, based on your selections from the advance registration list. Our staff will handle invites, confirmations, and reminders, and walk the guest over to the meeting area. This package also includes a meeting space at the venue, complimentary main-conference registrations, branding, an 8'x10' exhibit space, and more.

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

ADDITIONAL BRANDING AND PROMOTIONAL OPPORTUNITIES ARE AVAILABLE, INCLUDING:

- **Conference Tote Bags**
- **Literature Distribution** *(Tote Bag Insert or Chair Drop)*
- **Badge Lanyards**
- **Conference Materials Advertisement**
- **Padfolios and More…**

FOR MORE INFORMATION, PLEASE CONTACT:

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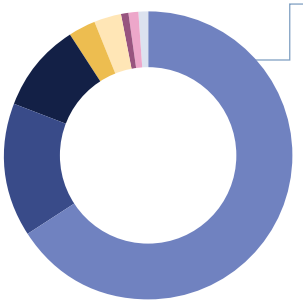
2023 ATTENDEE DEMOGRAPHICS



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Services	3%
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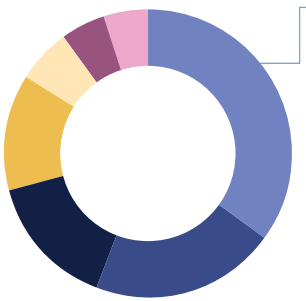

DELEGATE TITLE

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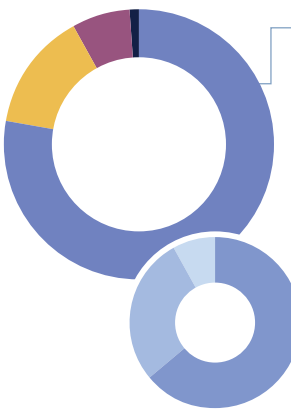
Sales & Marketing	21%
Executive	15%
Director	13%
Manager	6%
Professor	5%
Assistant	5%



GEOGRAPHIC LOCATION

USA	78%
Europe	14%
Asia	7%
Rest of World	1%

US BREAKDOWN

East Coast	64%
West Coast	28%
Midwest	8%

HOTEL & TRAVEL INFORMATION

CONFERENCE HOTEL AND VENUE:

Omni Boston Hotel at the Seaport
50 Summer Street
Boston, MA 02210

Discounted Room Rate:
$355 Artist Tower s/d /$389 s/d Patron Tower

** Includes Complimentary WiFi

Discounted Room Rate Cut-Off Date:
April 12, 2024

Visit the Travel page of PEGSummit.com
to make your hotel reservations and for additional information.

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REGISTRATION & PRICING INFORMATION

GROUP DISCOUNTS:
Have your colleagues or entire team attend PEGS Boston Summit. Purchase a full-price registration here and participants from the same organization will receive a 20% discount when registering through the Group Registration page. For more information on group discounts contact Bill Mote at 781-972-5479.

(Group registration package must be equal to or less than the value of the full-price package.)

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CHI appreciates your participation at its events. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

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Short Courses will be held in-person only.

	COMMERCIAL	ACADEMIC, GOVERNMENT, HOSPITAL-AFFILIATED
1 SHORT COURSE	$599	$399
2 SHORT COURSES	$999	$599

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Includes access to 1 training seminar only.

	COMMERCIAL	ACADEMIC, GOVERNMENT, HOSPITAL-AFFILIATED
ADVANCE REGISTRATION UNTIL MARCH 29	$1,999	$1,049
REGISTRATION AFTER MARCH 29 AND ONSITE	$2,199	$1,149

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REGISTRATION AFTER MARCH 29 AND ONSITE	$3,499	$1,799

STANDARD PACKAGE

Includes access to two conferences and/or training seminars and on-demand access for one month. Excludes short courses.

	COMMERCIAL	ACADEMIC, GOVERNMENT, HOSPITAL-AFFILIATED
ADVANCE REGISTRATION UNTIL MARCH 29	$2,949	$1,449
REGISTRATION AFTER MARCH 29 AND ONSITE	$3,149	$1,549

PLEASE USE KEYCODE
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WHEN REGISTERING!

How to Register: PEGSummit.com

reg@healthtech.com • P: 781.972.5400 or
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TABLE OF CONTENTS